**Online Supplemental Material**

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# Supplemental Figure S1. Enrollment, Randomization, Treatment Received, Follow Up



# Supplemental Figure S2. TIR Scatterplot of last 13 weeks of Preceding RCT vs. 13 weeks of Randomized by Treatment Group



# Supplemental Figure S3. TIR Scatterplot of last 13 weeks of Preceding RCT vs. 13 weeks of Randomized by Treatment Group – Excluding Periods of Study-wide Suspension of Device Use



**Supplemental Table S1A: CGM-Measured Outcomes during Daytime (6am-12mn)**

|  |  |  |
| --- | --- | --- |
|  | **Baseline****(Last 13 weeks of Preceding RCT)** | **13-week Follow-up** |
|  | **CLC****N=54** | **PLGS****N=55** | **CLC****N=54** | **PLGS****N=55** | **Risk-Adjusted****Difference****(95% CI)** | **P-value** |
| **Hours of Sensor Data** *median (IQR)* | 1592 (1555, 1603) | 1574 (1538, 1595) | 1538 (1472, 1618) | 1515 (1457, 1579) | NA | NA |
| **Overall Control** |
| **% in Target 70-180** mg/dL *mean ± SD* | 69.5% ± 12.2% | 68.5% ± 13.8% | 66.5% ± 13.5% | 60.8% ± 17.3% | +4.7% (+2.4%, +6.9%) | <0.001 |
| **% in Target 70-140** mg/dL *mean ± SD* | 43.4% ± 12.9% | 43.2% ± 12.5% | 41.3% ± 13.5% | 37.1% ± 14.4% | +3.9% (+1.7%, +6.2%) | 0.0062 |
| **Mean Glucose** mg/dL*mean ± SD* | 158 ± 19 | 160 ± 24 | 162 ± 22 | 170 ± 30 | -6 (-10, -2) | 0.0022 |
| **Standard Deviation** mg/dL*mean ± SD* | 53± 11 | 55 ± 13 | 55 ± 12 | 60 ± 15 | -2 (-4, 0) | 0.03 |
| **Coefficient of Variation***mean ± SD* | 33% ± 4% | 34% ± 5% | 34% ± 5% | 35% ± 5% | 0 (0, 0) | 0.62 |
| **Hypoglycemia** |
| **% Below 54 mg/dL***median (IQR)* | 0.14% (0.04%, 0.30%) | 0.21% (0.05%, 0.42%) | 0.18% (0.05%, 0.39%) | 0.18% (0.07%, 0.46%) |  | 0.73 |
| *mean ± SD* | 0.19% ± 0.18% | 0.30% ± 0.38% | 0.26% ± 0.24% | 0.31% ± 0.33% | +0.01% (-0.07%, +0.09%) |  |
