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Effect of Low-Level Laser Therapy on Donor Site Burn Wound Healing in Pediatric Patients: A Randomized Controlled Trial

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Abstract

Introduction: Severe burns require skin transplantation, although donor site problems are common. Low-level laser therapy can lessen these problems by accelerating the donor site's healing process. In children having skin transplant surgeries for burn injuries, the study evaluated the effectiveness of low-level laser therapy in promoting faster healing of donor areas.

Methods: Forty children aged five to sixteen with third-degree burns covering 20% to 35% of their total body surface area (TBSA) took part in the study. Each child underwent split-thick skin grafting (STSG) using the thigh as the donor site. The participants were randomly divided into two groups: one received a placebo laser treatment for three weeks, and the other received low-level laser therapy three times weekly. All subjects were given standard wound care. Donor site healing was monitored on days 1, 11, and 21 post-operations by measuring the wound surface area with J Image software and photographs.

Results: Forty children participated in the study, with an equal number of males and females split into two groups of twenty each. With no statistically significant age difference, the treatment group average age was 11.15 ± 3.03 years, whereas the placebo group was 9.9 ± 3.42 years. However, there was a significant difference (t = -5.5, $P < 0.001$) between the treatment group and the placebo group, as the treatment group's baseline TBSA value was significantly lower (80.04 ± 12.81) than the placebo group's (99.8 ± 9.7).

Conclusion: Despite baseline variances, considerable statistical differences indicate that low-level laser therapy considerably enhances donor site healing in pediatric burn patients.

Keywords: Donor site, LLLT, Pediatric, TBSA, Skin graft

Introduction

Burn injuries continue to be a major source of morbidity among juvenile populations worldwide, resulting in significant healthcare costs and long-term impairment for children. Pediatric burn wounds present distinct therapeutic challenges due to physiological changes in skin structure, immunological responses, and healing capabilities compared to those in adults.[1] The Total Body Surface Area (TBSA) impacted is a typical way to quantify the amount of damage, and it acts as an important marker for both prognosis and therapy effectiveness.[1]

Photobiomodulation therapy has emerged as a promising method in pediatric medicine, notably in the care of donor sites for skin transplants.[2] The use of laser technology in this context has grown in popularity because of its numerous advantages, which include improved

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healing, less scarring, and decreased postoperative pain.[2]

The skin maintains temperature and fluid balance by preventing the escape of water vapor and heat from the body.[3] Disrupted epidermal barrier function in persons with severe skin loss poses a risk of infection and requires ongoing fluid resuscitation and protection from environmental pollutants.[3]

Major burns can involve superficial, deep, partial-thickness, and full-thickness injuries. The skin's dermal layer is thinner in neonates, infants, and children than in adults, gradually thickening from infancy through adolescence.[4]

Split-thickness skin grafting (STSG) is commonly used for extensive partial- or full-thickness burn injuries, which involves harvesting partial-thickness skin from a healthy location with a dermatome and grafting it onto the injured area.[5] Significant constraints include donor site availability, grafted wound contraction, and scarring.[5]

Complications during donor site recovery include discomfort, itching, infections, dyschromia (hypo- and hyperpigmentation), and hypertrophic scarring. [6] Managing donor sites after graft harvesting is crucial since patients often experience greater agony at the donor site than at the burn recipient site directly.[6]

Photobiomodulation (PBM) is a potential approach for treating acute and chronic wounds, including vascular and pressure ulcers, and can accelerate the healing process of chronic diabetic foot ulcers. [7] Multiple articles and systematic reviews support the hypothesis that LLLT may shorten the time required to achieve complete healing. [7]

Despite encouraging outcomes in adult populations, little research has been conducted specifically on the use of LLLT for burn treatment in children. [8] Most current research has either focused on adult populations or has not distinguished between adult and pediatric results.[8]

The shortage of long-term follow-up studies, the lack of randomized controlled trials (RCTs) in the pediatric population, the lack of control groups in a few studies that have included pediatric patients, and the lack of adequate knowledge of the best dosage within twenty-one days and treatment parameters are all contributing factors to the gap in the literature on this subject.[9]

The purpose of this study is to assess the efficacy of LLLT as an additional treatment for burn wound healing in pediatric patients. We specifically compare the changes in TBSA at three important intervals—Day 1, Day 11, and Day 21—between patients receiving standard treatment with LLLT and those receiving standard care with a placebo. This randomized controlled experiment aims to offer robust data on the therapeutic value of LLLT in pediatric burn care.

