

SUPPLEMENTARY DATA

Supplementary Table 1. Failure analysis during closed loop.

Number of nights when closed-loop turned on	311
Number of nights with	
0 events	231 (74%)
1 event	70 (23%)
2 events	8 (3%)
3 events	0
4 events	1 (<1%)
5 events	1 (<1%)
Total duration of closed-loop operation (h)	3053
Number of events^a	
All reasons	95
due to battery drained	4
due to Companion failure	1
due to basal profile changed	1
due to extended bolus changed by user	10
due to temporary infusion changed by user	4
due to sensor data unavailability	29
due to lack of pump connectivity	36
due to other reasons ^b	10

^a Event defined as undesirable stopping of closed-loop

^b Other reasons include control algorithm device failure and unknown reasons

Supplementary Table 2. Primary outcome using adjusted sensor glucose values corroborated by unadjusted sensor glucose levels. Time when glucose in target between 23:00 and 07:00 during overnight closed loop insulin delivery (269 evaluable nights) and sensor-augmented insulin pump therapy (282 evaluable nights) is reported. Values are medians (interquartile ranges).

	Time (%) when overnight glucose in target range ^a			
	Closed loop (N=16 subjects)	Control (N=16 subjects)	Paired difference ^d (%)	P
Adjusted sensor glucose ^b	64 (45 to 79)	47 (18 to 70)	+15 (-9 to +43)	<0.001
Unadjusted sensor glucose ^c	68 (43 to 86)	46 (13 to 77)	+19 (-12 to +50)	<0.001

^a Target range 70 to 144mg/dl.

^b Primary outcome: percentage calculated using adjusted sensor values.

^c Secondary outcome corroboration: percentage using unadjusted glucose levels

^d Closed loop minus insulin pump. Positive value indicates measurement was higher on nights of closed loop delivery compared with nights of pump therapy.

Supplementary Table 3. Outcomes using native CGM values.

	Overnight closed loop (N = 16 subjects)	Control (N = 16 subjects)	Paired difference^a	P
From 23:00 to 07:00				
Number of evaluable nights	269	282		–
Time spent at glucose level (%) ^b :				
70 to 144mg/dl	68 (43 to 86)	46 (13 to 77)	+19 (–12 to +50)	<0.001
70 to 180 mg/dl	89 (68 to 100)	73 (37 to 95)	+11 (–7 to +46)	<0.001
< 54mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.05
< 63mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.02
< 70mg/dl	0.0 (0.0 to 0.2)	0.0 (0.0 to 6.2)	0.0 (–2.7 to 0.0)	<0.001
> 144mg/dl	28.3 (11.0 to 51.8)	43.2 (11.4 to 86.7)	–13.2 (–49.7 to +15.9)	<0.001
> 180mg/dl	6.2 (0.0 to 27.9)	13.3 (0.0 to 58.8)	–0.6 (–42.2 to +7.9)	<0.001
> 300mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.87
From midnight to midnight (24 hours)				
Number of evaluable days	252	264		–
Time spent at glucose level (%) ^b :				
70 to 144mg/dl	51 (37 to 64)	40 (23 to 56)	+11 (–7 to +28)	<0.001
70 to 180 mg/dl	70 (56 to 83)	61 (44 to 76)	+8 (–7 to +25)	<0.001
< 54mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 1.3)	0.0 (–0.2 to 0.0)	0.05
< 63mg/dl	0.0 (0.0 to 1.9)	0.0 (0.0 to 4.0)	0.0 (–1.9 to +0.8)	0.11
< 70mg/dl	1.3 (0.0 to 4.0)	1.7 (0.0 to 8.1)	0.0 (–4.2 to +2.1)	0.10
> 144mg/dl	45.7 (31.6 to 60.3)	53.5 (35.7 to 75.6)	–9.2 (–28.2 to +9.9)	<0.001
> 180mg/dl	25.1 (12.9 to 41.7)	33.0 (17.0 to 52.7)	–6.4 (–25.1 to +9.5)	<0.001
> 300mg/dl	0.0 (0.0 to 3.4)	0.0 (0.0 to 4.7)	0.0 (–2.1 to +0.6)	0.61

Data are mean (SD) or median (interquartile range).

