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A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL STUDY OF HERBO-MINERAL GUMMIES TO EVALUATE THE IMPACT ON ENERGY LEVELS, FATIGUE REDUCTION AND MUSCLE MASS IN ACTIVE MALES

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ABSTRACT

Background: ShilAbsorb™ gummies, containing Shilajit, Ashwagandha, Ginger, Black pepper, Mucuna pruriens, and Akarkara, intended to improve energy, reduced fatigue, and increased muscle mass in active males. This study evaluated their efficacy and safety in resistance-trained males aged 18–40 years. **Methods**: In a 60-day, randomized, double-blind, placebo-controlled trial, 66 participants received two ShilAbsorb™ or placebo gummies daily. Outcomes included muscle strength (1RM chest/leg press), endurance (reps at 50% 1RM), hypertrophy (arm, chest, thigh circumference), body composition, testosterone, cortisol, creatine kinase, cardiorespiratory endurance, perceived exertion, delayed onset muscle soreness, and safety. **Results**: The ShilAbsorb™ group showed significant improvements versus placebo in skeletal muscle mass (4.47% more than placebo), leg press and chest press 1RM was significantly improved ($p<0.001$) compared to placebo. Endurance (repetitions at 50% 1RM) increased by 7.65% (chest) and 3.17% (leg) in ShilAbsorb™ group. ShilAbsorb™ supplementation resulted in a significant 10.33% and 9.34% increase in free and total testosterone levels compared to placebo. The cortisol levels were significantly reduced by 26.5% in the ShilAbsorb™ group. The arm, and thigh circumference were increased post supplementation of ShilAbsorb™ significantly then placebo ($p<0.001$ and $p<0.02$ respectively). ShilAbsorb™ supplementation significantly lower post-exercise CK levels along with DOMS and RPE scores. Fitness Index assessed using Harvard step test showed significant improvement, reflecting enhanced cardiorespiratory endurance in the ShilAbsorb™ group.

Conclusion: ShilAbsorb™ gummies may support muscle performance and recovery through enhanced protein utilization and metabolic efficiency. The findings suggest modulation of key pathways like mTOR and hormonal balance, highlighting the need for further research.

KEYWORDS: Shilajit, Muscle Endurance, Testosterone, Cardiorespiratory Fitness.

BACKGROUND

Nutritional ergogenic aids (NEAs) are commonly used by athletes to enhance performance, recovery, and training adaptations. Despite a 32.1% decline in sports supplement sales during the COVID-19 pandemic, the market is projected to grow by 10–11% between 2022 and 2028, with elite athletes generally consuming more NEAs than non-elite athletes.[1] Regular exercise improves mitochondrial function, which is crucial for muscle performance, ATP production, and reducing oxidative stress, thereby enhancing exercise tolerance and cardiorespiratory fitness.[2]

Shilajit, a natural exudate from mountain ranges, is rich in fulvic acids, dibenzo-α-pyrones, and over 40 minerals. It improves mitochondrial function, increases testosterone levels, and enhances muscle mass, strength, and endurance, making it beneficial for fatigue resistance.[3,4] Ashwagandha is an adaptogen that supports exercise-induced stress management, enhances

muscular strength and endurance, and reduces cortisol levels, further improving performance.[5]

Ginger provides anti-inflammatory and analgesic properties, aiding post-exercise recovery by reducing muscle soreness.[6] Black pepper enhances the absorption of active ingredients, regulating inflammation and oxidative status.[7] *Mucuna pruriens* boosts dopamine production, improving mood and recovery,[8] while Akarkara enhances sexual function.[9] This formulation synergistically targets multiple aspects of exercise performance and recovery, improving testosterone levels, muscle strength, endurance, and cardiorespiratory fitness in healthy adults.

MATERIALS AND METHODS

Study Design

A randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of ShilAbsorb™ gummies in healthy adults over 60 days. The study design is depicted in Fig. 1.