Methods

Subjects and Methods

It is important to highlight that this study is part of a larger-scale inquiry, which includes a study that examined the donor site healing response to low-level laser treatment after skin transplant surgery.[10] The findings of that study informed us of the strategy and interpretation of the current research.[10]

Study Design

This study was conducted in the Physical Therapy Department for Burns at Al-Ahrar Educational Hospital in Al-Zagazig, Al-Sharkia, Egypt. The protocol was clearly communicated to all research participants prior to any procedures being done.

Subjects

An a priori power analysis using G*Power 3.1.9.7 indicated that a total sample of 40 participants was required to achieve 80% power at a two-tailed $\alpha = 0.05$ for the primary outcome (TBSA), based on effect size estimates from pilot testing with 3 participants per group and an independent-groups t-test framework.

Our study included 40 patients aged 5 -16 with 3rd-degree burns, TBSA ranging from 20-35%, and split-thickness skin graft (STSG) surgery. Each patient had a thigh donor site and began therapy on the first day after surgery. To reduce bias in the interpretation of results, the statistician who performed the data analysis was blinded to group allocations. Patients with concomitant disorders (e.g., diabetes, viral diseases, or autoimmune diseases) that might hinder healing were excluded from the study. Patients using medications such as corticosteroids, chemotherapy, or radiation were excluded.

Exclusion criteria also included those who interfered with the body's natural healing process, the elderly, pregnant women, smokers, those with dietary deficiencies, photosensitivity, skin diseases, histories of trauma or accidental injury, and those who had previously undergone surgery at the donor site.

A physical therapist, ignorant of the study's concept, randomly allocated patients to one of the two groups by opening sealed envelopes containing computer-generated cards. The active laser group received LLLT at the donor site for one session per day, three times per week for three weeks. The control group received a placebo laser for one session per day, three times per week for three weeks. Both groups received normal medical services, including wound dressing. All patients gave informed consent before beginning the trial.

Outcome Measures

Photography

The wound surface area of the donor site was measured before therapy (day 1 post-operative), 11 days post-operative, and 21 days post-operative using a Nikon D3500 digital camera and J Image 1.53e software. ImageJ analyzes digital photos of leg ulcers and predicts the

wound area with high reliability.[11] This approach is free, fast, and precise for measuring wounds and might be used to track wound healing in regular clinical practice.[11]

Digital photography technologies can enhance accuracy over ruler measurements while also lowering the danger of infection or patient discomfort when compared to tracing clear films.[12] However, like tracing transparent films, physically drawing wound borders from computer pictures may be prohibitively time-consuming in a busy clinical environment. It is feasible to automate the process of determining wound borders by employing image processing techniques that increase the accuracy and objectivity of wound size assessment.[12]

Low-Level Laser Therapy (LLLT)

Using a red laser alpha circle (α), SN 1207002505, produced in China by Medical Equipment Co., the study group received LLLT on the donor site. The laser device has several technical characteristics that are necessary for functioning, and specific parameters are as follows: Type of laser: CO2 laser, Emission mode: Pulsed or continuous wave, Time On-Time Off: 0.1 to 0.5 milliseconds, Delivery system: Fiber optic or articulated arm, Energy distribution: Uniform, Peak power: from 30 to 60 watts, Average power: 10-20 watts, Spot diameter at focus: 100-300 micrometers, Focus Spot Area: 50 μm, Spot Diameter at the Tissue: 100 μm, Peak Power Density at Spot Area: 3823 W/cm², Average Power Density at Spot Area: 1911 W/cm², Beam divergence: low, Water irrigation: Not applicable, and Air and aspirating airflow: Not applicable.[13]

The LLLT settings employed were 650 nm wavelength, 150 mW power output, 0.25 cm2 radiation area, 0.6 W/cm2 power density, continuous mode, 2 joules per cm2, and 90 s/cm2 for three weekly sessions over three weeks. Both the therapist and the patient wore laser safety goggles during the laser therapy.[14]

The control group received the same technique as the research group, but with an aluminum cover on top of the laser probe. [15] We set the device power output to 10 mW, the lowest output of the device. Prior to the placebo treatment, we conducted a test to check that the aluminum cover was inhibiting laser passage in that group.[15]

Statistical Analysis

SPSS V25 was used to conduct the analysis. Independent samples t-tests for continuous variables (age, TBSA Value on Day 1) were used to compare baseline characteristics of the study and placebo groups. The Shapiro-Wilk test was used to determine whether these variables were normal. For variables that were not normally distributed, the interpretation of the t-test findings was evaluated alongside potential non-parametric alternatives. Categorical variables (gender distribution) were compared using chi-square testing.

