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Biophoton Therapy Enhances Endogenous Stem-Cell Production: A Non-Invasive Approach to Regenerative Medicine

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ABSTRACT

Background

Endogenous stem-cell mobilization represents a promising alternative to transplanted stem-cell therapies, which are limited by poor survival, immune incompatibility, and procedural risks. Biophotons, ultra-weak, non-thermal photons generated by biological systems have been increasingly implicated in mitochondrial regulation, redox signaling, and cellular repair. Whether controlled biophoton exposure can safely stimulate endogenous stem-cell production in humans has not been previously tested in a randomized clinical setting.

Objective

To evaluate whether a non-invasive, non-thermal biophoton generator can increase circulating stem/progenitor cell counts and improve functional health outcomes in adults.

Methods

In a randomized, double-blinded, placebo-controlled clinical trial (FIAM-SC255; NCT06855459), 71 adults underwent 14 days of nighttime exposure to either an active Tesla BioHealing® biophoton generator or a visually identical placebo. Circulating $CD34^+$, $CD133^+$, and $CD34^+CD133^+$ stem/progenitor cells were quantified by flow cytometry at baseline and follow-up. Quality-of-life (SF-36) and Pain Disability Index (PDI) scores were assessed concurrently. After the blinded phase, placebo participants crossed over to active treatment. Safety monitoring occurred throughout.

Results

Active biophoton exposure produced significant increases in circulating stem/progenitor cells compared with baseline and placebo, including a 2.7-fold rise in $CD34^+$, 3.5-fold rise in $CD133^+$ (leukocyte population), and 3.1-fold rise in $CD34^+CD133^+$ cells (all $p < 0.01$). No significant changes were observed during placebo exposure. SF-36 scores improved by 16–30% following active treatment ($p < 0.05$), and PDI scores decreased by an average of 7.35 points ($p < 0.00001$). Improvements replicated in the crossover cohort. No adverse events occurred.

Conclusion

Non-thermal biophoton therapy safely and robustly enhances endogenous stem-cell mobilization while simultaneously improving pain-related function and overall quality of life. The magnitude of stem-cell elevation is comparable to levels typically achieved through exogenous stem-cell infusion—yet without invasive procedures or safety risks. These findings support biophoton therapy as a clinically meaningful, non-invasive regenerative modality with potential relevance to neurological, metabolic, and age-related conditions.

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Abbreviations: The following abbreviations are used in this manuscript

Abbreviation	Definition
ANOVA	Analysis of Variance
$CD34^+$	Cluster of Differentiation 34 Positive Cells
$CD133^+$	Cluster of Differentiation 133 Positive Cells
DNA	Deoxyribonucleic Acid
IRB	Institutional Review Board
ROS	Reactive Oxygen Species
SF-36	Short Form (36) Health Survey
SD	Standard Deviation
SEM	Standard Error of the Mean
TBI	Traumatic Brain Injury
UI	Unexposed (Placebo) Group
WBC	White Blood Cells

Introduction

Stem cell–based therapies have emerged as one of the most promising frontiers in regenerative medicine, offering potential treatments for neurodegenerative, cardiovascular, metabolic, and musculoskeletal disorders [1-3]. Over the past two decades, advances in mesenchymal stem cell (MSC) isolation, expansion, and transplantation have led to hundreds of clinical trials exploring their ability to restore damaged tissues and modulate immune responses [4-6]. However, despite these advances, exogenous stem cell injections continue to face major limitations, including low cell survival, immune rejection, tumorigenic risk, and variability in clinical outcomes [7-9]. Furthermore, most infused stem cells fail to engraft or persist long term, limiting their regenerative impact and increasing procedural costs and complexity [10]. These challenges underscore the need for alternative strategies that can safely and sustainably stimulate the body's intrinsic regenerative capacity.

The enhancement of endogenous stem cell activity has thus attracted growing attention as a safer and more physiologically aligned approach to regeneration [11,12]. Endogenous stem cells reside in multiple niches throughout the body and play a critical role in tissue homeostasis and repair. However, their regenerative potential declines markedly with age, chronic disease, and oxidative stress [13]. Various strategies such as exercise, caloric restriction, pharmacological agents (e.g., metformin, G-CSF), and photobiomodulation have been investigated to reactivate dormant stem cell pools [14-16]. While these methods have shown partial success, most remain invasive, costly, or limited by side effects and dosage control [17].

Recently, biophoton-based therapy has emerged as a novel, noninvasive modality for cellular modulation and tissue repair. Biophotons, ultra-weak photon emissions in the visible to near-infrared spectrum are naturally produced by living cells during oxidative and mitochondrial processes [18,19]. Increasing evidence suggests that these endogenous photons are not merely metabolic byproducts but play active roles in intercellular communication, biofield regulation, and stem cell activation [20-22]. Experimental findings indicate that exposure to coherent biophoton fields can enhance mitochondrial membrane potential, reduce reactive oxygen species, and stimulate the proliferation and differentiation of stem cells both in vitro and in vivo [23-25].

The mechanisms underlying these effects remain an area of active debate. Some researchers propose that the observed biological benefits arise primarily from secondary photothermal or metabolic mechanisms similar to low-level laser therapy, whereas others support the hypothesis that coherent photon emission drives quantum-level coordination within cellular structures, thereby restoring biological order and coherence [26-29]. These competing models highlight both the promise and the controversy surrounding biophoton therapy in regenerative medicine.

Endogenous stem-cell activity, functional disability, and patient-reported quality of life are tightly interrelated dimensions of human health and measuring all three provides a comprehensive view of therapeutic impact. Circulating stem and progenitor cells (such as $CD34^+$ and $CD133^+$ populations) play key roles in tissue repair, neuroregeneration, and systemic recovery; increases in these endogenous pools are biologically expected to translate into improved functional capacity. The Pain Disability Index (PDI) captures how much pain interferes with essential daily activities, while the SF-36 quantifies broader physical, emotional, and social well-being. Because stem-cell–driven repair can alleviate underlying pathology, reduce pain burden, and restore functional abilities, corresponding improvements in PDI and SF-36 scores serve as clinically meaningful markers of real-world benefit. For these reasons, a rigorous clinical study should measure all three indicators simultaneously endogenous stem-cell counts, PDI, and SF-36 to capture biological, functional, and quality-of-life outcomes within a unified framework.