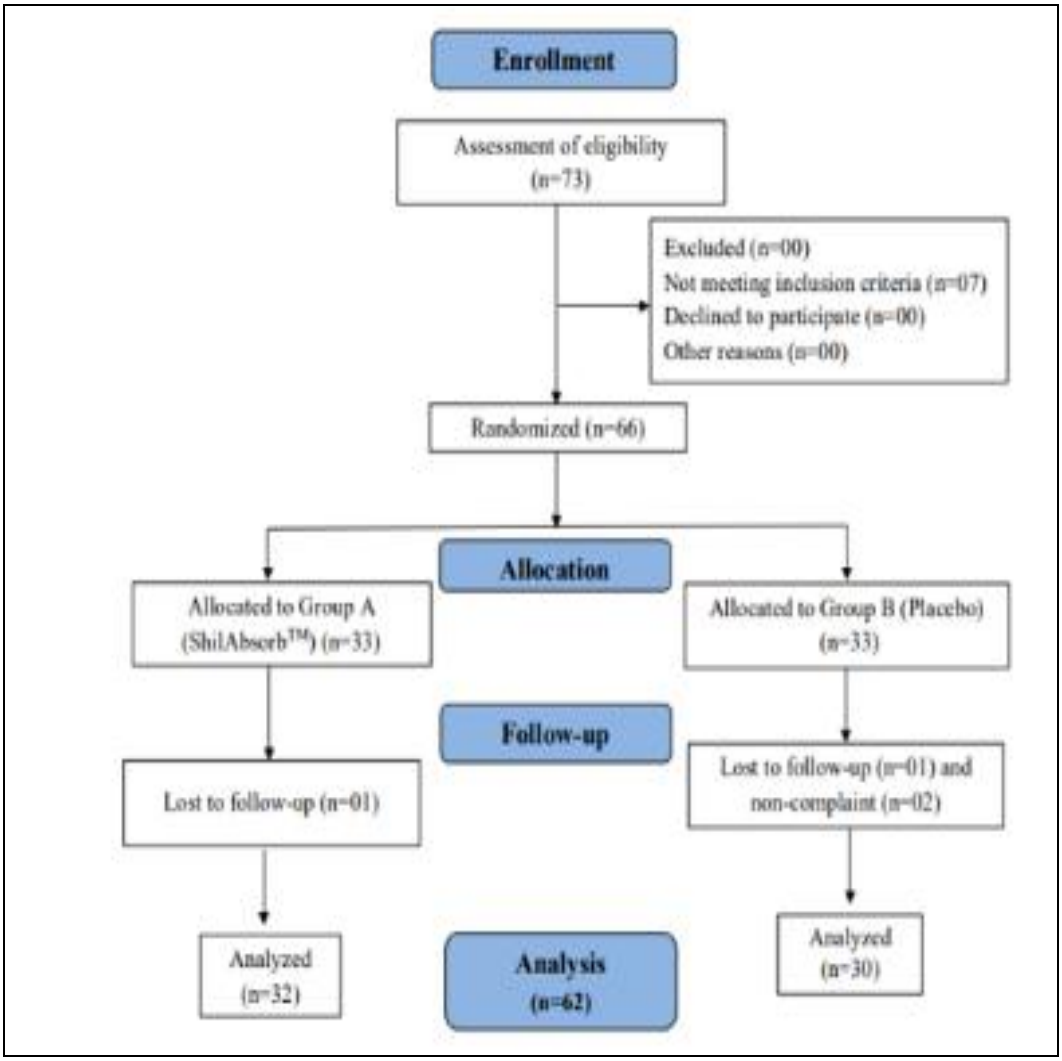


Figure 1: Participant flow diagram (Consort Chart).

Investigational Product

ShilAbsorb™ gummies or (Herbo-mineral gummies) (serving size: 2 gummies) contain 400 mg Shilajit (*Asphaltum Punjabianum* extract), 40 mg KSM-66® Ashwagandha (*Withania somnifera* extract), 10 mg Ginger (*Zingiber officinale* extract), 6 mg each of Black Musli (*Curculigo orchioides*), Gokshura (*Tribulus terrestris*), and Kaunch (*Mucuna pruriens*), 4 mg Akarkara (*Anacyclus pyrethrum*), and 2 mg Black pepper (*Piper nigrum*) along with inactive ingredients. Placebo gummies matched in appearance and colour but contained only inert excipients to ensure blinding. All products were manufactured in a GMP-certified facility. Participants consumed two ShilAbsorb™ gummies (test group) or two placebo gummies (placebo group) daily after a major meal.

Ethics approval and registration of a clinical trial

The clinical trial was conducted with the principles of Good Clinical Practice as per ICH-GCP guidelines. A clinical trial was conducted at Sangvi Multispecialty Hospital Pvt. Ltd., after approval from the ethics committee. The clinical trial was registered with the Clinical Trial Registry-India (CTRI) with approval

number CTRI/2024/11/076364. Data was collected from December 2024 to March 2025.

