



Figure S1 Representative images of the LenoMed ATA-I-1-0 insulin pump.



Figure S2 Representative images of the Medtronic MMT-712 insulin pump.

**Table S1** Recruited patients stratified by the 3 hospitals involved in the study

Centers	Group	No. of recruited patients	No. of dropout patients	Dropout rate (%)	Exclusion	Exclusion rate (%)	Final recruited subjects
Chinese People's Liberation Army General Hospital	Intervention	30	5	16.67	4	13.33	25
	Control	30	1	3.33	4	13.33	29
	Total	60	6	10.00	8	13.33	54
Beijing Chaoyang Hospital	Intervention	13	0	0.00	0	0.00	13
	Control	12	0	0.00	0	0.00	12
	Total	25	0	0.00	0	0.00	25
Beijing Pinggu District Hospital	Intervention	17	2	11.76	0	0.00	15
	Control	18	0	0.00	0	0.00	18
	Total	35	2	5.71	0	0.00	33
Total	Intervention	60	7	11.67	4	6.67	53
	Control	60	1	1.67	4	6.67	59
	Total	120	8	6.67	8	6.67	112

**Table S2** Recruited patients stratified by different datasets and hospitals

Centers	Per protocol set			Full analysis set			Safety analysis set		
	Intervention group	Control group	Total	Intervention group	Control group	Total	Intervention group	Control group	Total
Chinese People's Liberation Army General Hospital	21	25	46	25	30	55	25	30	55
Beijing Chaoyang Hospital	13	12	25	13	12	25	13	12	25
Beijing Pinggu District Hospital	15	18	33	16	18	34	16	18	34
Total	49	55	104	54	60	114	54	60	114

**Table S3** Detailed description of the enrolled patients and 3 datasets

Variables	Intervention group	Control group
Number of patients		
Recruited and randomized	60	60
Completed the treatment	53	59
Number of patients who stopped the treatment		
Not satisfied with the treatment	0	1
Had adverse events	1	0
Frequent hypoglycemia	0	0
Used prohibited medication	0	0
Protocol violation that threatened safety	0	0
Patients withdrew informed consent	3	0
Death	0	0
Others	3	0
Dataset to analyze safety		
Safety analysis set	54	60
Dataset to analyze efficacy		
Full analysis set	54	60
Per protocol set	49	55

**Table S4** Difference in fasting plasma glucose levels before and after treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	47 [7]	55 [5]	43 [6]	51 [4]
	Mean (SD)	11.48 (2.53)	11.36 (3.23)	11.38 (2.59)	11.43 (3.32)
	Median	10.70	10.80	10.60	10.80
	Min–Max	6.80–16.70	5.90–18.10	6.80–16.70	5.90–18.10
Comparison between groups	P value	0.833 <sup>a</sup>		0.937 <sup>a</sup>	
After treatment	N [missing]	54 [0]	59 [1]	49 [0]	55 [0]
	Mean (SD)	6.61 (1.44)	6.74 (1.49)	6.59 (1.44)	6.68 (1.44)
	Median	6.30	6.40	6.30	6.40
	Min–Max	4.60–10.60	4.10–10.60	4.60–10.60	4.10–10.20
Difference before and after the analysis	N [missing]	47 [7]	55 [5]	43 [6]	51 [4]
	Mean (SD)	–4.82 (2.36)	–4.67 (3.65)	–4.77 (2.41)	–4.82 (3.64)
	Median	–4.50	–4.60	–4.50	–4.60
	Min–Max	–10.70–0.50	–13.30–2.40	–10.70–0.50	–13.30–1.40
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.803 <sup>a</sup>		0.945 <sup>a</sup>	

<sup>a</sup>, the comparison was conducted using the Cochran-Mantel-Haenszel test.