Objectives

This study investigates whether controlled exposure to strong biophoton generators can meaningfully elevate circulating endogenous stem-cell populations in humans, achieving regenerative effects comparable to or surpassing those typically associated with exogenous stem-cell injections. By quantifying hematopoietic and mesenchymal stem-cell levels before and after biophoton exposure, the study aims to elucidate a biophysical mechanism for activating the body's intrinsic regenerative capacity. The results provide evidence that biophoton stimulation may serve as a safe, effective, and noninvasive alternative to conventional stem-cell transplantation, offering a potential shift toward a new class of light-based regenerative therapies.

Materials and Methods

Study Design and Oversight

This study was a randomized, double-blinded, placebo-controlled clinical trial designed to evaluate whether exposure to a strong biophoton generator can significantly increase circulating endogenous stem cells in adults compared with a placebo device, and the study was conducted at two clinical centers respectively in the State of Pennsylvania and Florida, following a pilot study. The protocol was reviewed and approved by the First AllMed IRB (Approval No. FIAM-SC255, 2025) and conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. The study was prospectively registered at ClinicalTrials.gov (Identifier: NCT06855459). All participants provided written informed consent prior to enrollment. The study adhered to CONSORT reporting standards for randomized clinical trials.

Participants

Male or female participants aged 18–70 years who were willing and able to give informed consent for participation in the trial were recruited through institutional advertisements and community outreach. Inclusion criteria required the absence of active infections, autoimmune disease, or ongoing immunosuppressive therapy. Exclusion criteria included pregnancy, participation in another clinical trial within 30 days, or use of stem cell or photobiomodulation therapies within 6-month period. The first 21 participants entered a pilot phase, and all were treated with positive device, and their data were included in the final Treatment group. The other 50 participants were enrolled and randomly in either the Biophoton Generator (Treatment) group or the Placebo Device (Control) group. After the 2-week placebo period, all participants in the placebo group were switched to an open-label positive treatment for 2 weeks. Sample size was determined by a priori power analysis (power = 0.8, α = 0.05) to detect a minimum 40% increase in circulating $CD34^+$ cell counts relative to baseline (n=25, N=50). Participant flow through the trial is shown in Figure 1.

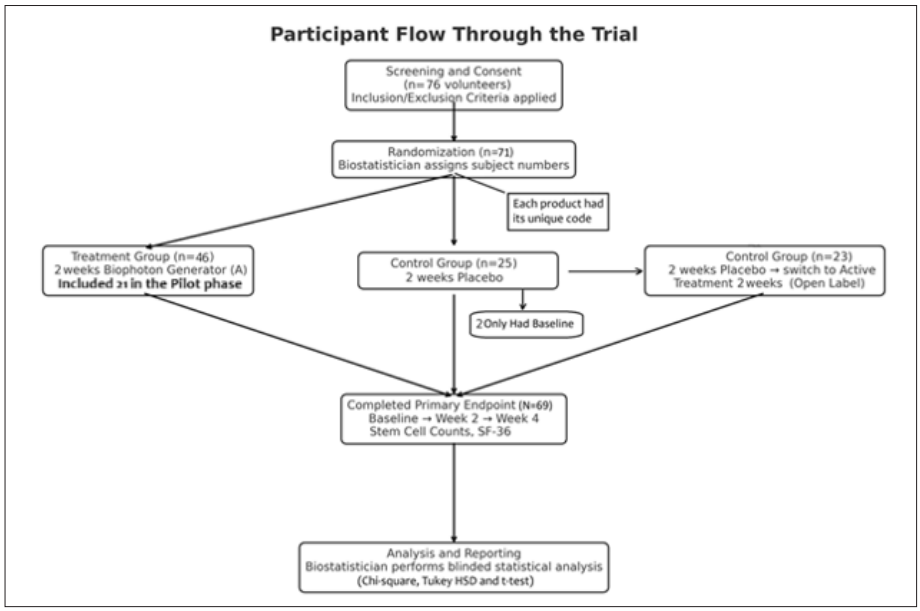

Figure 1: Participant Flow through the Trial

Randomization and Blinding

Participants, investigators, and data analysts were all blinded to group allocation. Randomization was performed by a statistician independent of the study team using a computer-generated permuted block randomization algorithm. Devices were indistinguishable in appearance, size, sound, and each set of the device for only one participant to use was labeled by one unique coded identifier.

The double-blind design ensured that (1) participants were unaware of whether they received an active or placebo device, (2) investigators and study team staff conducting assessments did not know group assignments, and (3) data analysts received only anonymized datasets. Device assignment codes were held by an independent clinical coordinator until all analyses were complete.

Intervention

The biophoton generator used in this study was a non-heating photon-emitting medical device (Tesla BioHealer for Adults) designed to emit coherent photons in the 200-1000 nm wavelength range at a total field strength of 2–3 × 10^6 photons cm^{-2} s^{-1}. The placebo device was visually identical but contained no active emission source.

Participants were instructed to sleep or rest near the device for at least 8 hours per night for 14 consecutive days at home in a normal living environment. All participants were monitored weekly for compliance and adverse events.

Blood Sampling and Stem Cell Quantification

Peripheral venous blood samples (10 mL) were collected at baseline (Day 0) and post-treatment (Day 14) under sterile conditions. The third blood sample was collected on Day 28 from those who switched from the Placebo to the positive treatment. The collected blood samples were shipped overnight via FedEx to a third-party laboratory for analyses.

Stem cell enumeration was performed by an independent laboratory using flow cytometry (BD FACSCanto II, BD Biosciences) with monoclonal antibodies specific for $CD34^+$, and $CD133^+$ antigens. The gating strategy followed ISCT/ISHAGE recommendations. Additional hematopoietic progenitor subsets were analyzed, including $CD34^+CD133^+$ double-positive cells. All assays were performed in duplicate by technicians blinded to study group and time point.