| **% Below 60 mg/dL***median (IQR)**mean ± SD* | 0.35% (0.17%, 0.66%)0.45% ± 0.37% | 0.44% (0.13%, 0.90%)0.60% ± 0.66% | 0.42% (0.17%, 0.92%)0.59% ± 0.51% | 0.42% (0.16%, 1.02%)0.65% ± 0.59% | +0.06% (-0.07%, +0.2%) | 0.36 |
| **% Below 70 mg/dL***median (IQR)**mean ± SD* | 1.16% (0.76%, 1.83%)1.39% 0.97% | 1.41% (0.67%, 2.40%)1.63% ± 1.31% | 1.41% (0.57%, 2.69%)1.78% ± 1.36% | 1.57% (0.67%, 2.73%)1.84% ± 1.40% | +0.17% (-0.13%, +0.47%) | 0.26 |
| **Low Blood Glucose Index***median (IQR)* | 0.41 (0.29, 0.60) | 0.44 (0.29, 0.70) | 0.47 (0.25, 0.80) | 0.49 (0.32, 0.92) | 0 (-0.07, +0.07) | 0.99 |
| *mean ± SD* | 0.46 ± 0.27 | 0.51 ± 0.31 | 0.54 ± 0.34 | 0.59 ± 0.36 |  |  |
| **Hypoglycemic Event Rate per Week\****median (IQR)* | 2.9 (1.7, 4.2) | 3.2 (1.4, 5.1) | 2.9 (1.4, 5.5) | 3.6 (1.8, 5.2) | +0.2 (-0.3, +0.7) | 0.49 |
| *mean ± SD* | 3.2 ± 2.1 | 3.6 ± 2.7 | 3.7 ± 2.5 | 3.9 ± 2.8 |  |  |
| **Hyperglycemia** |
| **% Above 180 mg/dL***median (IQR)* | 29% (22%, 38%) | 29% (18%, 38%) | 33% (21%, 40%) | 37% (23%, 51%) | -5% (-7%, -3%) | <0.001 |
| *mean ± SD* | 29% ± 12% | 30% ± 14% | 32% ± 14% | 37% ± 18% |  |  |
| **% Above 250 mg/dL***median (IQR)**mean ± SD* | 5.4% (2.6%, 9.9%)7.3% ± 6.1% | 5.5% (2.6%, 10.7%)8.7% ± 9.6% | 7.4% (3.1%, 11.9%)8.8% ± 7.8% | 9.2% (3.7%, 16.2%)12.6% ± 12.5% | -2.0% (-3.4%, -0.5%) | 0.01 |
| **% Above 300 mg/dL***median (IQR)* | 1.3% (0.4%, 3.3%) | 1.3% (0.5%, 3.6%) | 1.7% (0.4%, 3.7%) | 1.9% (0.7%, 5.9%) | -0.7% (-1.7%, +0.2) | 0.14 |
| *mean ± SD* | 2.3% ± 2.6% | 3.3% ± 5.4% | 3.0% ± 3.9% | 5.1% ± 7.5% |  |  |
| **High Blood Glucose Index***median (IQR)* | 6.4 (4.6, 8.3) | 6.1 (4.1, 8.4) | 7.3 (4.7, 9.0) | 7.4 (5.1, 11.3) | -1.1 (-1.7, -0.4)  | 0.001 |
| *mean ± SD* | 6.6 ± 2.9 | 7.1 ± 4.2 | 7.2 ± 3.6 | 8.9 ± 5.4 |  |  |