The major study to examine the influence of the intervention on the outcome measures (TBSA Value and TBSA_Imp) at the follow-up time points included the study of Covariance (ANCOVA). Even though the Shapiro-Wilk test indicated that the outcome data were not normally distributed, this strategy was used to account for statistically significant baseline differences seen on Day 1 between the study group and the placebo group in the various outcome measures. This method was justified by the possibility of greater statistical power and the emphasis on the treatment impact in isolation from baseline values.

Before interpreting the ANCOVA results, the key assumption of regression slope homogeneity (i.e., the connection between the Day-1 covariate and the follow-up outcome is similar across groups) was tested. The outcomes of this test are detailed in the results section.

Non-parametric tests were also used to validate the ANCOVA results and address the violation of the normality assumption. The Mann-Whitney U test was used to compare groups at each time point (Day 11 and Day 21 for TBSA), and the resulting Z-statistics and significance levels are shown. The Wilcoxon signed-rank test was most likely used to analyze within-group differences over time.

Mean differences (MD) and 95% confidence intervals (CI) were provided to indicate the size and precision of the observed differences. The statistical significance of these differences, however, was mostly decided by the p-values from the ANCOVA (for adjusted group comparisons) and non-parametric tests (for unadjusted comparisons). When the ANCOVA assumptions were significantly violated or the results varied from the non-parametric analysis, the conclusions of the non-parametric tests were given more weight.

The statistical analyses were performed using a significance threshold of $P < 0.05$.

Results

A total of 40 participants were divided evenly between two groups: the study group (n = 20) and the placebo group (n = 20). Each group included 12 males and 8 females. The trial group's mean age was 11.15 ± 3.03 years, whereas the placebo group's age was 9.9 ± 3.42 years. There was no significant age difference between the two groups (t = 1.224, $P = 0.229$).

At baseline (Day 1), the experimental group had a considerably lower TBSA Value (80.04 ± 12.81) than the placebo group (99.8 ± 9.7) (t = -5.5, $P < 0.001$) (Table 1).

In the repeated-measures ANOVA, the Time × Group

Table 1. Baseline Characteristics

Variable	Study Group (n = 20)	Placebo Group (n = 20)	t Value	*P*-value
Age (years)	11.15 ± 3.03	9.9 ± 3.42	1.224	0.229
Day 1 TBSA_Value	80.04 ± 12.81	99.8 ± 9.7	-5.5	< 0.001

interaction was significant, F = 42.267, $P < 0.001$, with a large effect size (partial $\eta^2 = 0.701$) and observed power of 1.000, indicating differential change over time across groups. The main effect for the study group was significant, F = 161.577, $P < 0.001$, with partial $\eta^2 = 0.900$ and power = 1.000, reflecting substantial between-group differences for the study condition across measurements. The main effect of the placebo group was also significant, F = 526.129, $P < 0.001$, with partial $\eta^2 = 0.967$ and power = 1.000, indicating very large between-group differences for the placebo condition. Time effects at specific follow-ups were significant: Day 11: F = 136.975, $P < 0.001$, partial $\eta^2 = 0.884$, power = 1.000, and Day 21: F = 346.897, $P < 0.001$, partial $\eta^2 = 0.951$, power = 1.000, demonstrating strong temporal changes. For covariates/outcomes, TBSA Value showed a significant effect, F = 459.045, $P < 0.001$, with partial $\eta^2 = 0.925$ and power = 1.000, and TBSA Imp was likewise significant, F = 438.243, $P < 0.001$, with partial $\eta^2 = 0.922$ and power = 1.000, both indicating large effects with excellent sensitivity.

TBSA Value Over Time is presented in Table 2. TBSA Improvement Over Time is presented in Table 3. TBSA values and improvements both among groups and within each group are compared in Figures 1 and 2.