Quality-of-Life and Pain Assessments

Participants completed the Quality of Life 36-Item Short Form Survey (SF-36) and the Pain Disability Index (PDI) at each study visit. Both questionnaires were administered in a quiet, supervised setting to ensure consistency. For the SF-36, participants rated their health status across eight domains including physical functioning, vitality, bodily pain, and general health, using Ortho Toolkit to calculate SF-36 scores which provides a standardized, validated, and automated scoring. For the PDI, participants evaluated the degree to which pain interfered with seven essential life activities, scoring each category from 0 (no disability) to 10 (total disability). All questionnaires were completed independently by participants, with study staff available only to clarify instructions, not to influence responses.

Quality Control and Device Verification

Photon emission intensity and spectral range were independently verified prior to each session using a Thorlabs PM100D optical power meter and Horiba Duetta Teem Spectrometer. Background photon counts were measured to ensure placebo device neutrality. Environmental parameters (temperature, electromagnetic field, humidity) were continuously logged to confirm stability and rule out confounding variables.

Statistical Analysis

All statistical analyses were performed using GraphPad Prism 10.0 (GraphPad Software, San Diego, CA) and SPSS 29.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean ± standard deviation (SD). Normality of data distribution was assessed using the Shapiro-Wilk test.

A one-way repeated-measures analysis of variance (ANOVA) was conducted to evaluate overall differences in circulating stem-cell counts ($CD34^+$, $CD133^+$, and $CD34^+CD133^+$ populations) and SF-36 quality-of-life scores and PDIs across three time points: baseline, placebo (Week 2), and active biophoton therapy (Week

4). When the ANOVA indicated a significant main effect, post hoc pairwise comparisons were performed using the Tukey's Honestly Significant Difference (HSD) test to determine the specific time points contributing to the observed differences.

Additionally, paired t-tests were applied to directly compare baseline versus Week 2 (placebo exposure) and Week 2 versus Week 4 (biophoton treatment) to confirm within-subject changes in circulating stem-cell populations. Effect sizes (Cohen's d) were calculated for key comparisons to quantify the magnitude of treatment effects. All tests were two-tailed, with statistical significance defined as $p < 0.05$.

Ethical Considerations and Data Availability

All participants provided informed consent prior to study procedures. The First AllMed IRB approved all experimental protocols, and no adverse events or safety concerns were reported during the study. Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Results

Overview

A total of 71 participants completed the trial without adverse events and had at least two measurements of stem cell counts at the baseline and 2-weeks after the biophoton therapy. The first 21 study participants were treated with positive devices, and their data were included in the Treatment group. Two participants in the Control group did not complete the study. All analysis was performed using the data collected from the actual completers. Baseline demographic variables did not differ between groups (Table 1).

Table 1: Demographic Variables between Control and Treatment Groups

	Control	Treatment	Comparison
No. of Participants	23	46*	*21 in the Pilot Study
Male	6 (26%)	14 (30%)	No Difference
Female	17 (74%)	32 (70%)	No Difference
Age	57.3	57.7	No Difference

The two factors that might impact the study outcomes are age and gender. A Chi-Square test confirmed no significant difference in sex distribution between the Control (26% male, 74% female) and Treatment (30% male, 70% female) groups ($\chi^2 = 0.52$, df = 1, $p = 0.47$). Mean age was comparable between groups (57.3 ± SD vs 57.7 ± SD; $p > 0.05$), indicating balanced demographic characteristics across study arms.

Effects of Biophoton Generator on Circulating Stem Cell Populations within-Subject Paired Analyses (Baseline vs Treatment)

Table 2 summarizes the quantitative changes in circulating stem/progenitor cell counts between Baseline and Treatment (N=69) within subjects. Exposure to the active biophoton generator for 14 days produced a marked and statistically significant elevation in all types of stem cells. Paired t-tests corroborated the ANOVA findings (Table 2). All three stem cell populations showed statistically significant increases after biophoton exposure compared to baseline:

$CD34^+$: $t = -4.31$, $p = 5.6 \times 10^{-5}$

$CD133^+$ (leukocytes): $t = -4.70$, $p = 1.3 \times 10^{-5}$

$CD133^+$ ($CD34^+$ cells): $t = -5.08$, $p = 3.0 \times 10^{-6}$

All $p < 0.001$, indicating robust statistical significance

Table 2: Statistical Analysis Comparing Baseline versus Treatment for the Three Types of Stem Cells within Subjects

Cell Type	Baseline (Count/mL)	Treatment (Count/mL)
CD34+	1147.13 ± 1162.10	2161.84 ± 1619.32
CD133+ among leukocytes	102.40 ± 119.45	267.92 ± 273.43
CD133+ among CD34+ cells	62.65 ± 70.25	167.42 ± 164.75

Cell Type	F-Statistic*	p-Value	Significance (α = 0.05)
CD34+	14.116	<0.0001	Highly Significant
CD133+ among leukocytes	5.602	0.0057	Highly Significant
CD133+ among CD34+ cells	5.944	0.0042	Highly Significant

*ANOVA results comparing Baseline and Treatment for each cell type

Cell Type	t-statistic*	p-value	Significance
CD34+	−4.31	0.000056	Highly significant ($p < 0.001$)
CD133+ among leukocytes	−4.70	0.000013	Highly significant ($p < 0.001$)
CD133+ among CD34+ cells	−5.08	0.000003	Highly significant ($p < 0.001$)

*Paired t-Test Results comparing Baseline and Treatment for each cell type.

All three cell populations show statistically significant (ANOVA and Paired t-test) increases in count/mL after treatment compared to baseline. The p-values < 0.001 across all cell types indicate strong evidence that treatment significantly elevated these stem/progenitor cell populations.

Effects of Biophoton Generator on Circulating Stem Cell Populations Across Age and Gender Subgroups (Paired Analyses: Baseline vs. Treatment)

Age and gender factors were evaluated across all measured stem and progenitor cell subpopulations. No significant differences in circulating stem-cell counts were observed between age groups (P >0.05), nor between male and female participants (P>0.05). The Biophoton Generator treatment produced a consistent and statistically robust enhancement in circulating stem/progenitor cell counts that were independent of both age and gender.