\*At least 15 consecutive minutes <70 mg/dL

**Supplemental Table S1B: CGM-Measured Outcomes during Nighttime (12mn – 6am)**

|  |  |  |
| --- | --- | --- |
|  | **Baseline****(Last 13 weeks of Preceding RCT)** | **13-week Follow-up** |
|  | **CLC****N=54** | **PLGS****N=55** | **CLC****N=54** | **PLGS****N=55** | **Risk-Adjusted****Difference****(95% CI)** | **P-value** |
| **Hours of Sensor Data** *median (IQR)* | 534 (524, 540) | 536 (524, 542) | 512 (495, 544) | 514 (486, 532) | NA | NA |
| **Overall Control** |
| **% in Target 70-180** mg/dL *mean ± SD* | 76.0% ± 11.6% | 74.4% ± 15.5% | 70.8% ± 12.4% | 59.3% ± 18.6% | +10.1% (+6.5%, +13.6%) | <0.001 |
| **% in Target 70-140** mg/dL *mean ± SD* | 49.6% ± 12.4% | 49.5% ± 16.5% | 44.1% ± 12.5% | 37.1% ± 16.2% | +7.1% (+3.7%, +10.5%) | <0.001 |
| **Mean Glucose** mg/dL*mean ± SD* | 151 ±17 | 153 ± 23 | 157 ± 19  | 171 ± 31 | -12 (-17, -7) | <0.001 |
| **Standard Deviation** mg/dL*mean ± SD* | 47± 12 | 50 ± 15 | 52 ± 12  | 60 ± 15 | -6 (-9, -3) | <0.001 |
| **Coefficient of Variation***mean ± SD* | 31% ± 6% | 32% ± 6% | 33% ± 5% | 35% ± 6% | -2% (-3%, 0%) | 0.06 |
| **Hypoglycemia** |
| **% Below 54 mg/dL***median (IQR)* | 0.15% (0.03%, 0.33%) | 0.17% (0.02%, 0.38%) | 0.19% (0.05%, 0.53%) | 0.21% (0.03%, 0.51%) |  | 0.22 |
| *mean ± SD* | 0.25% ± 0.30% | 0.30% ± 0.41% | 0.37% ± 0.57% | 0.29% ± 0.33% | +0.10% (-0.06%, +0.27%) |  |
| **% Below 60 mg/dL***median (IQR)**mean ± SD* | 0.29% (0.12%, 0.57%)0.45% ± 0.47% | 0.33% (0.08%, 0.79%)0.57% ± 0.69% | 0.39% (0.12%, 0.88%)0.68% ± 0.97% | 0.38% (0.18%, 0.91%)0.62% ± 0.64% | +0.12% (-0.16%, +0.41%) | 0.39 |
| **% Below 70 mg/dL***median (IQR)**mean ± SD* | 0.94% (0.44%, 1.74%)1.22% ± 0.97% | 1.02% (0.39%, 2.19%)1.39% ± 1.37% | 1.28% (0.56%, 2.42%)1.67% ± 1.62% | 1.38% (0.48%, 2.77%)1.83% ± 1.73% | -0.02% (-0.56%, +0.51%) | 0.93 |
| **Low Blood Glucose Index***median (IQR)* | 0.35 (0.22, 0.58) | 0.37 (0.25, 0.66) | 0.42 (0.22, 0.70) | 0.47 (0.27, 0.89) |  | 0.51 |
| *mean ± SD* | 0.42 ±0.29 | 0.47 ± 0.33 | 0.52 ± 0.40 | 0.60 ± 0.46 | -0.05 (-0.17, +0.09) |  |
| **Hypoglycemic Event Rate per Week\****median (IQR)* | 1.6 (0.9, 3.1) | 2.0 (0.6, 3.8) | 2.3 (1.1, 4.3) | 2.5 (1.2, 4.6) |  | 0.47 |
| *mean ± SD* | 2.2 ± 1.6 | 2.4 ± 2.1 | 2.6 ± 1.7 | 3.0 ± 2.3 | -0.2 (-0.8, +0.4) |  |
| **Hyperglycemia** |
| **% Above 180 mg/dL***median (IQR)* | 22% (15%, 29%) | 20% (11%, 36%) | 27% (20%, 33%) | 38% (23%, 54%) | -10% (-14%, -6%) | <0.001 |
| *mean ± SD* | 23% ± 12% | 24% ± 16% | 28% ± 13% | 39% ± 19% |  |  |
| **% Above 250 mg/dL***median (IQR)**mean ± SD* | 3.1% (1.3%, 6.8%)5.0% ± 5.4% | 3.1% (1.2%, 9.6%)6.8% ± 7.8% | 5.7% (2.2%, 8.9%)7.0% ± 6.5% | 9.7% (4.0%, 21.5%) 13.6% ± 12.4% | -4.3% (-6.4%, -2.2%) | <0.001 |
| **% Above 300 mg/dL***median (IQR)* | 0.7% (0.1%, 2.1%) | 0.7% (0.1%, 3.2%) | 1.3% (0.2%, 2.9%) | 2.5% (0.9%, 8.3%) | -1.6% (-2.7%, -0.5%) | 0.0047 |
| *mean ± SD* | 1.6% ± 2.3% | 2.5% ± 4.0% | 2.3% ± 3.4% | 5.2% ± 6.3% |  |  |
| **High Blood Glucose Index***median (IQR)* | 4.8 (3.7, 6.2) | 4.9 (2.6, 8.3) | 6.1 (4.0, 7.5) | 8.1 (5.1, 13.0) | -2.2 (-3.1, -1.3) | <0.001 |
| *mean ± SD* | 5.2 ± 2.7 | 5.8 ± 3.9 | 6.4 ± 3.1 | 9.2 ± 5.3 |  |  |

