

SUPPLEMENTARY DATA

Supplementary Table 1. Hypoglycemia awareness, severe hypoglycemia, biomedical and patient-reported outcomes in MDIs vs CSII and SMBG vs RT-CGM comparisons at 24-month endpoint (ITT)

	MDI	CSII	P-value	SMBG	RT-CGM	P-value
Hypoglycemia awareness						
Gold score	3.5±1.7 (n=29)	3.9±2.1 (n=27)	0.35	3.8±2.0 (n=28)	3.5±1.8 (n=28)	0.57
Median (IQR)	3 (2-4)	4 (2-6)		4 (2-5.5)	3 (2-5)	
Clarke score	2.3±2.3 (n=26)	2.8±1.9 (n=24)	0.39	2.7±2.2 (n=25)	2.3±2.0 (n=25)	0.51
Median (IQR)	1 (0-4)	3 (1.5-4.5)		3 (0-5)	2 (1-4)	
HypoA-Q 'Impaired Awareness' scale	7.6±5.0 (n=29)	9.2±5.0 (n=28)	0.24	8.3±5.0 (n=29)	8.4±5.1 (n=28)	0.90
Median (IQR)	8 (3-11)	9.5 (4.5-12)		9 (4-11)	8.5 (3.5-12)	
Severe hypoglycemia						
Annualized rate over 24-month follow-up, per person/year	0.4±0.8 (n=34)	0.4±0.9 (n=35)	0.97	0.5±1.0 (n=35)	0.3±0.6 (n=34)	0.33
Median (IQR)	0 (0-0.5)	0 (0-0.5)		0 (0-0.5)	0 (0-0.5)	
Proportion affected, %	40 (n=40)	32 (n=38)	0.44*	32 (n=38)	40 (n=40)	0.44*
HbA1c, mmol/mol	62±12 (n=37)	61±9 (n=35)	0.87	61±11 (n=36)	61±10 (n=36)	
Weight, kg	75.2±12.7 (n=39)	75.2±14.3 (n=35)	0.99	75.1±13.7 (n=39)	75.4±13.2 (n=35)	0.93
Total daily insulin dose, u/kg	0.56±0.17 (n=25)	0.51±0.14 (n=26)	0.27	0.52±0.12 (n=27)	0.56±0.18 (n=24)	0.27
Biochemical hypoglycemia, % time interstitial glucose ≤3mmol/L	2.4±3.8 (n=30)	2.8±4.5 (n=25)	0.72	2.6±3.6 (n=27)	2.6±4.6 (n=28)	0.98
Satisfaction with diabetes treatment: DTSQ						
Total satisfaction	30.7±5.0 (n=29)	31.7±4.6 (n=27)	0.43	31.0±4.8 (n=31)	31.3±4.8 (n=25)	0.81
Perceived frequency of hyperglycemia	2.9±1.3 (n=29)	3.2±1.4 (n=28)	0.40	3.0±1.3 (n=31)	3.2±1.4 (n=26)	0.61
Perceived frequency of hypoglycemia	2.4±1.3 (n=29)	3.0±1.3 (n=28)	0.09	2.8±1.3 (n=31)	2.6±1.4 (n=26)	0.66
Fear of hypoglycemia: HFS-II						
Total	38.3±26.2 (n=23)	42.2±27.3 (n=24)	0.62	40.5±24.9 (n=24)	40.0±28.8 (n=23)	0.95
Behavior	18.3±10.6 (n=24)	20.4±11.8 (n=25)	0.52	18.7±8.9 (n=26)	20.0±13.5 (n=23)	0.68
Worry	20.6±17.5 (n=25)	22.6±17.3 (n=27)	0.69	23.1±11.3 (n=27)	20.0±17.5 (n=25)	0.52

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Data are mean±SD unless stated otherwise. Number with available data denoted by n number in parentheses. P-values compare MDI and CSII groups at month 24, using two-sample t test, except *X² test.

