

The effect of the Panbrain EC2 on sleep improvement

1. Introduction

Sleep is an important part of human physiological and mental health. Not only is it a key process for body recovery and energy replenishment, it is also essential for cognitive function, mood regulation, and the normal functioning of the immune system.^[1, 2] Healthy sleep patterns usually include different stages of deep sleep, rapid eye movement sleep and light sleep. The normal rotation of each stage helps the body and brain recover. However, as the pace of life in modern society accelerates and stress levels rise, more and more people are facing sleep disorders, which manifest as poor sleep quality, difficulty falling asleep, early awakening, or unstable sleep.

Transcranial direct current stimulation (tDCS), as an emerging non-invasive brain stimulation technology, has attracted widespread attention in recent years in terms of improving sleep quality and alleviating insomnia. Relevant studies have shown that tDCS can improve sleep quality by regulating sleep brain rhythms and increasing slow-wave sleep.^[3] This experiment was conducted based on the Panbrain EC2 (Shenzhen Panbrain Technology Co., Ltd., using tDCS technology), aiming to evaluate the device's effect on improving sleep.

2. Experimental method

2.1. General information

Table 1 Comparison of the general information of the two groups of subjects

Group	n	age(years, $\bar{x} \pm s$)	Gender (n)	
			Male	Female
Stimulation	28	26.61±8.77	12	16
Control	28	30.93±8.86	11	17
t/χ^2		-1.835	0.074	
P		0.072	0.786	

This study recruits social groups. After screening, 56 subjects were finally

included. They were divided into stimulation group and control group using random number table method, with 28 subjects in each group. Comparing the general information of the two groups of subjects, the difference was not statistically significant. See Table 1.

Inclusion criteria: (1) Self-reported sleep distress in the past month, and the Pittsburgh Sleep Quality Index score is >7 points, and the Epworth Sleepiness Scale >10 points; (2) No major physical illness or mental illness; (3) Have good living habits and regular work and rest; (4) Aged ≥ 18 years old; (5) Voluntarily participate and sign an informed consent form, and are willing to cooperate in completing the intervention and evaluation during the trial.

Exclusion criteria: (1) There is a history of sleep disorders, such as sleep breathing disorder; (2) Suffering from organic diseases such as epilepsy and heart disease; (4) Suffering from tDCS contraindications.

2.2. Intervention

The stimulation group used the Panbrain EC2 for tDCS treatment. The electrode cover is first soaked with 0.9% sodium chloride solution, and then the excess water is squeezed out by hand to ensure that the water does not drip, and then the electrode cover is fixed on the electrode. According to the 10-20 international standard system, the anode electrode is placed in the F3 area, which is the left dorsolateral prefrontal cortex, and the cathode electrode is placed in the F4 area, which is the right dorsolateral prefrontal cortex. Each treatment lasted 15 minutes, once a day, 5 days a week, for 4 consecutive weeks (20 sessions).

The operation of the control group was the same as that of the stimulation group, but no current stimulation was applied during the treatment process.

2.3. Evaluation indicators

Before treatment and after the completion of 4 weeks of treatment, the subjects' sleep quality was evaluated using the Pittsburgh Sleep Quality Index (PSQI) and the Epworth Sleepiness Scale (ESS).

The PSQI scale is a sleep quality test scale compiled by Buysse et al. and translated into Chinese by Liu Xianchen et al..^[4,5] It has good reliability and validity and is widely used in clinical practice.^[6] This scale contains 18 items, and professionals evaluate the subject's condition based on the question-and-answer situation and behavioral performance. The 18 items can be summarized into 7 components, including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. Each component is scored from 0 to 3 points, with a total score of 0 to 21 points. The higher the PSQI total score, the worse the sleep quality.

ESS was developed by Johns and measures the likelihood of dozing off in different situations during the day. It is suitable for assessing sleep-related sleepiness and is widely used in clinical and scientific research.^[7] The scale includes 8 items, scored from 0 to 3 (0=never doze, 3=very likely to doze), with a total score of 0 to 24. A high score indicates severe sleepiness, and a score >10 indicates abnormality.

After the scale evaluation, the scores of PSQI and ESS are converted into a percentage system, and the composite score is calculated based on the weight of PSQI accounting for 50% and ESS accounting for 50%. The specific calculation method is as follows:

$$\text{Score} = \frac{\text{PSQI}}{21} \times 100 \times 50\% + \frac{\text{ESS}}{24} \times 100 \times 50\%$$

2.4. Statistical method

SPSS 27.0 statistical software was used for data analysis. Continuous data are expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$), unpaired t test is used for comparison between groups, paired t test is used for comparison within groups before and after treatment; Categorical data are expressed as counts (n), and χ^2 test is used. $P < 0.05$ was considered as a statistically significant difference.