**Table S5** Difference in plasma glucose levels 2 hours after breakfast before and after treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	35 [19]	37 [23]	31 [18]	33 [22]
	Mean (SD)	18.36 (5.18)	16.23 (5.21)	18.30 (5.21)	15.88 (4.88)
	Median	16.80	16.10	16.80	15.40
	Min–Max	10.00–29.70	7.70–30.50	10.00–29.70	7.70–30.50
Comparison between groups	P value	0.087 <sup>a</sup>		0.060 <sup>a</sup>	
After treatment	N [missing]	44 [10]	51 [9]	40 [9]	48 [7]
	Mean (SD)	10.12 (3.33)	10.17 (3.20)	10.18 (3.42)	10.02 (3.07)
	Median	9.45	9.70	9.45	9.65
	Min–Max	4.70–21.60	4.70–19.20	4.70–21.60	4.70–19.20
Difference before and after analysis	N [missing]	27 [27]	33 [27]	24 [25]	30 [25]
	Mean (SD)	–8.04 (5.10)	–6.60 (4.76)	–7.76 (5.26)	–6.28 (4.26)
	Median	–7.80	–6.30	–7.50	–5.95
	Min–Max	–16.30–3.30	–16.80–3.50	–16.30–3.30	–16.00–3.50
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.263 <sup>a</sup>		0.259 <sup>a</sup>	

<sup>a</sup>, the comparison was conducted using the Cochran-Mantel-Haenszel test.

**Table S6** Difference in plasma glucose levels 2 hours before lunch before and after treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	40 [14]	46 [14]	36 [13]	43 [12]
	Mean (SD)	14.62 (4.31)	14.11 (5.33)	14.71 (4.52)	14.34 (5.36)
	Median	13.50	13.60	13.50	13.90
	Min–Max	8.90–26.80	6.20–31.60	8.90–26.80	6.20–31.60
Comparison between groups	P value	0.565 <sup>a</sup>		0.727 <sup>a</sup>	
After treatment	N [missing]	50 [4]	59 [1]	46 [3]	55 [0]
	Mean (SD)	8.36 (3.19)	8.09 (3.03)	8.50 (3.23)	7.96 (2.93)
	Median	7.35	7.50	7.50	7.50
	Min–Max	4.40–17.10	3.70–16.60	4.40–17.10	3.70–16.60
Difference before and after analysis	N [missing]	38 [16]	46 [14]	35 [14]	43 [12]
	Mean (SD)	–6.19 (4.14)	–6.00 (4.99)	–6.14 (4.17)	–6.33 (4.82)
	Median	–6.35	–6.20	–6.10	–6.30
	Min–Max	–19.90–1.90	–16.90–4.70	–19.90–1.90	–16.90–2.90
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.856 <sup>a</sup>		0.856 <sup>a</sup>	

<sup>a</sup>, the comparison was conducted using the Cochran-Mantel-Haenszel test.

**Table S7** Difference in plasma glucose levels 2 hours after lunch before and after treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	43 [11]	50 [10]	39 [10]	46 [9]
	Mean (SD)	17.04 (4.01)	16.01 (5.85)	16.86 (4.06)	16.20 (5.92)
	Median	16.70	16.45	16.50	16.90
	Min–Max	9.30–25.80	4.80–28.20	9.30–25.80	4.80–28.20
Comparison between groups	P value	0.319 <sup>a</sup>		0.545 <sup>a</sup>	
After treatment	N [missing]	51 [3]	57 [3]	46 [3]	53 [2]
	Mean (SD)	10.36 (3.12)	10.08 (3.49)	10.41 (3.18)	9.92 (3.54)
	Median	10.10	9.90	10.15	9.20
	Min–Max	4.20–18.50	4.30–22.20	4.20–18.50	4.30–22.20
Difference before and after analysis	N [missing]	41 [13]	49 [11]	37 [12]	45 [10]
	Mean (SD)	–6.39 (4.68)	–5.66 (6.23)	–6.16 (4.78)	–6.02 (6.32)
	Median	–5.60	–4.80	–5.30	–4.90
	Min–Max	–16.90–3.60	–21.50–5.70	–16.90–3.60	–21.50–5.70
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.538 <sup>a</sup>		0.914 <sup>a</sup>	

<sup>a</sup>, the comparison was conducted using the Cochran-Mantel-Haenszel test.