Supplementary Table 2. Hypoglycemia awareness, severe hypoglycemia, biomedical and patient-reported outcomes at 24-month endpoint (per protocol): insulin delivery modality (MDI only vs. CSII only vs. switched) and RT-CGM use (<50% of time vs ≥50% of time)

	Insulin delivery modality throughout 24-month study (n=80)			RT-CGM use (n=14)	
	MDI only (n=10)	Switched (MDI & CSII) (n=45)	CSII only (n=25)	<50% time (n=6)	≥50% time (n=8)
Hypoglycemia awareness					
Gold score	2.9±1.2 (n=8)	3.6±1.9 (n=28)	3.9±2.1 (n=18)	2.8±1.9 (n=5)	3.3±2.0 (n=7)
Median (IQR)	3 (2-3.5)	4 (2-5)	4 (2-6)	2 (2-3)	3 (2-4)
Clarke score	1.4±1.9 (n=7)	2.5±2.0 (n=25)	2.8±2.2 (n=16)	1.0±1.4 (n=5)	1.8±1.7 (n=6)
Median (IQR)	1 (0-3)	3 (1-4)	2 (0.5-5)	0 (0-2)	1.5 (1-2)
HypoA-Q 'Impaired Awareness'	6.6±3.5 (n=8)	7.9±5.2 (n=27)	9.2±5.2 (n=20)	4.2±2.2 (n=5)	7.7±5.7 (n=7)
Median (IQR)	6 (3.5-10)	9 (3-11.5)	9.5 (4-11.5)	3 (3-6)	5 (3-13)
Severe hypoglycemia					
Annual rate over 24-month follow-up, per person/year	0.2±0.5 (n=10)	0.4±0.8 (n=33)	0.5±1.0 (n=25)	0.0±0.0 (n=6)	0.3±0.4 (n=8)
Median (IQR)	0 (0-0.5)	0 (0-0)	0 (0-0.5)	0 (0-0)	0 (0-0.5)
Proportion affected, %	30 (n=10)	36 (n=39)	32 (n=25)	0 (n=6)	38 (n=8)
HbA1c, mmol/mol	66±13 (n=9)	62±11 (n=38)	59±8 (n=23)	57±7(n=6)	56±9 (n=8)
Weight, kg	79.0±11.6 (n=10)	75.0±13.7 (n=37)	73.8±14.2 (n=24)	73.9±13.8 (n=6)	79.9±14.3 (n=8)
Total daily insulin dose, u/kg	Data not collected	0.55±0.16 (n=30)	0.52±0.15 (n=20)	0.58±0.16 (n=5)	0.66±0.13 (n=5)
Biochemical hypoglycemia, % time interstitial glucose ≤3mmol/L	2.8±4.8 (n=10)	2.8±4.7 (n=25)	2.3±3.0 (n=18)	4.3±8.8 (n=5)	3.0±4.8 (n=6)
Satisfaction with diabetes treatment: DTSQ					
Total satisfaction	30.1±2.9 (n=7)	30.8±6.0 (n=28)	31.9±3.4 (n=19)	31.2±4.4 (n=5)	31.2±5.0 (n=6)
Perceived frequency of hyperglycemia	2.3±0.8 (n=7)	3.3±1.4 (n=29)	3.1±1.4 (n=19)	3.2±1.9 (n=5)	3.5±1.0 (n=6)
Perceived frequency of hypoglycemia	2.1±1.2 (n=7)	2.6±1.5 (n=29)	3.2±1.1 (n=19)	2.4±1.3 (n=5)	2.8±1.3 (n=6)

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	Insulin delivery modality throughout 24-month study (n=80)			RT-CGM use (n=14)	
	MDI only (n=10)	Switched (MDI & CSII) (n=45)	CSII only (n=25)	<50% time (n=6)	≥50% time (n=8)
Fear of hypoglycemia: HFS-II					
Total	31.8±15.7 (n=6)	43.7±29.9 (n=23)	39.8±25.7 (n=17)	24.5±12.1 (n=4)	28.1±17.4 (n=7)
Behavior	18.3±5.9 (n=6)	18.8±12.4 (n=24)	20.7±11.4 (n=18)	15.3±6.3 (n=4)	16.4±9.0 (n=7)
Worry	13.5±11.2 (n=6)	26.0±19.4 (n=25)	19.1±15.5 (n=19)	15.0±15.4 (n=5)	11.7±10.1 (n=7)

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No formal hypothesis testing was performed due to small numbers of observations in certain groups.

Complete RT-CGM usage data were available for 14 of the 17 participants who continued to use RT-CGM.

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Supplementary Figure 1. Flow diagram showing number of participants allocated at random to each intervention, completing the 24-week RCT and completing 24-month follow-up.

Numbers using MDI and CSII during the RCT and post-RCT follow-up are shown. No participants randomized to SMBG commenced RT-CGM throughout the 24-month study and RT-CGM provision was not withdrawn from any participant randomized to RT-CGM (although not all continued active use, with 11 (30%) confirmed active users of this technology at study completion).