3. Test results

Before treatment, there was no statistically significant difference in the PSQI,

Table 2 Comparison of PSQI scores of the two groups of subjects before and after treatment

($\bar{x} \pm s$)				
Group	Before	After	<i>t</i>	<i>P</i>
Stimulation	12.25±1.84	7.79±1.47 ^{ab}	-10.645	<0.001
Control	12.43±1.60	11.43±1.83	-1.954	0.061
<i>t</i>	-0.388	-8.190		
<i>P</i>	0.700	<0.001		

Note: Compared with before treatment, ^a*P*<0.05; Compared with the control group, ^b*P*<0.05;

Table 3 Comparison of ESS scores of the two groups of subjects before and after treatment ($\bar{x} \pm s$)

Group	Before	After	<i>t</i>	<i>P</i>
Stimulation	13.82±1.91	8.89±2.15 ^{ab}	-9.098	<0.001
Control	13.25±1.94	12.32±1.49 ^a	-3.099	0.004
<i>t</i>	1.113	-6.935		
<i>P</i>	0.271	<0.001		

Note: Compared with before treatment, ^a*P*<0.05; Compared with the control group, ^b*P*<0.05;

Table 4 Comparison of the composite scores of the two groups of subjects before and after

treatment ($\bar{x} \pm s$)				
Group	Before	After	<i>t</i>	<i>P</i>
Stimulation	57.96±8.14	37.06±5.92 ^{ab}	-11.702	<0.001
Control	57.20±7.75	52.88±5.57 ^a	-2.558	0.016
<i>t</i>	0.360	-10.296		
<i>P</i>	0.720	<0.001		

Note: Compared with before treatment, ^a*P*<0.05; compared with the control group, ^b*P*<0.05;

ESS, and composite scores of the two groups of subjects (*P*≥0.05); after treatment, the scores of the stimulation group and the ESS and composite scores of the control group were significantly lower than before treatment (*P*<0.05), while the PSQI score of the

control group was only marginally significant ($P=0.061$). Comparing between groups, the scores of the stimulation group after treatment were significantly lower than those of the control group ($P<0.05$), and the difference was statistically significant. See Tables 2-4.

4. Conclusion

This study shows through a randomized controlled trial that the Panbrain EC2 using tDCS technology can significantly improve an individual's sleep quality after 4 weeks (20 sessions). The results of the study showed that the PSQI score of the stimulation group decreased by 36.44% ($P<0.001$) with a responder rate of 92.86%; the ESS score decreased by 35.66% ($P<0.001$) with a responder rate of 82.14%; the composite score decreased by 36.05% with a responder rate of 92.86%. In contrast, the PSQI score of the control group only decreased by 8.05% ($P=0.061$) with a responder rate of 53.57%; the ESS score decreased by 7.01% ($P=0.075$) with a responder rate of 60.71%; the composite score decreased by 7.54% with a responder rate of 57.14%. The comparison results between groups showed that the reduction in various indicators in the stimulation group was significantly greater than that in the control group, and the difference was statistically significant ($P<0.05$). This shows that as a non-invasive neuromodulation device, the Panbrain EC2 can provide a safe and feasible intervention option for individuals with poor sleep quality.

References

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Appendix A

Table A.1 General information and scores of the two groups of subjects

Group	Subject	Gender	Age	Before treatment			After treatment		
				PSQI	ESS	Composite score	PSQI	ESS	Composite score
Stimulation group (1~28)	1	Female	23	10	12	48.81	7	6	29.17
	2	Female	34	12	14	57.74	6	9	33.04
	3	Male	25	10	13	50.89	7	8	33.33
	4	Male	21	12	15	59.82	8	7	33.63
	5	Male	18	11	11	49.11	5	6	24.4
	6	Female	41	16	18	75.6	9	10	42.26
	7	Female	22	14	16	66.67	7	8	33.33
	8	Female	29	8	10	39.88	9	10	42.26
	9	Female	18	13	14	60.12	8	7	33.63
	10	Female	27	10	12	48.81	4	8	26.19
	11	Male	19	12	13	55.65	7	8	33.33
	12	Male	19	13	15	62.2	10	9	42.56
	13	Male	18	14	16	66.67	8	8	35.71
	14	Female	20	12	14	57.74	10	8	40.48
	15	Male	28	15	17	71.13	8	9	37.8
	16	Female	27	12	13	55.65	9	8	38.1
	17	Female	50	13	15	62.2	7	9	35.42
	18	Male	25	13	14	60.12	8	9	37.8
	19	Female	28	12	13	55.65	7	8	33.33
	20	Male	18	14	16	66.67	8	10	39.88
	21	Male	25	13	15	62.2	8	9	37.8
	22	Female	19	11	12	51.19	9	5	31.85
	23	Female	31	9	11	44.35	11	11	49.11
	24	Female	39	15	15	66.96	9	10	42.26
	25	Female	35	11	13	53.27	7	14	45.83
	26	Female	23	12	12	53.57	7	13	43.75