\*At least 15 consecutive minutes <70 mg/dL

# Supplemental Table S2: Subgroup Analysis for Outcomes of CGM-Measured Percent Time in Range 70-180 mg/dL

|  |  |
| --- | --- |
|  | **% Time in Range 70-180 mg/dL** |
| **Baseline Factors** | **CLC Group** *(N)* *Baseline/* *Post Randomization* | **PLGS Group***(N)* *Baseline/* *Post Randomization* | **P-value for interaction** |
| **Overall** | (54) 71.1%/ 67.6% | (55) 70.0%/60.4%  |  |
| **HbA1c** |  |  | <0.001 |
|  ≤7.5% (≤58 mmol/mol) | (39) 75.3%/72.3%  | (43) 74.8%/65.3% |  |
|  >7.5% (>58 mmol/mol) | (15) 60.2%/55.5% | (12) 52.7%/42.7% |  |
| **% Time Below 70mg/dL** |  |  | <0.001 |
|  ≤1% | (24) 68.4%/64.3% | (21) 69.4%/58.6% |  |
|  >1% | (30) 73.3%/70.3% | (34) 70.3%/61.5% |  |
| **% Above 180 mg/dL** |  |  | <0.001 |
|  ≤40% | (46) 74.1%/70.6% | (44) 75.0%/65.7% |  |
|  >40% | (8) 53.8%/50.5% | (11) 50.0%/39.0% |  |
| **% in Range 70-180 mg/dL** |  |  | <0.001 |
|  ≤60% | (9) 54.4%/51.5% | (12) 50.7%/39.4% |  |
|  >60% | (45) 74.5%/70.8% | (43) 75.4%/66.3% |  |
| **Age** |  |  | 0.20 |
| 14-24 years | (17) 63.6%/59.6% | (22) 62.1%/51.6% |  |
| 25-71 years | (37) 74.6%/71.3% | (33) 75.2%/66.2% |  |
| **Gender** |  |  | 0.76 |
| Female | (28) 72.9%/68.3% | (25) 71.5%/61.4% |  |
| Male | (26) 69.2%/66.8% | (30) 68.7%/59.6% |  |
| **Race (White)a** |  |  | 0.02 |
| No | (7) 63.7%/57.5% | (7) 71.8%/60.4% |  |
| Yes | (46) 72.2%/69.2% | (46) 70.1%/61.2% |  |
| **BMI** |  |  | 0.58 |
| ≤25 | (22) 70.0%/66.5% | (26) 68.3%/58.3% |  |
| >25 | (32) 71.9%/68.4% | (29) 71.5%/62.3% |  |
| **Incomeb** |  |  | >0.99 |
| <$100,000 | (13) 73.4%/68.8% | (18) 72.0%/60.1% |  |
| ≥$100,000 | (29) 71.4%/68.4% | (26) 66.7%/57.2% |  |
| **Educationc** |  |  | 0.54 |
| ≤ Bachelor’s Degree | (34) 72.7%/69.9% | (31) 69.1%/59.0% |  |
| ≥ Master’s Degree | (19) 69.5%/64.7% | (24) 71.2%/62.2% |  |
| **Insuranced** |  |  | 0.87 |
| Private | (49) 70.9%/67.7% | (51) 70.2%/60.9% |  |
| Other | (2) 73.6%/63.2% | (3) 62.7%/46.0% |  |
| None | (2) 75.4%/68.4% | 0 |  |
| **Hypoglycemia Awareness Score** |  |  | 0.29 |
| ≤1 | (27) 72.7%/70.8% | (33) 66.2%/56.5% |  |
| >1 | (27) 69.5%/64.4% | (22) 75.6%/66.3% |  |
| **Hypoglycemia Fear****Total Score** |  |  | 0.10 |
| <Median | (22) 72.7%/68.4% | (32) 70.4%/62.5% |  |
| ≥Median | (32) 70.0%/67.1% | (23) 69.4%/57.5% |  |
| **Site** |  |  | 0.49 |
| A | (8) 75.1%/72.0% | (7) 63.6%/52.7% |  |
| B | (8) 71.0%/66.5% | (8) 65.8%/55.5% |  |
| C | (8) 71.8%/68.3% | (7) 76.2%/67.0% |  |
| D | (7) 73.7%/70.5% | (8) 80.8%/71.4% |  |
| E | (7) 66.6%/64.0% | (9) 72.8%/65.0% |  |
| F | (8) 66.2%/63.6% | (8) 57.0%/48.3% |  |
| G | (8) 73.1%/68.2% | (8) 73.2%/62.2% |  |

aOne patient in the CLC-CLC group and two in the CLC-PLGS group did not provide race information.

bTwelve patients in the CLC-CLC group and 11 in the CLC-PLGS group did not provide income information.

cHighest level completed by patient, or by primary caregiver if patient <18 years old. One patient in the CLC-CLC group did not provide education information.

dOne patient in the CLC-CLC group and one in the CLC-PLGS group did not provide insurance information.