^a Closed loop minus control. A positive value indicates the value was higher on the closed loop compared with control.

^b Percentage time calculated using conservatively corrected sensor values.

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Supplementary Table 4. Safety evaluation.

	Overnight closed loop (N = 16 subjects)	Control (N = 16 subjects)
Number of severe hypoglycaemia	0	0
Number of subjects experiencing severe hypoglycaemia	0	0
Number of elevated ketones measurements^a	2	2
Number of subjects experiencing elevated ketones measurements	2	1

^a Ketones > 1.5mmol/l

Supplementary Table S5. Weekly trends during overnight closed-loop insulin delivery.

	Week 1 (N = 16 subjects)	Week 2 (N = 16 subjects)	Week 3 (N = 16 subjects)
From 23:00 to 07:00			
Number of evaluable nights	88	90	91
Time spent at glucose level (%) ^a :			
70 to 144mg/dl	64 (42 to 81)	65 (47 to 81)	64 (46 to 77)
< 70mg/dl	0.1 (0.0 to 0.2)	0.1 (0.0 to 0.5)	0.1 (0.0 to 0.4)
> 144mg/dl	31.0 (17.4 to 55.2)	27.5 (13.6 to 49.0)	30.1 (15.3 to 50.3)
Basal insulin delivery (U)	8.6 (6.7 to 11.1)	7.7 (6.3 to 10.1)	8.4 (6.4 to 10.8)
Bolus insulin delivery (U)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Total insulin delivery (U)	9.3 (7.0 to 13.1)	8.1 (6.5 to 11.1)	8.9 (6.8 to 12.8)
From midnight to midnight (24 hours)			
Number of evaluable days	87	89	76
Time spent at glucose level (%) ^a :			
70 to 144mg/dl	47 (35 to 61)	51 (40 to 61)	50 (39 to 61)
< 70mg/dl	0.3 (0.1 to 1.0)	0.4 (0.1 to 1.6)	0.4 (0.1 to 1.0)
> 144mg/dl	47.9 (34.1 to 60.8)	46.0 (30.6 to 57.5)	45.5 (33.8 to 58.2)
Basal insulin delivery (U)	24.3 (18.9 to 32.4)	23.3 (18.0 to 29.0)	21.4 (17.7 to 29.8)
Bolus insulin delivery (U)	23.2 (19.3 to 33.3)	24.6 (19.7 to 32.8)	26.5 (20.7 to 33.2)
Total insulin delivery (U)	49.0 (39.4 to 63.5)	50.3 (39.6 to 57.1)	51.2 (39.9 to 61.7)

Data are mean (SD) or median (interquartile range).

^a Percentage time calculated using conservatively corrected sensor values.

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Supplementary Table 6. Outcomes using native CGM values from 0200 to 0700.

		Overnight closed loop (N = 16 subjects)	Control (N = 16 subjects)	Paired difference^a	P
From 02:00 to 07:00					
	Time spent at glucose level (%) ^b :				
	70 to 144mg/dl	84 (60 to 100)	46 (3 to 89)	+30 (-3 to +70)	<0.001
	70 to 180 mg/dl	100 (88 to 100)	81 (29 to 100)	+10 (0 to +59)	<0.001
	< 54mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.05
	< 63mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.04
	< 70mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.02
	> 144mg/dl	9.0 (0.0 to 34.2)	40.9 (0.0 to 96.7)	-18.3 (-70.4 to +4.7)	<0.001
	> 180mg/dl	0.0 (0.0 to 4.0)	0.0 (0.0 to 61.1)	0.0 (-54.2 to 0.0)	<0.001
	> 300mg/dl	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.47

Data are mean (SD) or median (interquartile range).

^a Closed loop minus control. A positive value indicates the value was higher on the closed loop compared with control.