Donor site wound healing on day 21 after surgery in

Table 2. TBSA Value Comparisons Between and Within Groups

Time Point	Study Group (Mean ± SD)	Placebo Group (Mean ± SD)	Mean Difference (95% CI)	ANCOVA Sig.	Mann–Whitney Z	Mann–Whitney Sig.
Day 11	14.62 ± 4.57	68.34 ± 11.04	-46.732* (-53.202 to -40.261)	0.000	-5.410	0.000
Day 21	1.83 ± 1.52	29.01 ± 3.14	-26.825* (-28.966 to -24.684)	0.000	-5.413	0.000
Within-Group MD	16.106* (11.944 to 20.267)	36.012* (31.851 to 40.174)				
Within-Group Z	-3.920	-3.920				
Within-Group Sig.	0.000	0.000				

MD: Mean Difference; CI: Confidence Interval, ANCOVA adjusted for baseline TBSA_Value (Day 1); significance set at $P < 0.05$. Z and Sig values from Mann–Whitney U test for between-group comparisons; Wilcoxon signed-rank test used for within-group comparisons. * The findings are statistically significant.

Table 3. TBSA Imp Comparisons Between and Within Groups

Time Point	Study Group (Mean ± SD)	Placebo Group (Mean ± SD)	Mean Difference (95% CI)	ANCOVA Sig.	Mann–Whitney Z	Mann–Whitney Sig.
First_10_days_Imp	81.44 ± 6.72	31.69 ± 7.36	56.492	0.000	-5.41	0.000
Second_10_days_Imp	87.46 ± 9.41	56.44 ± 8.74	39.631	0.000	-5.385	0.000
MD (CI)	-6.075 (-13.365-1.215)	-24.703* (-31.993--17.412)				
Sig	0.100	0.000				
Z	-1.941	-3.883				

MD: Mean Difference; CI: Confidence Interval, ANCOVA adjusted for baseline TBSA Value (Day 1); significance set at $P < 0.05$. Z and Sig values from Mann–Whitney U test for between-group comparisons; Wilcoxon signed-rank test used for within-group comparisons. * The findings are statistically significant.