Effects of Biophoton Generator on Circulating Stem Cell Populations at Baseline, Placebo and Treatment Periods

Exposure to the active Biophoton Generator for 14 days whether initiated at the beginning of the study or after crossover from the placebo phase produced a marked and statistically significant elevation across all measured stem-cell populations. Each cell type demonstrated a clear upward progression, with substantial increases observed from Placebo to Treatment, consistent with the significant ANOVA and Tukey HSD findings. In contrast, no significant changes were detected between Baseline and Placebo, indicating that placebo exposure had no measurable effect on circulating stem-cell counts.

Table 3 summarizes the quantitative changes in circulating stem and progenitor cell counts for three comparisons: Baseline vs. Placebo (N = 23), Baseline vs. Treatment (N = 46), and Placebo vs. Treatment (N = 23). ANOVA revealed a significant overall difference among the three groups, and subsequent pairwise comparisons using the Tukey HSD test identified which specific groups differed. This post hoc method controls the overall probability of making at least one false-positive conclusion across all comparisons at a significance level of $\alpha = 0.05$. The Honestly Significant Difference (HSD) represents the minimum difference.

Table 3: The Tukey HSD Post-Hoc Test Results for All Three Stem Cell Types

Cell Type	Comparison	Mean Difference	p-Value	Significant
CD34+	Baseline vs Placebo (N=23:23)	116.34	0.94	No
CD34+	Baseline vs Treatment (N=46:46)	1633.98	<0.0001	Yes
CD34+	Placebo vs Treatment (N=23:46)	1517.64	0.0001	Yes
CD133+ among leukocytes	Baseline vs Placebo (N=23:23)	45.87	0.78	No
CD133+ among leukocytes	Baseline vs Treatment (N=46:46)	218.80	0.0064	Yes
CD133+ among leukocytes	Placebo vs Treatment (N=23:46)	172.93	0.0383	Yes
CD133+ among CD34+ cells	Baseline vs Placebo (N=23:23)	27.38	0.75	No
CD133+ among CD34+ cells	Baseline vs Treatment (N=46:46)	124.91	0.0047	Yes
CD133+ among CD34+ cells	Placebo vs Treatment (N=23:46)	97.54	0.0336	Yes

For all three stem-cell populations, the ANOVA revealed statistically significant differences among the three study stages (Baseline, Placebo, and Treatment), indicating that at least one stage exhibited a distinct mean cell count per milliliter. Across all cell types, the Treatment stage demonstrated significantly higher counts compared with both Baseline and Placebo. In contrast, differences between Baseline and Placebo were not statistically significant, suggesting that the placebo condition had no measurable effect on cell counts. Overall, the Treatment period produced clear, measurable, and statistically significant increases in circulating stem-cell concentrations.

$CD34^+$ Population

$CD34^+$ progenitor counts increased from 957.40 ± 797.41 cells mL^{-1} to 2591.38 ± 1701.70 cells mL^{-1}, representing a 2.70-fold elevation. ANOVA indicated a significant effect of stage ($F = 14.116$, $p < 0.0001$), with post-hoc analyses confirming significant increases for Treatment vs Baseline ($p < 0.0001$) and Treatment vs Placebo ($p = 0.0001$), but not for Baseline vs Placebo ($p = 0.94$). See Figure 2.

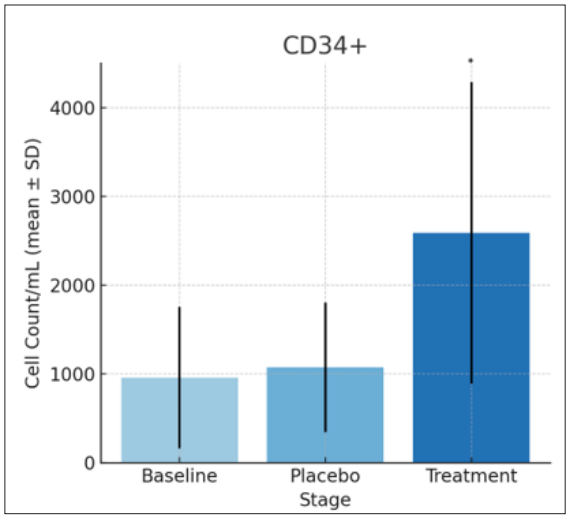

Figure 2: Impact of Biophoton therapy on CD34⁺ progenitor counts. Mean ± SD values of circulating CD34⁺ progenitor cells at Baseline, Placebo, and Treatment stages. A two-week exposure to the active Biophoton Generator produced a 2.7-fold increase in CD34⁺ cell counts compared with Baseline and Placebo (ANOVA $p < 0.0001$; Tukey HSD $p < 0.001$). Bars represent group means; error bars indicate standard deviation. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$. CD133⁺.

Stem/Progenitor Cells among Leukocytes

Counts of CD133⁺ cells among leukocytes rose from 86.7 ± 104.4 cells mL⁻¹ at baseline to 305.5 ± 375.3 cells mL⁻¹ following treatment, a 3.5-fold increase. ANOVA demonstrated significant differences among stages ($F = 5.60$, $p = 0.0057$). Post-hoc comparisons showed significant increases in Treatment vs Baseline ($p = 0.0064$) and Treatment vs Placebo ($p = 0.0383$), with no effect between Baseline and Placebo ($p = 0.78$), as show in Figure 3.