# Supplemental Table S3: HbA1c Results

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **CLC****N=54** | **PLGS****N=55** | **Difference****(95% CI)**  | **P-value** |
| **HbA1c at Start of Preceding RCT: % (mmol/mol)***mean±SD* | 7.48% ± 1.10%(58 ± 12) | 7.35% ± 0.83%(57 ± 9.1) |  |  |
| **HbA1c at Start of This Study (Baseline): % (mmol/mol)***mean±SD* | 7.05% ± 0.78%(54 ± 8.5) | 7.06% ± 0.77%(54 ± 8.4) |  |  |
| **HbA1c at 13 Weeks: % (mmol/mol)***mean±SD* | 7.18% ± 0.80%(55 ± 8.7) | 7.53% ± 1.14%(59 ± 12.5) | -0.34% (-0.57%, -0.11%)[-3.7 (-6.2, -1.2]  | 0.0035 |
| **HbA1c <7.0% (<53 mmol/mol) at 13 Weeks** *n (%)* | 23 (43%) | 15 (27%) | 13% (-6%, 32%) | 0.05 |
| **HbA1c <7.5% (<58 mmol/mol) at 13 Weeks** *n (%)* | 35 (65%) | 32 (58%) | 9% (-14%, 31%) | 0.20 |
| **HbA1c Improvement by >0.5% (>5.5 mmol/mol) from Baseline to 13 Weeks** *n (%)* | 1 (2%) | 2 (4%) |  |  |
| **HbA1c Improvement by >1.0% (10.9 mmol/mol) from Baseline to 13 Weeks** *n (%)* | 0 | 0 |  |  |
| **HbA1c Relative Improvement by >10% (>86 mmol/mol) from Baseline to 13 Weeks** *n (%)* | 0 | 0 |  |  |
| **HbA1c Improvement by >1.0% (>10.9 mmol/mol) from Baseline to 13 Weeks or HbA1c <7.0% (<53 mmol/mol) at 13 Weeks** *n (%)* | 23 (43%) | 15 (27%) | 13% (-6%, 32%) | 0.05 |

# Supplemental Table S4: Insulin, Weight, and Body Mass Index

|  |  |  |
| --- | --- | --- |
|  | **Start of This Study (Baseline)** | **At 13-week Follow-up** |
|  | **CLC****N=54** | **PLGS****N=55** | **CLC****N=54** | **PLGS****N=55** | **Difference****(95% CI)**  | **P-value** |
| **Total Daily Insulin (per Kg)***median (IQR)* | N = 540.59 (0.49, 0.86) | N = 540.68 (0.46, 0.93) | N = 530.62 (0.50, 0.84) | N = 550.67 (0.48, 0.88) | -0.02 (-0.05, 0.01) | 0.25 |
| **Basal: Bolus Ratio***median (IQR)* | N = 540.9 (0.7, 1.2) | N = 540.8 (0.6, 1.2) | N = 531.0 (0.8, 1.2) | N = 550.9 (0.6, 1.3) | +0.10 (-0.06, +0.25) | 0.21 |
| **Weight (kg)***median (IQR)* | N = 5477.2 (66.3, 93.4) | N = 5573.0 (65.5, 87.8) | N = 5479.2 (65.9, 93.4) | N = 5572.8 (65.8, 87.8) | +0.3 (-0.4, +1.1) | 0.39 |
| **Body Mass Index (kg per m2)***median (IQR)* | N = 5425.7 (23.4, 30.0) | N = 5525.1 (22.6, 28.5) | N = 5425.6 (23.3, 29.2) | N = 5525.1 (23.1, 28.1) | +0.1 (-0.2, +0.3) | 0.48 |

# Supplemental Table S5: Safety Outcomes

|  |  |
| --- | --- |
|  | **13-week Follow-up** |
|  | **CLC****N=54** | **PLGS****N=55** |
| **All Adverse Events** *- count*  | 0  | 3  |
| **Severe Hypoglycemia Events** *- n(%) of participants [# of events)* | 0 | 0 |
| **Diabetic Ketoacidosis Events***- n(%) of participants [# of events)* | 0 | 0 |
| **Serious Adverse Events Related to Study Device** *n(%) of participants [# of events)* | 0 | 0 |
| **Other Serious Adverse Events**-*n(%) of participants [# of events)* | 0 | 0 |
| **Hyperglycemia/Ketosis Events without DKA -***n(%) of participants [# of events)* | 0 | 3 |
| **Glycated Hemoglobin Worsening by >0.5% (>5.5 mmol/mol) -***n (%) of participants* | 8 (15%) | 20 (36%) |
| **CGM-Measured Hypoglycemic Eventd Rate per Week***median (IQR)* | 0.4 (0.1, 0.9) | 0.5 (0.1, 0.9) |
| **CGM-Measured Hyperglycemic Evente Rate per Week***median (IQR)* | 1.6 (0.5, 3.1) | 2.3 (0.9, 5.3) |
| **Days with At Least One Ketone Measurement >1.0 mmol/L** *n (% of days)* | 5 (0.10%) | 1 (0.02%) |