

Acute Effects of Transcranial Photobiomodulation, Sham Photobiomodulation, and Cranial Manual Therapy on Anxiety, Sleep Quality, and Postural Control in Young Women: A Randomized Clinical Trial

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Abstract

Purpose

This study aimed to evaluate the acute effects of 5 consecutive days of transcranial photobiomodulation (TPBM), or sham TPBM (TPBM-sham), or cranial manual therapy (CMT) on anxiety levels, sleep quality, and postural control in young women.

Methods

This randomized clinical trial included young women allocated to three groups: TPBM ($n = 15$), TPBM-sham ($n = 15$), and CMT ($n = 15$). The TPBM intervention was delivered using a helmet equipped with light-emitting diodes (LEDs) emitting wavelengths of 660 and 850 nm, 7.5 and 23 mW, energy densities of 33.75 and 103.5 J/cm², and irradiances of 33.5 and 115 mW/cm², respectively. Anxiety was assessed using the Beck Anxiety Inventory, sleep quality using the Pittsburgh Sleep Quality Index, and postural control by analyzing center-of-pressure displacement during a semi-static single-leg stance on a force platform. Assessments were performed before and immediately after five consecutive days of intervention. Statistical analyses were performed according to the intention-to-treat principle using one-way analysis of variance and generalized estimating equations.

Results

No significant between-group differences were observed for anxiety ($p = 0.516$), sleep quality ($p = 0.225$), or postural control ($p = 0.995$). However, reductions in anxiety scores were observed across all groups. In the within-group analysis, the TPBM-sham group demonstrated improvements in both sleep quality and postural control.

Conclusion

TPBM and CMT did not produce superior acute effects compared with sham treatment on anxiety, sleep quality, or postural control in young women. Furthermore, the findings highlight the potential influence of placebo effects and structured rest on reducing anxiety symptoms.

Introduction

The mental health of college students is widely recognized as a global public health concern. This population is particularly vulnerable to psychological disorders, including stress, anxiety, and depression[1]. Across diverse settings, approximately 39% of students experience moderate to extremely severe anxiety, whereas 29.5% report moderate to severe depression. In China, prevalence rates of depression and anxiety have been reported as 9.8% and 15.5%, respectively, with a comorbidity rate of

6.5%[2]. Similarly, high levels of stress (89.3%), anxiety (83.1%), and depression (80.9%) have been reported among Brazilian university students[1], because they are frequently exposed to stressors such as highly competitive academic environments, extensive study demands, emotional exhaustion, and financial pressures related to tuition fees and student debt[3].

Mental health is strongly influenced by behavioral and lifestyle factors, among which sleep quality is one of the most important predictors, alongside dietary habits, physical activity levels, and substance use, including alcohol and tobacco[4]. Alterations in sleep quality have been associated with adverse effects on physical health, emotional well-being, and cognitive performance[5]. Moreover, anxiety and sleep disorders are thought to share common neurophysiological mechanisms, including dysregulation of the hypothalamic–pituitary–adrenal axis and autonomic nervous system imbalance. These alterations may negatively affect not only mental health but also motor function and postural control[6].

In this context, non-pharmacological interventions such as transcranial photobiomodulation (TPBM) have gained attention for improving emotional regulation and sleep quality. TPBM involves applying red and near-infrared light to the scalp to modulate brain activity, potentially enhancing mitochondrial ATP production, cerebral oxygenation, and oxidative stress regulation while reducing inflammation[7–9]. These effects have been associated with improved mood, cognitive performance, sleep quality, and anxiolytic and antidepressant outcomes in clinical and healthy populations[7, 10, 11].

Another physiotherapeutic intervention that has shown potential benefits for psychoemotional health is cranial manual therapy (CMT). This approach is used to address dysfunctions of the cranial, facial, and mandibular regions and aims to restore autonomic balance, alleviate pain and stress, and improve sleep quality[12]. CMT involves the application of gentle manual techniques intended to modulate autonomic nervous system activity by enhancing parasympathetic function and reducing physiological stress responses[13]. Consequently, CMT may contribute to reductions in anxiety and perceived stress while promoting better sleep quality.