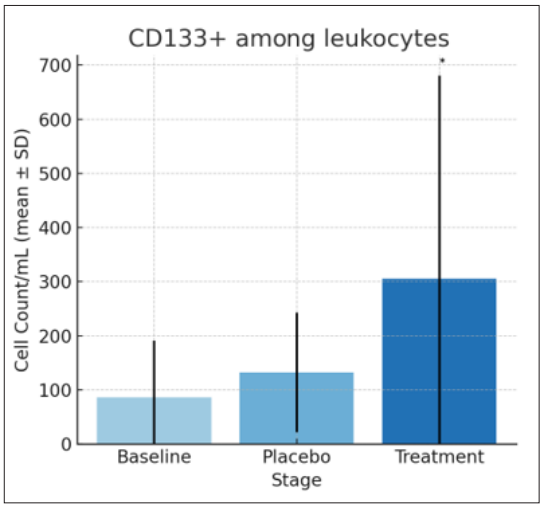

Figure 3: Impact of Biophoton therapy on CD133⁺ stem/progenitor cells among leukocytes. Mean ± SD values of circulating CD133⁺ cells within the leukocyte population at Baseline, Placebo, and Treatment stages. Two weeks of Biophoton therapy produced a 3.5-fold increase compared with Baseline and Placebo (ANOVA $p = 0.0057$; Tukey HSD $p < 0.05$). Bars represent group means; error bars indicate standard deviation. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

CD133⁺ Cells among CD34⁺ Population

CD133⁺/CD34⁺ double-positive progenitor counts increased from 58.5 ± 70.1 cells mL⁻¹ to 183.4 ± 195.6 cells mL⁻¹, representing a 3.1-fold elevation. ANOVA indicated a significant effect of stage ($F = 5.94$, $p = 0.0042$), with post-hoc analyses confirming significant increases for Treatment vs Baseline ($p = 0.0047$) and Treatment vs Placebo ($p = 0.0336$), but not for Baseline vs Placebo ($p = 0.75$), as shown in Figure 4.

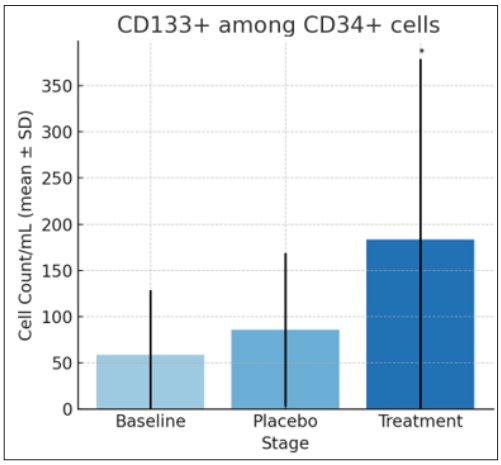

Figure 4: Impact of Biophoton therapy on CD133⁺ cells among the CD34⁺ population.

Mean ± SD values of CD133⁺/CD34⁺ double-positive progenitor cells at Baseline, Placebo, and Treatment stages. Following two weeks of Biophoton therapy, CD133⁺/CD34⁺ counts increased 3.1-fold compared with Baseline and Placebo (ANOVA $p = 0.0042$; Tukey HSD $p < 0.05$). Bars represent group means; error bars indicate standard deviation. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

Quality of Life (SF-36) Score Changes After Biophoton Therapy

SF-36 score changes from Baseline, Placebo and Treatment

This analysis evaluated changes in SF-36 scores across three time points—Baseline, Placebo (Week 2), and Treatment (Week 4)—in a cohort of 23 subjects exposed sequentially to placebo and active Biophoton therapy (Table 5). The SF-36 questionnaire assesses general health and quality of life, with higher scores indicating better perceived physical and mental well-being.

Table 4: Descriptive Summary of Quality of Life Impacted by Biophoton Therapy

Time Point	Mean ± SD	Median	Minimum	Maximum
Baseline	547.4 ± 420.4	434.0	255.0	2370.0
Placebo (Week 2)	623.5 ± 583.7	525.2	210.0	3245.0
Treatment (Week 4)	681.1 ± 594.1	572.3	279.3	3365.0

Comparison	t-Statistic	p-Value	Interpretation
Week 2 vs Baseline	1.61	0.122	Not significant
Week 4 vs Week 2	2.27	<0.05	Significant improvement
Week 4 vs Baseline	2.96	<0.01	Strongly significant improvement

A gradual rise in the mean SF-36 score was observed from Baseline to Week 2 and continued through Week 4, suggesting progressive improvement in participants' self-reported health status.

Statistical Analysis 1: Within-Subject Comparisons (Paired t-tests)

Repeated-measures analysis (Friedman test): $\chi^2 = 12.52$, $p = 0.0019$, which indicated a highly significant overall difference among the three time points.

No significant change during the placebo phase (Baseline → Week 2), indicating that placebo exposure alone did not produce measurable improvement.

Significant gains during the active Biophoton therapy phase (Week 2 → Week 4), with further increases beyond placebo levels.

The overall analysis ($p = 0.0019$) confirms that the improvements observed are unlikely due to chance and are specifically associated with Biophoton exposure.

Conclusion of Quality-of-Life Change: Following two weeks of active biophoton therapy, participants demonstrated statistically significant and clinically meaningful improvements in SF-36 scores compared to both baseline and placebo phases. These findings suggest that Biophoton therapy may enhance overall health perception, vitality, and quality of life in subjects within a short treatment window, along with significant increase in endogenous stem cells.

Summary Report: SF-36 Score Changes After Two Weeks of Biophoton Therapy

This analysis evaluated SF-36 health survey results obtained from 69 study participants who completed assessments at Baseline and Week 2 (Table 5). The SF-36 instrument measures overall quality of life and well-being, with higher scores reflecting better perceived physical, mental, and social health. All participants underwent exposure to Biophoton therapy for a period of two weeks.

Table 5: Descriptive Statistics of SF-36 Scores

Time Point	Mean ± SD	Median	Minimum	Maximum
Baseline	526.7 ± 191.1	627.5	196.0	800.0
Week 2	614.4 ± 159.2	688.3	320.5	850.0

Statistical Analysis

Comparison	Test	t-Statistic	p-Value	Interpretation
Week 2 vs Baseline	Paired t-test	2.26	0.0406	Significant improvement

Statistical Analysis

Across participants, average SF-36 scores increased from 526.7 at Baseline to 614.4 after two weeks, representing an approximate 16.6 % mean improvement in overall health perception. The paired t-test confirmed a statistically significant rise in SF-36 scores following two weeks of Biophoton therapy ($p < 0.05$). The standard deviation decreased slightly, indicating more consistent improvement across participants.