Informed Consent

Patients received a clear explanation of the study design, expected benefits, and potential risks in an understandable format and language. They were informed of their right to withdraw at any time. Written informed consent was obtained from each participant before enrollment. Details about the study's objectives, methods, potential risks and benefits, confidentiality policies, and contact information of the ethics committee and investigator were shared. To protect confidentiality, all personal data were coded, securely stored, and accessible only to authorized personnel. Participant anonymity was maintained in all reports and publications.

Study Participants

Inclusion Criteria: Eligible participants were healthy males aged 18–40 years with a BMI <35 kg/m² and resting blood pressure <140/90 mmHg. All were required to have a minimum of one year of consistent resistance training (including both cardiovascular and strength exercises), regular whey protein supplementation, and a sound understanding of relevant dietary and lifestyle practices, and not on any medication for cardiovascular and metabolic disorders as assessed by the investigator. Written informed consent and willingness to adhere to study procedures and follow-up visits were mandatory.

Exclusion Criteria: Exclusion criteria included any acute illness requiring immediate medical attention, chronic conditions, or known cardiovascular/metabolic disorders. Participants with sedentary lifestyles, those deemed medically unfit for resistance training, or with clinically significant nutritional deficiencies were excluded. The use of herbal supplements, nutraceuticals, creatine, anabolic steroids, testosterone boosters, or any non-prescribed substances influencing muscle mass, endurance, or testosterone levels was not permitted, except for protein supplements. Any condition that, in the investigator's opinion, could interfere with safety, compliance, or study completion led to exclusion.

Clinical Study Procedure

Sixty-six eligible participants were randomized 1:1 using a computer-generated sequence by a biostatistician into ShilAbsorb™ (n=33) and placebo (n=33) groups (Figure 1). Study products were pre-packaged and coded per the randomization sequence. Blinding was maintained for participants and investigators, with codes securely stored; no unblinding occurred.

Concomitant use of medications or supplements for energy, fatigue, or muscle mass was prohibited. Rescue medications were allowed per investigator discretion and recorded in CRFs.

Assessments occurred at baseline, day 30, and day 60. Muscle strength (estimated 1RM: leg/chest press), endurance (repetitions at 50% 1RM), and hypertrophy (arm, chest, thigh circumferences) were measured. Bioelectrical impedance analysis (BIA) assessed body fat and muscle mass. Hormonal (total/free testosterone, cortisol) and blood parameters were measured at screening and day 60. CK levels were tested pre-/post-/24h post-exercise. Delayed-onset muscle soreness (DOMS) was evaluated 48h post-exercise. The rating of perceived exertion (RPE) (scale 1–10), cardiorespiratory fitness (Harvard step test), body weight, and BMI were recorded at all visits. Adverse events, vitals were monitored on days 1, 30, and 60. Treatment compliance and tolerability were assessed on days 30 and 60.

Statistical Analysis

Sample size

A total of 62 participants completed the study (ShilAbsorb™: n=32; Placebo: n=30). Sample size was calculated using G*Power (v3.1.9.3), assuming an effect size of 0.9 for change in 1RM bench press, with α=0.05 and 90% power. This required 30 participants per group. Accounting for a 10% dropout, the target sample was 60.[10]

Analysis of parameters

Descriptive statistics summarized baseline characteristics (mean ± SD for continuous data; frequencies for categorical data). Normality was assessed using the Kolmogorov–Smirnov test. Paired t-tests evaluated within-group changes; between-group differences were analyzed using independent t-tests or Mann–Whitney U tests as appropriate. Safety parameters and vital signs were analyzed similarly. Adverse events and compliance were reported as counts and percentages. A p-value < 0.05 was considered statistically significant. Analyses were conducted using SPSS version 10.0.

RESULTS

Descriptive Characteristics, Resistance Training History, and Anthropometric Outcomes

The study included 62 participants with a mean age of 27.37 ± 6.03 years. The ShilAbsorb™ and placebo groups had similar average ages (27.72 ± 5.64 vs. 27 ± 6.49 years) and had been engaged in resistance training for an average of 21.13 ± 12.07 months.

At screening, no statistically significant differences were observed between groups in most anthropometric and muscle hypertrophy parameters, except chest circumference. By Day 60, the ShilAbsorb™ group showed significantly greater improvements in body weight, skeletal muscle percentage, mid-upper arm circumference, and upper thigh circumference compared to placebo. Fat percentage reduced more in the ShilAbsorb™ group, though not significantly, while chest circumference changes were comparable between groups (Table 1).