Despite promising findings for TPBM and CMT, the evidence is limited by small samples, heterogeneous treatment protocols, and methodological weaknesses, including inadequate blinding and lack of sham controls [11, 14, 15]. Well-designed randomized controlled trials are therefore needed to establish their effectiveness. Accordingly, this study compared TPBM, sham TPBM (TPBM-sham), and CMT on anxiety, sleep quality, and postural control in female university students. We hypothesized that TPBM and CMT would reduce anxiety and improve sleep quality and postural control compared with sham treatment.

Methods

Study design

This study was a randomized, controlled, parallel-group clinical trial with concealed allocation, a 1:1:1 allocation ratio, and intention-to-treat analysis. The study was registered in the Brazilian Registry of Clinical Trials (ReBEC No. RBR-4bdqq3q). It was conducted in accordance with the Consolidated

Standards of Reporting Trials (CONSORT) guidelines. Ethical approval was obtained from the Institutional Research Ethics Committee (Protocol No. XXXXXXXXX), and all participants provided written informed consent before participation.

The study was conducted between December 2025 and July 2026. No modifications to the assessment or intervention protocols were required during the study period.

Randomization and Blinding

Participants were randomly allocated to one of three groups (TPBM, TPBM-sham, or CMT) in a 1:1:1 ratio using a randomization sequence generated at www.random.org. Allocation concealment was ensured through the use of sequentially numbered, opaque sealed envelopes, which were opened only after completion of the baseline assessment. The random allocation sequence and the method used were generated by a researcher external to the study.

Baseline and post-intervention assessments were conducted by a single researcher who was blinded to the treatment protocols and group allocation. Participants assigned to the TPBM and TPBM-sham groups were also blinded to the intervention condition, as they were not informed whether the device was active or inactive during treatment. However, participant blinding was not feasible in the CMT group because of the nature of the intervention.

Participants

Participants were recruited through printed posters and advertisements on social media platforms directed at the university and the surrounding community. Eligible participants were female university students aged 18–25 year who scored > 11 points on the Beck Anxiety Inventory (BAI). Participants were excluded if they failed to attend scheduled sessions, were using medication for sleep or anxiety disorders, or presented with migraines, neoplasms, neurological, rheumatological, or orthopedic conditions, musculoskeletal pain, or a history of previous surgery.

Sample size estimation was performed using G*Power version 3.1.6.7 (F tests → ANOVA: repeated measures, within-between interaction → a priori), with an effect size of 0.80, statistical power of 80%, three groups, and two measurement time points. The minimum required sample size was 10 participants. To account for potential dropouts, 15 participants were recruited for each intervention group.

Interventions

The interventions were conducted at the Human Movement Analysis Laboratory of the University's Research and Graduate Center between 12:00 and 14:00 h. During the intervention sessions, participants

remained in a temperature-controlled environment (24°C) and rested in a supine position on a treatment table.

The TPBM, TPBM-sham, and CMT interventions were delivered according to standardized protocols by three physiotherapists who had received prior training for the study procedures. All therapists participated in a standardized training session and received detailed instructions regarding the interventions to ensure consistency in treatment delivery. Participants in all groups underwent five intervention sessions administered on consecutive days.

Participants in the Photobiomodulation Group (TPBM) received transcranial photobiomodulation using the Capellux® Infrared Helmet (ANVISA registration No. 80455469002) during 5 consecutive days (Fig. 1). The irradiation parameters are presented in Supplementary Table 1. The helmet was positioned on the participant's head and remained active for 15 min as recommended by the manufacturer. Participants remained in a supine position throughout the intervention to minimize awareness of the emitted light.

Please insert Fig. 1

Participants in the Photobiomodulation Sham Group (TPBM-sham) received the same Capellux® Infrared Helmet (ANVISA registration No. 804 55469002) during 5 consecutive days; however, the device remained switched off throughout the 15-min intervention period to apply the sham condition. Participants remained in a supine position to prevent them from perceiving that the device was switched off.

Participants allocated to the Cranial Manual Therapy group (CMT) underwent a standardized 15-min CMT protocol during 5 consecutive days. A detailed description of the techniques and maneuvers performed is provided in the Supplementary Table 2.