^b Percentage time calculated using conservatively corrected sensor values.

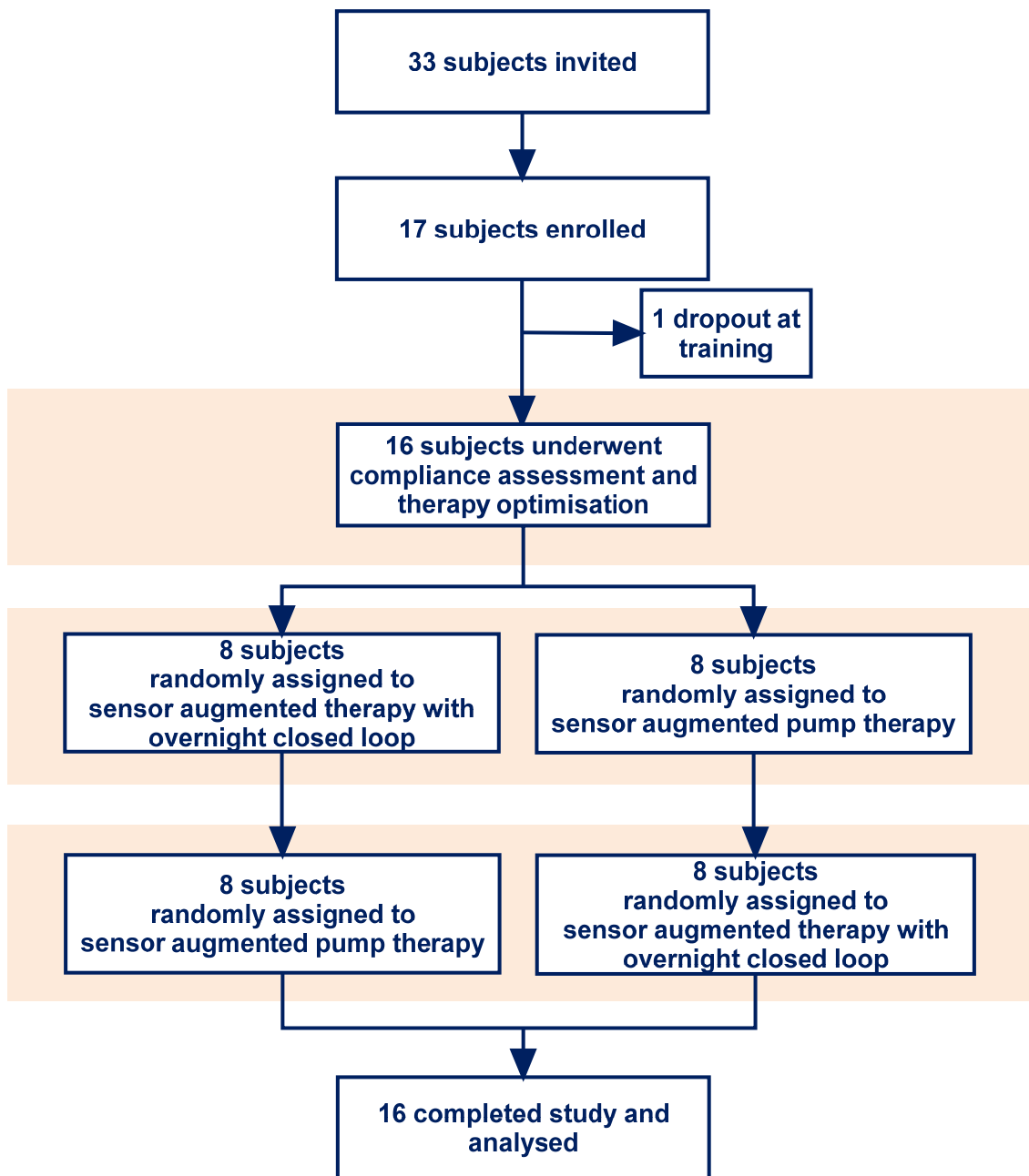
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Supplementary Table 7. List of competencies assessed at the end of training on closed loop system.