**Table S8** Difference in plasma glucose levels 2 hours before dinner before and after treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	41 [13]	47 [13]	36 [13]	43 [12]
	Mean (SD)	14.02 (5.33)	13.68 (5.67)	14.16 (5.57)	13.87 (5.80)
	Median	14.30	12.40	14.35	12.40
	Min–Max	5.90–33.30	5.70–33.30	5.90–33.30	5.70–33.30
Comparison between groups	P value	0.682 <sup>a</sup>		0.802 <sup>a</sup>	
After treatment	N [missing]	52 [2]	55 [5]	48 [1]	51 [4]
	Mean (SD)	8.11 (2.51)	8.14 (3.04)	8.11 (2.48)	8.06 (3.08)
	Median	7.30	7.50	7.30	7.30
	Min–Max	4.10–14.40	3.90–20.80	4.10–14.40	3.90–20.80
Difference before and after analysis	N [missing]	40 [14]	43 [17]	36 [13]	39 [16]
	Mean (SD)	–6.07 (4.69)	–5.18 (4.87)	–6.20 (4.84)	–5.47 (4.91)
	Median	–5.75	–3.80	–6.05	–3.80
	Min–Max	–18.90–3.40	–19.00–3.10	–18.90–3.40	–19.00–3.10
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.403 <sup>a</sup>		0.519 <sup>a</sup>	

<sup>a</sup>, the comparison was conducted using the Cochran-Mantel-Haenszel test.

**Table S9** Differences in plasma glucose levels at 2 hours after dinner before and after treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	47 [7]	47 [13]	43 [6]	43 [12]
	Mean (SD)	16.61 (4.77)	15.44 (5.59)	16.58 (4.93)	16.07 (5.32)
	Median	16.30	14.50	16.00	14.90
	Min–Max	9.90–32.80	3.60–33.10	9.90–32.80	6.80–33.10
Comparison between groups	P value	0.150 <sup>a</sup>		0.419 <sup>a</sup>	
After treatment	N [missing]	51 [3]	57 [3]	47 [2]	53 [2]
	Mean (SD)	8.74 (3.00)	9.15 (2.72)	8.87 (3.05)	9.17 (2.79)
	Median	8.50	8.10	8.50	8.10
	Min–Max	4.70–16.30	4.10–15.60	4.70–16.30	4.10–15.60
Difference before and after analysis	N [missing]	44 [10]	45 [15]	41 [8]	42 [13]
	Mean (SD)	–7.97 (5.36)	–6.64 (5.58)	–7.85 (5.37)	–7.00 (5.49)
	Median	–7.30	–6.10	–7.10	–6.40
	Min–Max	–22.40–2.20	–25.50–4.20	–22.40–2.20	–25.50–2.50
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.135 <sup>a</sup>		0.287 <sup>a</sup>	

<sup>a</sup>The comparison was conducted using the Cochran-Mantel-Haenszel test.

**Table S10** Difference in plasma glucose levels before sleep (10 pm) before and after treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	51 [3]	51 [9]	46 [3]	47 [8]
	Mean (SD)	15.08 (4.78)	13.30 (5.21)	15.02 (4.90)	13.80 (5.06)
	Median	14.20	13.00	14.10	13.10
	Min–Max	5.60–27.50	4.30–32.10	5.60–27.50	5.70–32.10
Comparison between groups	P value	0.051 <sup>a</sup>		0.201 <sup>a</sup>	
After treatment	N [missing]	54 [0]	58 [2]	49 [0]	54 [1]
	Mean (SD)	7.56 (2.10)	8.01 (2.52)	7.66 (2.07)	8.10 (2.53)
	Median	7.25	7.15	7.30	7.30
	Min–Max	3.80–13.40	4.10–13.70	4.10–13.40	4.10–13.70
Difference before and after analysis	N [missing]	51 [3]	49 [11]	46 [3]	46 [9]
	Mean (SD)	–7.51 (4.86)	–5.42 (5.77)	–7.35 (4.83)	–5.69 (5.80)
	Median	–6.80	–5.50	–6.65	–6.00
	Min–Max	–19.40–2.40	–26.20–3.50	–19.40–2.40	–26.20–3.50
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.024 <sup>a</sup>		0.080 <sup>a</sup>	

<sup>a</sup>, the comparison was conducted using the Cochran-Mantel-Haenszel test.