Adherence and Treatment Fidelity

Adherence was assessed through attendance records completed by the supervising physiotherapist after each session and reached 100% across all scheduled sessions. Treatment fidelity was ensured through continuous supervision of the intervention protocols, while participant engagement was supported by individualized supervision and flexible scheduling.

Assessments

Participants initially completed a sample characterization questionnaire that included age, body weight, height, and self-perceived anxiety and sleep quality. Self-perceived anxiety and sleep quality were assessed using a numerical rating scale ranging from 0 to 10 points.

Anxiety was considered the primary outcome and was assessed using the BAI[16]. The BAI is a self-report instrument designed to measure the severity of anxiety symptoms. The instrument consists of 21 items assessing symptoms such as nervousness, fear, panic, and excessive worry. Each item is scored from 0 to 3, with total scores classified as minimal (0–10), mild (11–19), moderate (20–30), or severe anxiety (31–63)[17]. The instrument has been translated and validated for Portuguese-speaking populations and is appropriate for assessing anxiety in Brazilian populations[17].

Sleep quality was a secondary outcome assessed using the Portuguese-validated Pittsburgh Sleep Quality Index (PSQI)[18]. The PSQI evaluates seven components of sleep quality: subjective sleep quality, sleep latency, duration, efficiency, disturbances, use of sleep medication, and daytime dysfunction. Component scores are summed to generate a global score, with higher scores indicating poorer sleep quality[19].

Postural control was a secondary outcome assessed using the BIOMECH411 force platform (Serial No. NS_BIO1470, EMG System do Brazil, SP Ltda.). The platform measures the three components of ground reaction force (F_x , F_y , and F_z) and corresponding force moments (M_x , M_y , and M_z), allowing analysis of center-of-pressure (COP) displacement in the anteroposterior (AP) and mediolateral (ML) directions. Postural control was assessed during a semi-static single-leg stance on the force platform. Participants stood on their dominant lower limb, defined as the limb used to kick a ball, with the knee extended, while the contralateral knee was flexed at 90°. The task was performed for 30 s in three trials, with 30-s seated rest intervals. Participants maintained an upright trunk and fixed their gaze on an eye-level target. Postural control variables were averaged across trials and normalized to participant height[20].

All assessments were performed before day 1 of intervention session (baseline), and reassessments were performed 24 h after completion of the final intervention session using the same procedures adopted during the baseline evaluation. All reassessments were conducted by a blinded assessor.

Statistical Analysis

Statistical analyses were conducted according to the intention-to-treat principle, whereby participants were analyzed in the groups to which they were originally allocated. Missing data were imputed using the expectation-maximization algorithm[21].

The Shapiro–Wilk test was used to assess data normality. One-way analysis of variance (ANOVA) was performed to compare baseline characteristics among the three groups. Generalized estimating equations were used to compare outcomes, including the BAI, the PSQI, and postural control variables, namely COP displacement, anteroposterior velocity (APV), and mediolateral velocity (MLV). A covariance matrix was specified a priori using a robust estimator and an independent working correlation structure. The models were fitted using a gamma distribution with a log-link function. Standard errors were adjusted to account for correlations between repeated measurements. When appropriate, multiple comparisons were performed using Bonferroni-adjusted post hoc tests.

All statistical analyses were performed using the Statistical Package for the Social Sciences, version 29.

Results

A total of 77 women were assessed for eligibility. Of these, 32 were excluded, resulting in a final sample of 45 participants who were randomly allocated to three intervention groups: TPBM (*n* = 15), TPBM-sham (*n* = 15), and CMT (*n* = 15) (Fig. 2). No participants withdrew from the study, resulting in a 100% adherence rate. The interventions were conducted as planned, and no protocol modifications were required. In addition, no adverse events were reported during the intervention period. However, participants in the TPBM group reported a mild warming sensation during the final minute of the protocol.

At baseline, the groups were homogeneous with respect to age, body mass, height, perceived anxiety, and sleep quality (Table 1).

Table 1
Sample characteristics and comparison between TPBM, TPBM-sham, and CMT groups.