Continued Table A.1 General information and scores of the two groups of subjects

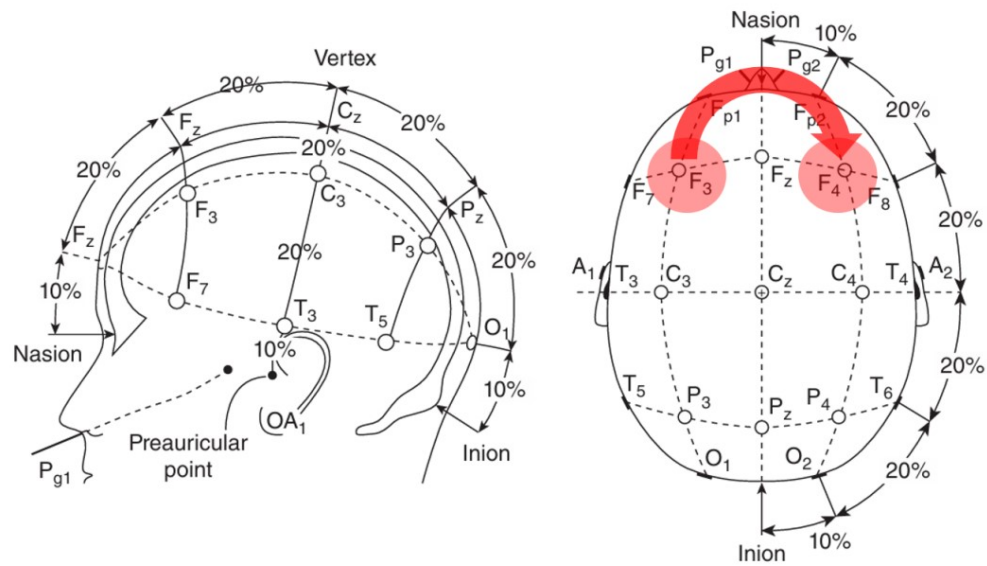
Group	Subject	Gender	Age	Before treatment			After treatment		
				PSQI	ESS	Composite score	PSQI	ESS	Composite score
Stimulation group (1~28)	27	Male	18	13	15	62.2	8	8	35.71
	28	Male	45	13	13	58.04	7	14	45.83
	29	Male	51	11	12	51.19	10	12	48.81
	30	Female	32	12	13	55.65	13	12	55.95
	31	Male	20	12	14	57.74	9	12	46.43
	32	Female	43	15	16	69.05	12	14	57.74
	33	Male	24	11	11	49.11	13	12	55.95
	34	Male	26	14	15	64.58	10	12	48.81
	35	Male	39	13	14	60.12	10	12	48.81
	36	Female	18	12	12	53.57	13	13	58.04
	37	Female	18	11	11	49.11	13	12	55.95
	38	Male	35	12	13	55.65	10	10	44.64
	39	Female	34	12	12	53.57	13	12	55.95
Control group (29~56)	40	Female	31	10	10	44.64	10	9	42.56
	41	Male	35	13	14	60.12	11	12	51.19
	42	Male	41	11	12	51.19	13	11	53.87
	43	Male	40	12	13	55.65	9	13	48.51
	44	Female	25	13	15	62.2	14	14	62.5
	45	Male	39	11	11	49.11	15	11	58.63
	46	Female	32	12	12	53.57	11	11	49.11
	47	Male	25	13	14	60.12	15	13	62.8
	48	Female	18	9	10	42.26	11	10	47.02
	49	Female	37	14	16	66.67	8	11	41.96
	50	Female	27	16	17	73.51	10	15	55.06
	51	Female	31	14	15	64.58	10	14	52.98
	52	Female	22	12	13	55.65	13	12	55.95
	53	Female	18	13	14	60.12	12	14	57.74

Continued Table A.1 General information and scores of the two groups of subjects

Group	Subject	Gender	Age	Before treatment			After treatment		
				PSQI	ESS	Composite score	PSQI	ESS	Composite score
Control group (29~56)	54	Female	32	11	11	49.11	11	14	55.36
	55	Female	30	15	16	69.05	10	13	50.89
	56	Female	43	14	15	64.58	11	15	57.44

Appendix B

Schematic diagram of intervention points based on the 10-20 international standard system



Appendix C Pittsburgh Sleep Quality Index Scale (sample format)