**Table S11** Difference in hemoglobin A1c (HbA1c) levels before and after treatment between the control and intervention group

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Baseline	N [missing]	54 [0]	60 [0]	49 [0]	55 [0]
	Mean (SD)	10.71 (1.43)	10.86 (1.66)	10.68 (1.49)	10.92 (1.71)
	Median	10.35	10.50	10.30	10.50
	Q1–Q3	9.60–11.60	9.70–11.25	9.50–11.80	9.80–11.30
	Min–Max	9.00–14.40	9.10–16.20	9.00–14.40	9.10–16.20
Comparison between groups	P value	0.685 <sup>a</sup>		0.346 <sup>a</sup>	
After treatment	N [missing]	53 [1]	59 [1]	48 [1]	55 [0]
	Mean (SD)	10.18 (1.30)	10.35 (1.50)	10.15 (1.35)	10.39 (1.55)
	Median	9.80	9.90	9.60	9.90
	Q1–Q3	9.10–11.10	9.40–10.70	9.10–11.15	9.40–10.90
	Min–Max	8.50–13.50	8.30–15.80	8.50–13.50	8.30–15.80
Comparison between groups	P value	0.514		0.337	
Difference before and after analysis	N [missing]	53 [1]	59 [1]	48 [1]	55 [0]
	Mean (SD)	–0.47 (0.30)	–0.54 (0.39)	–0.46 (0.30)	–0.53 (0.40)
	Median	–0.40	–0.50	–0.40	–0.50
	Q1–Q3	–0.70–0.30	–0.70–0.30	–0.70–0.25	–0.70–0.30
	Min–Max	–1.20–0.10	–1.90–0.30	–1.20–0.10	–1.90–0.30
Comparison between groups	P value	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>	<0.001 <sup>a</sup>
Comparison before and after treatment between groups	P value	0.411 <sup>a</sup>		0.353 <sup>a</sup>	
	95% CI	–0.06–0.20		–0.06–0.22	

<sup>a</sup>, the comparison was conducted using the Wilcoxon rank sum test.

**Table S12** Daily accuracy of the LenoMed ATA-I-1-0 insulin pump during treatment

Variable	Indicators	Full analysis set		Per protocol set	
		Intervention group	Control group	Intervention group	Control group
Total base rate on 1 <sup>st</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	60 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	60 [0]	49 [0]	55 [0]
Large dose on 1 <sup>st</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	52 (100.00)	57 (100.00)	47 (100.00)	53 (100.00)
	Total [missing]	52 [2]	57 [3]	47 [2]	53 [2]
Total base rate on 2 <sup>nd</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	60 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	60 [0]	49 [0]	55 [0]
Large dose on 2 <sup>nd</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	60 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	60 [0]	49 [0]	55 [0]
Total base rate on 3 <sup>rd</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	59 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	59 [1]	49 [0]	55 [0]
Large dose on 3 <sup>rd</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	59 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	59 [1]	49 [0]	55 [0]
Total base rate on 4 <sup>th</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	59 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	59 [1]	49 [0]	55 [0]
Large dose on 4 <sup>th</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	59 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	59 [1]	49 [0]	55 [0]
Total base rate on 5 <sup>th</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	59 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	59 [1]	49 [0]	55 [0]
Large dose on 5 <sup>th</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	59 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	59 [1]	49 [0]	55 [0]
Total base rate on 6 <sup>th</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	54 (100.00)	59 (100.00)	49 (100.00)	55 (100.00)
	Total [missing]	54 [0]	59 [1]	49 [0]	55 [0]
Large dose on 6 <sup>th</sup> treatment day	No, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Yes, n (%)	53 (100.00)	59 (100.00)	48 (100.00)	55 (100.00)
	Total [missing]	53 [1]	59 [1]	48 [1]	55 [0]