Age (yr)	TPBM	TPBM-sham	CMT	<i>p</i>
	Mean (SD)	Mean (SD)	Mean (SD)	
	95% CI	95% CI	95% CI	
	21.73 (2.12)	21.93 (2.28)	21.93 (2.28)	0.961
	20.55–22.90	20.66–23.19	20.66–23.19	
Height (m)	1.60 (0.05)	1.62 (0.06)	1.61 (0.04)	0.550
	1.57–1.66	1.59–1.66	1.58–1.63	
Body mass (kg)	61.00 (11.05)	60.93 (12.29)	62.33 (11.53)	0.933
	54.87–67.12	54.12–67.73	55.94–68.71	
Perceived anxiety (0–10)	5.06 (1.94)	6.00(2.20)	5.73 (2.18)	0.467
	3.98–6.14	4.77–7.22	4.52–6.94	
Perceived sleep quality (0–10)	5.40 (1.59)	5.00 (2.29)	6.00 (1.85)	0.372
	4.51–6.28	3.72–6.27	4.97–7.02	
Note. 95% CI, 95% confidence interval; CMT, cranial manual therapy group; TPBM, transcranial photobiomodulation group; TPBM-sham, sham transcranial photobiomodulation group. Results are presented as mean (<i>M</i>), standard deviation, and 95% confidence interval (95% CI). Statistical significance was assessed using one-way ANOVA.				

Insert Fig. 2.

Insert Table 1.

All three groups showed improvements in anxiety scores, with no statistically significant differences between groups. Within-group analyses indicated that the TPBM group demonstrated a reduction in mediolateral postural control velocity. The TPBM-sham group showed improvements in sleep quality and reductions in both anteroposterior and mediolateral postural control velocities following the intervention (Table 2).

Table 2

Comparative results of the Beck Anxiety Inventory, postural control variables, vertical ground reaction force, and dynamic balance among the TPBM, TPBM-sham, and CMT groups.

	TPBM group		TPBM-sham		CMT group		Between-group differences	
	Median [25–75%]		Median [25–75%]		Median [25–75%]		<i>P</i>	
	Baseline	Post	Baseline	Post	Baseline	Post	Baseline	Post
BAI	19 [14–28]	13 [5–18]*	26 [17–34]	18 [7–23]*	24 [20–29]	15 [9–20]*	0.071	0.516
PSQI	10 [8–12]	9 [7–11]	12 [9–15]	11 [8–13]*	10 [8–14]	10 [7–12]	0.136	0.225
COP	7.70 [5.11–9.80]	6.55 [5.91–9.67]	7.44 [6.33–9.30]	7.78 [6.28–9.44]	6.98 [5.97–8.28]	7.82 [5.40–10.08]	0.871	0.995
APV	2.89 [2.44–3.44]	2.73 [2.49–3.19]	2.97 [2.63–3.49]	2.72 [2.52–3.00]*	2.52 [2.42–3.06]	2.48 [2.35–2.87]	0.167	0.293
MLV	3.20 [2.82–3.47]	3.10 [2.80–3.14]*	3.10 [2.94–3.59]	2.99 [2.77–3.46]*	3.07 [2.66–3.29]	2.82 [2.55–3.26]	0.205	0.323
Note. APV, anteroposterior velocity; BAI, Beck Anxiety Inventory; CMT, cranial manual therapy group; COP, Center of Pressure; MLV, mediolateral velocity; PSQI, Pittsburgh Sleep Quality Index; TPBM, transcranial photobiomodulation group; TPBM-sham, transcranial photobiomodulation sham group. Results are presented as median (25 – 75%). Shaded results are * <i>P</i> < 0.05 for within-group comparisons between baseline and post-intervention.								

Insert Table 2.

Discussion

This study compared the effects of 5 consecutive days of TPBM, TPBM-sham, and CMT on anxiety, sleep quality, and postural control in female university students. The initial hypothesis was not supported, as no significant between-group differences were observed. However, anxiety scores decreased in all groups over the study period. Baseline homogeneity across outcomes supports the internal validity of

the findings. Additionally, the use of commercially available TPBM and CMT protocols commonly applied by physiotherapists enhances their clinical relevance.