Pittsburgh sleep quality index, PSQI

No.: _____ Date of Completion: _____ Gender: ☐ M ☐ F Age: _____

The following information is filled in by the evaluator based on the interview with the subject

Item	Item		Rating			
			0 points	1 point	2 points	3 points
1	Time to go to bed at night					
2	Bed to bed time		<15 minutes	16-30 minutes	31-60 minutes	>60 minutes
3	Wake up time		5 o'clock	6 o'clock	7 o'clock	8 o'clock
4	Actual sleep time per night		>7 hours	6-7 hours	5-6 hours	<5 hours
5	Have any of the following conditions affected your sleep	a. Difficulty falling asleep (cannot fall asleep within 30 minutes)	None	<1 time a week	1-2 times a week	≥ 3 times a week
		b. Wake up easily or early at night	None	<1 time a week	1-2 times a week	≥ 3 times a week
		c. Going to the toilet at night	None	<1 time a week	1-2 times a week	≥ 3 times a week
		d. Suffering from breathing	None	<1 time a week	1-2 times a week	≥ 3 times a week
		e. Coughing or snoring	None	<1 time a week	1-2 times a week	≥ 3 times a week
		f. Feeling cold	None	<1 time a week	1-2 times a week	≥ 3 times a week
		g. Feeling hot	None	<1 time a week	1-2 times a week	≥ 3 times a week
		h. Nightmares	None	<1 time a week	1-2 times a week	≥ 3 times a week
		i. Pain and discomfort	None	<1 time a week	1-2 times a week	≥ 3 times a week

Item	Item		Rating			
			0 points	1 point	2 points	3 points
5		j. Other things that affect sleep	None	<1 time a week	1-2 times a week	≥ 3 times a week
6	Sleep quality		Very good	Better	Poor	Very poor
7	Use of hypnotic drugs		None	<1 time a week	1-2 times a week	≥ 3 times a week
8	Sleepiness: Frequent yawning, heavy and droopy eyelids, poor concentration and slow reaction		None	<1 time a week	1-2 times a week	≥ 3 times a week
9	Low energy: slow movement, lack of interest, muscle weakness, weak voice		Very good	Better	Poor	Very poor

Pittsburgh sleep quality index scoring method

Ingredient	Content	Rating			
		0 points	1 point	2 points	3 points
A. subjective sleep quality	Score for item 6	Very good	Better	Poor	Very poor
B. sleep latency	Total score for items 2 and 5a	0 points	1~2 points	3~4 points	5~6 points
C. sleep duration	Score for item 4	>7h	6~7h (excluding 6h)	5~6h (Including 6h)	<6h
D. habitual sleep efficiency	Calculated based on the responses to items 1, 3, and 4	>85%	75~85% (excluding 75%)	65~75% (Including 75%)	<65%
E. sleep disturbances	Total points for items 5b~5j	0 points	1~9 points	10~18 points	19~27 points
F. use of sleep medication	Points for item 7	None	<1 time/week	1~2 times/week	≥3 times/week
G. daytime dysfunction	Total points for items 8 and 9	0 points	1~2 points	3~4 points	5~6 points

Note: The total score of the PSQI scale ranges from 0 to 21 points, and >7 points are considered poor sleep quality.

Sleep efficiency calculation method:

$$\text{sleep efficiency} = \frac{\text{item 4 (Actual sleep time per night)}}{\text{item 3 (Wake up time)} - \text{item 1 (Time to go to bed at night)}} \times 100\%$$

$$\text{Total score T} = \text{A} \times 1 + \text{B} \times 2 + \text{C} \times 3$$

Evaluator: _____

Appendix E Epworth Sleepiness Scale (sample format)

Epworth Sleepiness Scale, ESS

No.: _____ Date of Completion: _____ Gender: ☐ M ☐ F Age: _____

Based on the situation in the past week, select the degree option that applies to your situation in each item (use " ✓ " Underline your answer)	Never doze off	Slightly likely to doze off	Moderately likely to doze off	Very likely to doze off
1. While sitting in a quiet room reading	0	1	2	3
2. While watching TV	0	1	2	3
3. While sitting quietly on a bus or train	0	1	2	3
4. While sitting in a quiet office in the afternoon	0	1	2	3
5. When lying down to rest (not intending to sleep)	0	1	2	3
6. When sitting quietly on a vehicle for more than 15 minutes (not driving)	0	1	2	3
7. When chatting or talking to others	0	1	2	3
8. Sitting in the quiet moments after a meal, when not drinking	0	1	2	3

Note: All items are scored on a 4-point scale from 0 to 3, with a total score of 0 to 24. A high score indicates severe sleepiness.

The following information is summarized by the evaluator based on the information filled in by the subjects

Total score T _____ = _____ × 1 + _____ × 2 + _____ × 3

Evaluator: _____