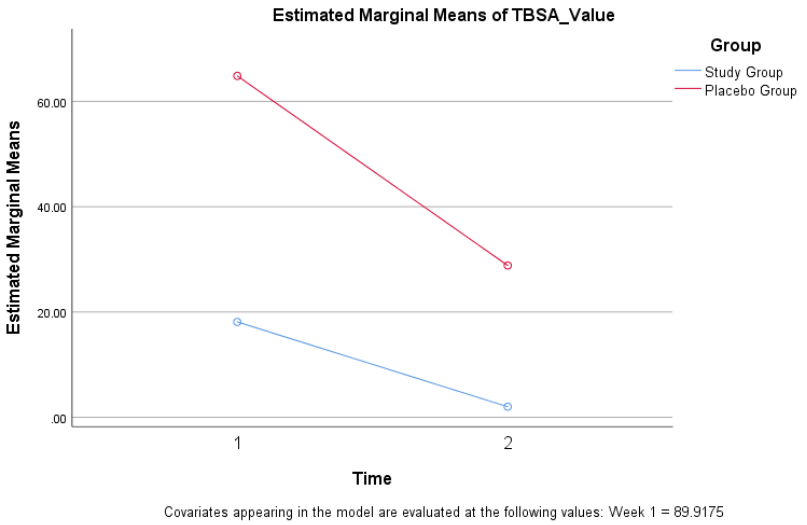

Figure 1. TBSA value among and within groups

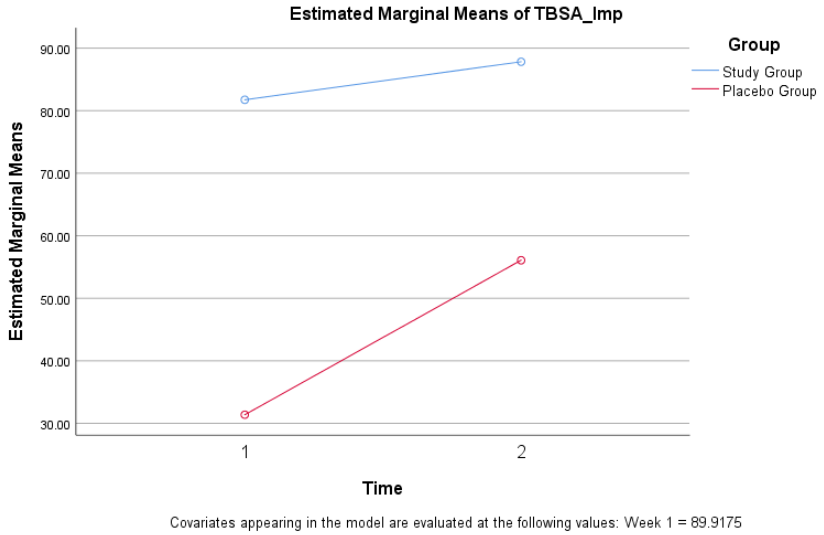

Figure 2. TBSA Improvement among and within groups

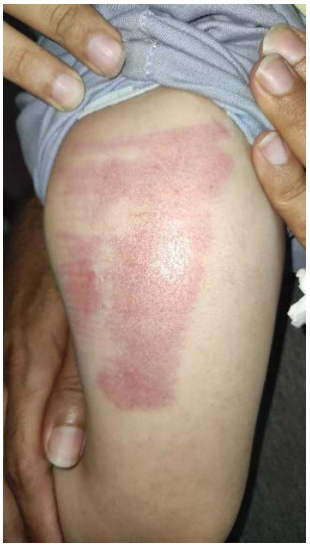

Figure 3. Donor site wound healing on day 21 after surgery in the laser group

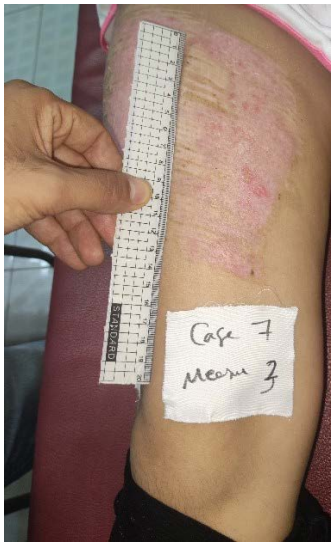

Figure 4. Donor site wound healing on day 21 after surgery in the placebo group

both the laser and placebo groups is presented in Figures 3 and 4.

Discussion

The key finding was a significant interaction between time and group, which demonstrates that the LLLT administered to the study group resulted in a distinct trajectory of change in TBSA Value compared to the placebo.[16] This implies that it had a different influence during the 21-day research period. Specifically, on Days 11 and 21, participants in the study group had significantly lower TBSA Values than the placebo group, even after accounting for the large baseline difference in TBSA Value using ANCOVA.[16]

Although treating burn scars in children can be difficult, extended perforator flap transplantation and low-level laser therapy provide long-lasting, efficient ways to improve wound healing, function, and appearance in comparison to traditional surgical techniques.[17]

Complications of donor site skin transplant surgery include infection, scar development, hypertrophic scarring, and hyperpigmentation, which can delay recovery and reduce patient satisfaction.[18] In addition, photobiomodulation is a painless, cost-effective, and safe therapy that might be used to treat children's burn ulcers. It appears that the stimulation of HSP and TGF-a expression may be essential mechanisms of action for photobiomodulation in burns.[19]

Laser irradiation increased energy-producing enzyme activity, including cytochrome c oxidase (CCO), ATP, and NADPH, while reducing the NADP/NADPH ratio.[20] Furthermore, GLUT1 and pAMPKa were upregulated, whereas GS1 was downregulated, indicating improved glucose transport across cell membranes [20] and improved

burn wound healing and intracellular energy levels by modifying aerobic metabolism for maximum energy output.[20]

Screening, preventive, and early intervention tools should be integrated into pediatric health care settings to improve children's psychosocial adjustment after a burn injury.[21] Additionally, low-level lasers effectively cure injuries, although few studies have examined the effectiveness of photobiomodulation in managing burn scars and improving blood circulation.[22]

Laser and light treatments provide a minimally invasive, low-risk therapeutic option with a quick postoperative recovery time.[23] Studies have demonstrated that laser technology reduces scar thickness, neuropathic pain, and the requirement for surgical excision, while also improving scar color, erythema, pliability, texture, height, and pruritus.[23]

In contrast, the incidence of burn and donor site scar contractures varies significantly among researchers.[24] When prevalence is unknown, it is difficult to examine potential drivers and assess changes in treatments.[24] Well-designed longitudinal studies are needed to explore the prevalence, progression, and risk factors of scar contractures over time.[24]