Investigating interventions aimed at reducing anxiety in female university students is justified by the high prevalence of anxiety in this population[1] as well as its association with increased stress, depressive symptoms[22], poorer quality of life, and sleep disturbances. Previous studies have also suggested that women experience higher levels of stress and anxiety because of gender-related expectations and social pressures[2]. These conditions may negatively affect the physical, psychological, and social well-being of students, potentially resulting in reduced academic performance, lower productivity, and even withdrawal from higher education[1, 2].

Regarding anxiety, all groups showed reduced scores, with no significant between-group differences, questioning the specific effects of TPBM and CMT. Schiffer et al. reported beneficial effects of TPBM (810-nm wavelength, 250 mW/cm², 60 J/cm²) on depression and psychiatric disorders[23] although direct comparisons are limited by differences in treatment parameters and device characteristics. In the present study, TPBM was applied over hair-covered scalp, where melanin may reduce light penetration[24]. On other hand, Schiffer et al. applied the light on the forehead (without hair) and higher irradiance (250 mW/cm²), improving the light penetration through the scalp and skull[23]. These differences may have resulted in greater superficial energy delivery with the Capellux® Infrared Helmet, potentially limiting light penetration to deeper brain structures.

The reduction in anxiety symptoms observed in the CMT group was expected and has been previously reported in studies investigating CMT as a complementary strategy for anxiety management[25]. These effects have been attributed to autonomic regulation and improved functioning of the hypothalamic–pituitary–adrenal axis[26, 27]. Nevertheless, the underlying neurobiological mechanisms remain incompletely understood.

The improvement in anxiety observed across all groups does not support the superiority of TPBM or CMT over the sham condition. It is possible that the 15-min period of supine rest performed during lunchtime (12pm to 2pm), which was common to all groups, contributed substantially to the reduction in anxiety symptoms. Previous research has suggested that periods of psychological and physiological recovery during work or study breaks may reduce activation of the hypothalamic–pituitary–adrenal axis and perceived stress while promoting recovery of the nervous system, factors that are inversely associated with anxiety and emotional exhaustion[28]. Furthermore, active or relaxation-based lunch breaks have been shown to increase feelings of calmness, reduce muscle tension[29], and improve perceived stress recovery[30].

With respect to sleep quality and postural control, no significant between-group differences were observed. Improvements identified in the TPBM-sham group suggest that these changes may be related to participants' expectations regarding treatment [31], previous positive experiences, or activation of endogenous opioid systems, dopaminergic pathways, and other neural circuits associated with well-being and symptom modulation[32]. Importantly, the placebo effect should not be viewed solely as a

psychological phenomenon but rather as a process associated with measurable changes in brain activity and subjective symptom perception[33].

This study has limitations. First, the sample comprised only young female university students, limiting generalizability. Second, the effects of TPBM may have been influenced by the Capellux® Infrared Helmet parameters (7.5 and 23 mW/LED; 37.5 and 115 mW/cm²; 33.75 and 103.5 J/cm² for red and infrared LEDs, respectively) and participants' hair characteristics, potentially reducing light penetration. Finally, the short 5-day intervention assessed only acute effects and may have been insufficient to induce substantial changes. Future studies should include diverse populations, use devices with greater penetration, and evaluate longer protocols (≥ 6 weeks, 2–3 sessions/week).

Conclusions

Transcranial photobiomodulation, TPBM-sham, and CMT produced similar effects on anxiety, sleep quality, and postural control in female university students, as no significant between-group differences were observed. Nevertheless, anxiety improved across all groups, highlighting the potential importance of a 15-min rest period during the academic routine. Notably, only the TPBM-sham group demonstrated improvements in anxiety, sleep quality, and postural control following the five intervention sessions, emphasizing the potential influence of the placebo effect.

Declarations

Author Contribution

J.U.B. - 1-4.C.G.A.A.- 1-4.G.A.D.Y. - 1-3.B.P.G -- 1-3.M.J.V. -- 1-3.I.F -- 1-3.B.C.D.S.S. -- 1-3.C.F - 2-3.C.S.G.M. -- 1-4.