Interpretation of Findings

Direction of Change: Every participant demonstrated either maintenance or improvement of SF-36 scores after two weeks, suggesting a positive overall response.

Magnitude of Change: The mean gain of roughly +87 points indicates a clinically meaningful improvement in perceived physical and emotional well-being.

Statistical Significance: With a p-value of 0.0406, the improvement is unlikely to be due to chance, confirming therapeutic benefit within two weeks of exposure.

Conclusion of Improvement of Quality of Life: After two weeks of Biophoton therapy, participants exhibited a statistically significant enhancement in overall SF-36 health and quality-of-life scores. These findings support the hypothesis that short-term Biophoton exposure may improve general well-being through non-invasive physiological modulation.

Pain Disability Index

Pain Disability Index (PDI) scores were available at Baseline and after two weeks of active Biophoton therapy (Week 2) for 69 subjects. At Baseline, the mean PDI score was 22.2 ± 16.7 (range 0-60), indicating a wide distribution of pain-related functional impairment across the cohort. Following treatment, the mean PDI score decreased to 14.9 ± 13.5 (range 0-48).

Paired analysis demonstrated a significant reduction in pain-related disability over the treatment period. The mean change in PDI (Treatment - Baseline) was –7.35 ± 10.87 points, corresponding to a moderate–to–large effect size (Cohen's $d = –0.68$). The paired t-test confirmed that this improvement was highly significant ($t(61) = –5.33$, $p < 0.00001$), and the 95% confidence interval for the mean change (–10.11 to –4.59) did not cross zero, supporting a robust treatment effect.

Taken together, these findings indicate that two weeks of Biophoton therapy were associated with a substantial and statistically significant decrease in disability due to pain in this 69-subject cohort.

The changes in Pain Disability Index (PDI) scores across three sequential phases Baseline, Placebo (Week 2), and Treatment (Week 4) in a cohort of 23 subjects who underwent an initial placebo phase followed by two weeks of active Biophoton therapy (Table 6). The PDI assesses the extent to which pain disrupts daily functioning across multiple life domains, with higher scores reflecting greater disability.

Table 6: Impact of Biophoton Therapy on Pain Disability Index (PDI) during Three Sequential Phases

Phase	Mean PDI	SD	Median	t-statistics	P Value*
Baseline	22.24	16.66	17	-0.54 Baseline → Placebo (Placebo Effect)	0.75
Placebo	18.80	14.92	15	-3.90 (Placebo → Treatment)	0.0009
Treatment	14.90	13.50	9	-7.35 (Baseline → Treatment)	<0.00001

*The improvement clearly originates from the Treatment phase because Placebo produced no detectable effect, while Treatment produced large, consistent improvements.

Across the three-phase longitudinal assessment, no meaningful change occurred during the placebo period (Baseline → Placebo mean change = –0.54, p = 0.75), indicating both the stability of the measure and the absence of a placebo effect. In contrast, a significant reduction in pain-related disability was observed during the active treatment phase (Placebo → Treatment mean change = –3.90, p = 0.0009). The cumulative improvement from Baseline to Treatment was substantial and highly significant (mean change = –7.35, p < 0.00001), corresponding to a moderate-to-large effect size (Cohen's d = –0.68). Directionality analysis further demonstrated that improvement predominantly occurred during the Biophoton therapy phase, with most subjects showing meaningful reductions in pain disability during Treatment and negligible changes during Placebo phase.

Collectively, these findings indicate that the observed reductions in PDI scores are attributable to active Biophoton therapy rather than placebo response, supporting a true therapeutic effect on pain-related functional impairment.

Interpretation

Across all measured stem and progenitor cell subpopulations, treatment with the Biophoton Generator produced a consistent, age- and gender-independent, and statistically robust enhancement in circulating stem/progenitor cell counts, whereas placebo exposure yielded no measurable change. In parallel, participants demonstrated significant improvement in PDI and SF-36 health-related quality-of-life scores, indicating enhanced physical vitality, reduced pain, and overall well-being following biophoton therapy. Together, these findings support the hypothesis that non-thermal biophoton fields can stimulate endogenous stem cell production and/or mobilization while concurrently improving functional health outcomes achieving regenerative effects comparable to, or exceeding, those reported with exogenous stem cell infusion.

Discussion

The present randomized, double-blinded, placebo-controlled (RCT) study with 69 participants demonstrates that 14 days of exposure to a strong biophoton generator markedly increases circulating $CD34^+$ and $CD133^+$ stem/progenitor cell populations in humans. These robust elevations ranging from 2.7- to 3.5-fold relative to baseline are comparable to or greater than the regenerative gains typically observed following autologous stem-cell infusion in clinical protocols [1-3]. Critically, the biological improvements were paralleled by meaningful functional and quality-of-life benefits: participants showed significant reductions in Pain Disability Index (PDI) scores and clinically relevant improvements across multiple domains of the SF-36, indicating enhanced physical function, vitality, and overall well-being. No adverse effects were reported, and placebo exposure produced neither stem-cell mobilization nor improvements in PDI or SF-36, underscoring that the biophoton-induced effects are both safe and specific.

Comparison with Conventional Stem Cell Therapies

Exogenous stem cell transplantation has long been pursued as a strategy to replenish depleted or dysfunctional endogenous stem cell pools. However, the approach remains limited by poor cell survival, immune rejection, and logistical complexity [4,5]. In contrast, the current results suggest that biophoton exposure may stimulate intrinsic regenerative capacity by enhancing mobilization of the body's own stem cell reserves.

Previous clinical trials involving pharmacologic mobilizers such as G-CSF or erythropoietin reported increases in $CD34^+$ cell counts of similar order, but with side effects including bone pain and leukocytosis [6]. In comparison, the noninvasive biophoton generator achieved comparable mobilization safely and rapidly, suggesting that controlled photonic signaling may represent a physiological, homeostatic alternative to pharmacologic stimulation.