- Switching *CAD ON/OFF
- Checking battery level on CAD
- Awareness of importance of connecting CAD to mains power with lead provided overnight
- Connecting CAD to Companion via USB cable
- Being aware of keeping the CAD and DANA-R insulin pump as close together as possible to ensure connectivity
- Checking if Companion is connected on CAD screen
- Starting closed-loop
- Stopping closed-loop
- Understanding “Hypo alarms will be switched-off” message
- Understanding meaning of “Suspended closed-loop” mode and “Cannot continue-reverted to open loop”
- Understanding how to check alarms audio
- Understanding the concept of closed-loop delivery
- Understanding information on DANA-R pump screen during closed-loop delivery
- Understanding you must deliver a manual bolus with food
- Understanding the process of delivering a meal bolus during closed-loop
- Understanding the importance of calibration checks
- Understanding the importance of alarms being switched ON on the Companion during closed-loop

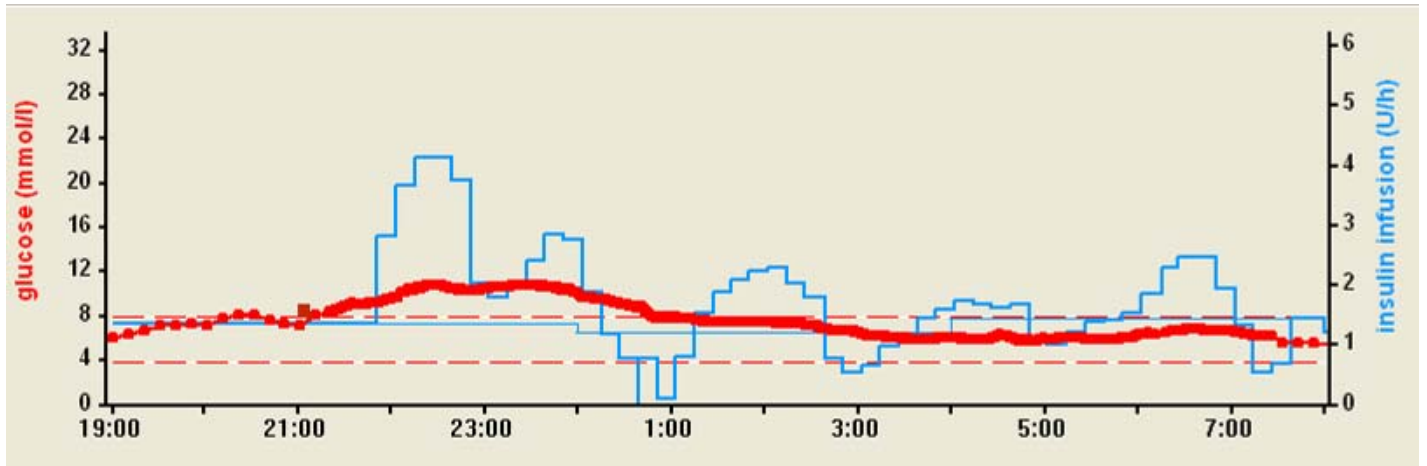
*CAD stands for control algorithm device (ultraportable OQO laptop)

Supplementary Figure 1. Flow of participants through the trial.



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Supplementary Figure 2. Overnight closed loop during a sample study night. Closed loop started at 21:40 and stopped at 07:30. Continuous glucose measurements are shown by light red squares, fingerstick calibration check is shown by a dark square (21:10), insulin delivery is shown by heavy blue line, and preprogrammed insulin delivery (not administered but shown for illustration) by thin blue line. The target range between 3.9 and 8.0mmol/l (70 and 144mg/dl) is denoted by dashed red line.



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Supplementary Figure 3. 24hour profiles of sensor glucose (top panel) and insulin delivery (bottom panel) during closed loop and control. The target glucose range 70 to 144 mg/dl is denoted by the dashed lines. Median [interquartile range] is shown.