Data Availability

Data sharing and Protocol and statistical analysis plan: They can be accessed at DOI 10.5281/zenodo.22709118.

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Figures



Figure 1

Application of the transcranial photobiomodulation helmet.

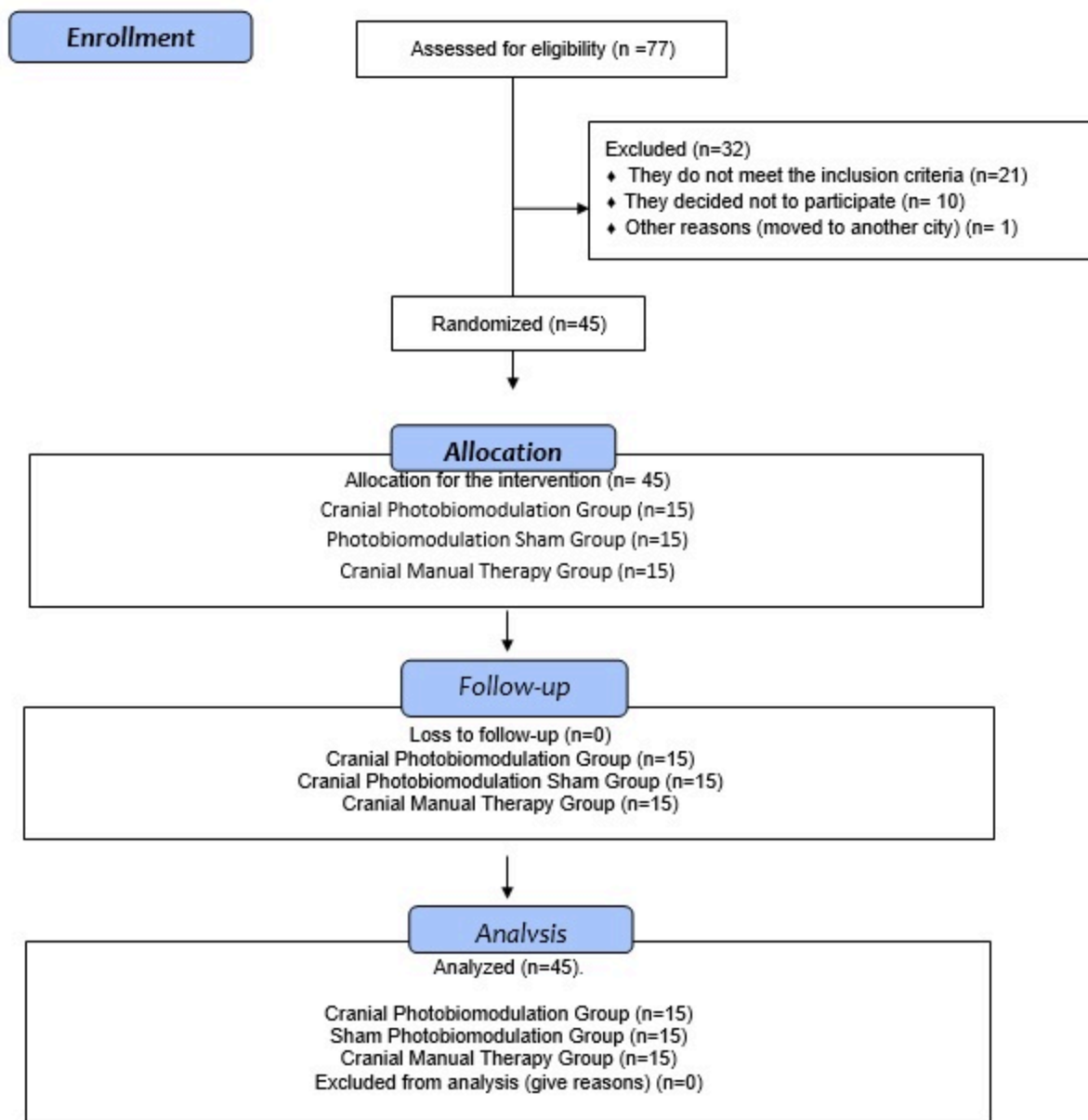


Figure 2

Study flow diagram.

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