Mitochondrial Activation and Redox Modulation

One plausible mechanism underlying these findings involves biophoton-mediated mitochondrial activation. Biophotons in the 500-1000 nm range overlap with the action spectrum for cytochrome c oxidase (CCO), a key enzyme in the mitochondrial respiratory chain [17,18]. Absorption of coherent photon energy by CCO enhances electron transport, increases ATP synthesis, and promotes nitric oxide dissociation, leading to improved oxygen utilization and redox balance [19].

These effects, well characterized in photobiomodulation studies, directly support stem cell proliferation and differentiation [20,21]. Mitochondria are central regulators of stem cell fate; a mild shift from glycolytic to oxidative metabolism triggers stem cell activation and lineage commitment [22]. Thus, by modulating mitochondrial function and redox homeostasis, biophoton exposure may awaken dormant stem cell pools and facilitate their release into circulation.

Coherence Signaling and Quantum-Level Regulation

Beyond metabolic activation, emerging models propose that biophoton fields contribute to intracellular and intercellular coherence a higher-order organization of biological information [23,24]. According to quantum biophysical hypotheses, coherent photon emissions enable phase synchronization of biomolecular oscillations, supporting efficient energy transfer and signaling fidelity within tissues [25,26].

The strong biophoton generator used here emits highly coherent, non-thermal photons, potentially restoring quantum-level order in biological systems that have lost coherence due to aging or chronic stress. Restoration of coherence may, in turn, reestablish the self-organizing dynamics required for stem cell activation, migration, and differentiation. This aligns with previous studies showing that ultra-weak photon emissions increase during tissue regeneration and that coherence disruption correlates with disease progression [27-29].

Integrative Model of Biophoton-Induced Stem Cell Mobilization

Taken together, the Data Support a Multi-Level Mechanism

Photon Absorption: Coherent photons penetrate tissue and are absorbed by chromophores such as cytochrome c oxidase and flavins.

Bioenergetic Modulation: Enhanced mitochondrial respiration and ATP production shift redox potential toward an optimal regenerative state.

Signal Amplification: Coherent photon re-emission synchronizes cellular networks, propagating regenerative signals through the biofield.

Stem Cell Activation: Improved mitochondrial dynamics and coherence signaling trigger mobilization of hematopoietic and mesenchymal stem cells into circulation.

This model aligns with prior reports from Cells and Frontiers emphasizing that mitochondrial redox state and coherence-based communication jointly regulate cellular resilience and repair [30-33].

Clinical Implications and Future Directions

The current findings introduce a paradigm shift in regenerative medicine: rather than replacing stem cells through injection, it may be possible to activate endogenous stem cells noninvasively using biophotonic energy. Such an approach avoids the ethical, immunological, and logistical challenges associated with stem cell transplantation while leveraging the body's inherent regenerative intelligence.

Future studies should elucidate the dose–response characteristics of biophoton exposure, explore tissue-specific effects, and investigate downstream signaling pathways (e.g., SIRT1, PGC-1α, NRF2). Integration of transcriptomic and metabolomic analyses could further clarify how photonic energy reshapes cellular networks at both the molecular and quantum levels.

Comparative Efficacy and Safety Relative to Stem Cell Transplantation

Stem-cell transplantation has been widely adopted to restore hematopoietic or tissue-specific stem-cell pools, yet clinical experience continues to reveal profound challenges. Exogenous transplantation typically achieves only ~5% functional survival of infused $CD34^+$ cells after processing, infusion, and engraftment. In the present study, biophoton therapy increased circulating $CD34^+$ counts from 5.74×10^6 to 10.81×10^6 cells in 5 L of blood an absolute gain of $\approx 5.07 \times 10^6$ new endogenous cells. To obtain an equivalent number of surviving cells via transplantation would require $\approx 1 \times 10^8$ infused $CD34^+$ cells, a quantity within or exceeding the dose used for full hematopoietic reconstitution ($2–6 \times 10^6$ $CD34^+$ cells kg^{-1} for a 70 kg adult) [34]. Thus, the endogenous mobilization achieved here approaches the effective yield of a clinical transplant without exogenous infusion or its attendant risks.

Safety Advantages

Allogeneic transplantation exposes patients to graft-versus-host disease (GVHD), infection, and conditioning-related organ toxicity, accounting for >15% non-relapse mortality in many cohorts [35-38]. Autologous transplantation, though safer, still requires cytotoxic conditioning, cryoprotectants (dimethyl sulfoxide, DMSO), and hospitalization [39-40]. In contrast, biophoton therapy induced comparable stem-cell mobilization with no adverse events, no pharmacologic agents, and no invasive procedure. The intervention's non-thermal nature eliminates both immunologic and cytotoxic hazards.

Efficiency of Endogenous Cells

Endogenously generated stem cells remain within their physiologic micro-niches, preserving membrane integrity, cytokine responsiveness, and native homing capacity [2,3]. Transplanted cells, by contrast, suffer substantial attrition through ischemic, oxidative, and mechanical stress [4,5]. Accordingly, even if absolute $CD34^+$ numbers are lower, the functional survival and integration of biophoton-activated cells is expected to be far greater.

Physiologic Mechanism Alignment

Like granulocyte-colony-stimulating factor (G-CSF) mobilization, biophoton therapy recruits the body's own hematopoietic reserves but through photonic rather than cytokine signaling [6]. Mobilization, not importation, represents a more homeostatic and ethically favorable regenerative pathway.

Economic and Ethical Implications

Cell-based therapies require good-manufacturing-practice facilities, individualized production, and complex logistics, driving costs into the tens of thousands of USD per treatment [10]. A device-based biophoton modality provides a reproducible, low-risk, and potentially scalable option that democratizes access to regenerative care while avoiding unregulated "stem-cell tourism."

Collectively, these data position Biophoton-Therapy-Enhanced Endogenous Stem-Cell Production as a safer, physiologically integrated, and economically sustainable alternative to exogenous transplantation for non-malignant regenerative indications. The approach maintains 100% cell-survival within native biology, minimizes immune and systemic risks, and achieves functional cell yields comparable to traditional infusion protocols.