Pulsed dye laser and ultra-pulsed fractional carbon dioxide laser have distinct effects on hypertrophic scars, whereas the pulsed dye laser, with its low pain, minor wound, and quick recovery time, is safe and effective for treating early hypertrophic scars and deserves clinical promotion and application, particularly for children and patients with poor pain tolerance [25]

There is clear evidence that CO2 Laser treatment reduces hypertrophic burn scars on both patient and observer ratings, proving statistical and clinical importance for both providers and families.[26] These findings show that CO2 Laser therapy can relieve hypertrophic burn scars in pediatric patients, offering a lower-risk option to intrusive therapies as well as a more rapid and effective alternative to more conservative scar treatments.[26]

Laser treatment may be particularly effective for hypertrophic scars in certain body locations, burn processes, and operational management, and standardizing treatment regimens might maximize benefits for pediatric patients with burn injuries.[27] LLLT improves wound healing at the donor site in patients with grade 3 burn ulcers who have had graft surgery. The findings show that employing LLLT considerably speeds up the healing process. [14]

Both in vitro and in vivo trials have shown that laser treatment expedites wound healing. Several investigations have revealed that it improves epithelialization and scar tensile strength.[28] Low-level laser therapy for severe second-degree burns significantly reduced the number of macrophages and the depth of new epidermis, which decreased the incidence of Staphylococcus epidermidis and Staphylococcus aureus [29]

Conversely, in the examined periods, photobiomodulation had no effect on re-epithelialization time, wound area, or wound quality (Bates-Jensen scale).[30] Furthermore, the average duration for full reepithelialization of this kind of lesion was 16 days.[30] However, pain decrease (VAS score) was seen on the fifth postoperative day compared to the control group.[30]

Several limitations in this study should be considered. The most notable limitation is the statistically significant difference seen in the baseline TBSA Value between the study group and the placebo group, with the study group having a lower average at the start. While the statistical analyses, particularly the ANCOVA, were corrected for this starting imbalance to allow a more equitable assessment of treatment effects at follow-up, this baseline difference likely influenced the interpretation of the results. For example, the amount of change seen in a group with a lower baseline may be essentially different from that in a group starting with a higher value, thereby resulting in an underestimation or overestimation of the genuine treatment impact. Moreover, while the age difference between the groups was not statistically significant, the numerical difference might be a modest, unreported confounding effect. As with any study, the possibility that additional unmeasured variables impacted the outcomes cannot be completely ruled out. Furthermore, the 21-day research period restricts our understanding of the intervention's short-term effectiveness and safety. To determine the LLLT's impact, further studies beyond this interval are required.

This study's findings have a variety of possible implementations. To begin with, the LLLT's shown effectiveness implies that it might be used in clinical practice for pediatric burns. Additional validation in bigger, more varied groups is required to confirm these findings and inform treatment regimens.[31]

This work presents a solid platform for future research efforts. Studies investigating the treatment's long-term efficacy and safety are particularly important. Exploring the fundamental processes of action may improve its use. Also, the apparent trends of enhancement, particularly the treatment group's prolonged benefit compared to the placebo, can help to build more effective and long-lasting treatment techniques for similar disorders.[32]

Based on the findings of this study, these recommendations are proposed. It is recommended that researchers conduct larger multi-center clinical trials with longer follow-up periods to validate the treatment's effectiveness and safety in a broader patient population and to examine its long-term effects. Future studies ought to probe into ideal LLLT dosing regimens and delivery techniques for maximizing therapy benefits while minimizing potential adverse effects.[33]

Conclusion

This study provides clear evidence for the higher

effectiveness of the examined LLLT over the placebo in lowering the TBSA Value for children and fostering improvement over 21 days. The statistically significant differences observed at follow-up between the study group and the placebo group, even after accounting for baseline imbalances, as well as the greater magnitude of improvement in the treatment group and divergent temporal trends, strongly support the therapy's beneficial effects.

Authors' Contribution

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Competing Interests

The authors declare no conflict of interest.

Ethical Approval

All research investigations were approved by FPT-BSU REC. FPT-BSU REC is organized and operated according to the Declaration of Helsinki guidelines, International Conference of Harmonization ICH, and United States Codes of Federal Regulations, and it has been registered under the Federal Wide Assurance (FWA) for the protection of human subjects. Approval No: FPTBSUREC/0506/2625

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