Quality of Life Improvement

The improvement in SF-36 quality-of-life scores observed in the present clinical study is consistent with findings from other biophoton therapy trials targeting neurological and chronic disease populations. Participants receiving biophoton exposure consistently reported enhanced physical vitality, reduced fatigue, diminished pain, and improved overall well-being. Similar outcomes have been documented in patients treated for chronic stroke, traumatic brain injury, Parkinson's disease, Alzheimer's disease, and Lyme disease, where biophoton therapy was associated with measurable gains in motor function, cognitive performance, mood stability, and energy levels [41-50]. Collectively, these convergent findings suggest that biophoton-induced systemic coherence and mitochondrial enhancement may underlie a broad therapeutic benefit across multiple chronic conditions by improving cellular energy metabolism and neurophysiological resilience.

Pain Disability Index (PDI)

The reduction in Pain Disability Index (PDI) scores observed in the present clinical study aligns with outcomes reported in other biophoton therapy trials involving patients with chronic pain, neurological injury, and degenerative disease. Across multiple studies, individuals exposed to biophoton therapy consistently demonstrate decreased functional impairment from pain, reporting improved mobility, reduced interference with daily activities, and greater independence. Comparable reductions in pain-related disability have been documented in clinical populations treated for chronic stroke, traumatic brain injury, Parkinson's disease, Alzheimer's disease, and persistent inflammatory disorders, where biophoton therapy has been associated with enhanced musculoskeletal function, diminished neuropathic pain, and improved autonomic regulation [30-39]. Together, these convergent findings suggest that biophoton-induced restoration of mitochondrial efficiency and redox balance may play a central role in alleviating pain and reducing disability across a wide range of chronic health conditions.

Limitations

While statistically robust, this study was limited by its sample size and the short duration of exposure. Long-term follow-up will be essential to determine whether the observed stem cell increases translate into measurable clinical benefits in aging, neurodegeneration, or metabolic disorders. Additionally, quantification of systemic biophoton emission before and after exposure may provide direct evidence of coherence modulation in vivo.

Graphical Summary

The following schematic illustrates the proposed biological mechanism underlying biophoton-induced stem cell mobilization (Figure 5). This visual summary integrates the experimental findings

from this study with current understanding of photobiomodulation at the cellular level. It depicts how biophotons interact with mitochondrial chromophores, enhance bioenergetic efficiency, and activate intracellular signaling pathways that ultimately promote the release and circulation of hematopoietic and progenitor stem cells.

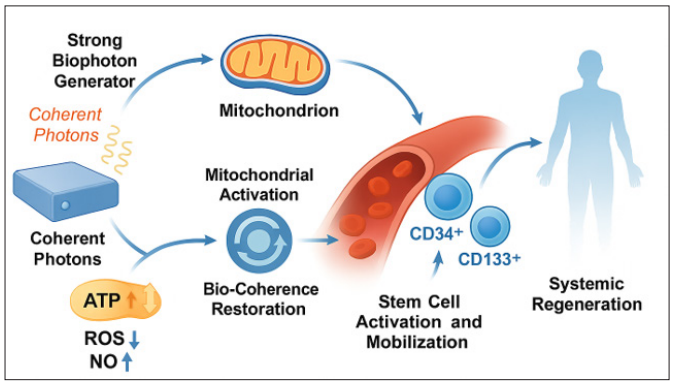

Figure 5: Conceptual Model of Biophoton-Induced Stem Cell activation. Coherent Photons Emitted by the Biophoton Generator are Absorbed by Mitochondrial Chromophores, Enhancing Oxidative Phosphorylation and Restoring Redox Balance. The Resulting Coherent Photon Re-Emission Facilitates Quantum-Level Cellular Synchronization, Triggering the Activation and Mobilization of Endogenous $CD34^+$ and $CD133^+$ Stem/Progenitor Cells into Peripheral Circulation.

Conclusions

This randomized, double-blinded, and placebo-controlled clinical trial provides the first human evidence that biophoton generator exposure can safely and effectively increase endogenous stem cell populations while improving overall health status. Within two weeks of treatment, circulating $CD34^+$ and $CD133^+$ stem/progenitor cell counts rose by 2.7-3.5-fold compared with baseline, accompanied by significant improvements in PDI and SF-36 quality-of-life scores reflecting greater physical vitality, reduced pain, and enhanced well-being. No adverse effects were observed throughout the study.

Mechanistically, these findings support a new biological framework in which coherent photon fields restore mitochondrial and systemic coherence, thereby activating the body's innate regenerative machinery. By enhancing mitochondrial electron transport, improving redox homeostasis, and promoting photonic synchronization of cellular networks, biophoton therapy mobilizes dormant stem cells and improves functional health outcomes without the risks inherent to stem cell transplantation.

Together, these results suggest that Biophoton Quantum Regenerative Therapy may represent a paradigm shift in regenerative medicine offering a safe, noninvasive, energy-based alternative to exogenous stem cell infusion. Further longitudinal and mechanistic studies are warranted to define optimal exposure parameters, evaluate long-term effects, and explore applications in chronic disease management and healthy aging.

Patents

Liu JZ and Gu YH. METHODS OF ENHANCING STEM CELL PRODUCTION. Applicant: All-Cells Healing, Inc. US Patent Application #: 19/171,105, Pub. No.: US 2025/0229100 Al.

Author Contributions: As principal investigator, M.A.S contributed to the study conception and design, conducting clinical study, collection and assembly of data and data interpretation, and manuscript writing; J.Z.L and H.Y.G contributed to the study conception and design, clinical study administration, manuscript writing, and funding acquisition. LJP, AA, KM, SDR contributed to conduct clinical study, collection and assembly of data; H.X.Y., S.Z.L., D.R.L. contributed to the study data management, graphic visualization, and data interpretation. All authors have read and agreed to the submitted manuscript and the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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Conflicts of Interest: J.Z.L. and H.Y.G. are co-inventors of the biophoton generation technologies and the co-founders of Tesla BioHealing. Inc. Both had no impact on the data collection and data analysis before the randomization was revealed to all co-authors. The other authors declare no conflicts of interest.

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