Table 1: Effects of ShilAbsorb™ on Body Composition, Muscle Hypertrophy Parameters and Blood Markers.

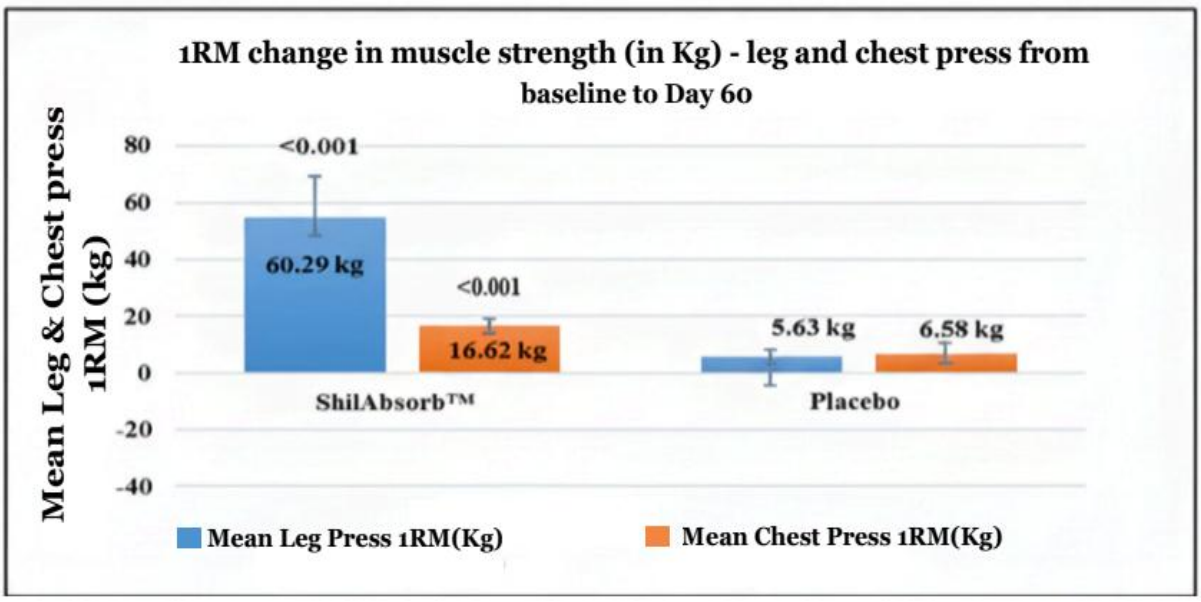
Visits	Screening			Day 60		
Study Groups	**ShilAbsorb™**	**Placebo**	**P-value**	**ShilAbsorb™**	**Placebo**	**P- value**
Anthropometric parameters						
Body weight (kg)	71.56 ± 7.80	76.54 ± 9.75	0.030	72.82 ± 6.99* (1.26kg)	75.89 ± 8.88 (0.65kg)	0.003
Fat %	24.08 ± 4.77	24.36 ± 4.75	0.814	22.85 ± 4.82* (1.23%)	23.94 ± 6.02 (0.42%)	0.183
Skeletal muscle %	46.11 ± 3.52	44.60 ± 3.34	0.089	48.18 ± 3.18* (2.07%)	45.38 ± 3.93 (0.78%)	0.002
Muscle hypertrophy						
Mid-upper arm circumference (cm)	31.97 ± 4.22	32.00 ± 5.68	0.980	34.88 ± 4.17* (2.91cm)	32.83 ± 4.78 (0.83cm)	<0.001
Upper thigh circumference (cm)	51.50 ± 7.11	52.67 ± 7.87	0.542	54.50 ± 6.38 (3cm)	53.77 ± 7.31* (1.1cm)	0.020
Chest circumference (cm)	89.22 ± 14.28	88.17 ± 5.18	0.019	93.41 ± 13.06* (4.19cm)	92.60 ± 9.63* (4.43cm)	0.944
Blood Marker Levels						
Total Testosterone (ng/mL) (0 - 7.89)	3.24 ± 1.27	2.80 ± 1.48	0.214	3.71 ± 1.31	2.94 ± 1.23	0.298
Free Testosterone (pg/mL) (0 – 46)	32.50 ± 8.57	31.42 ± 9.01	0.630	36.14 ± 6.13*	31.14± 9.31	0.013
Cortisol Levels (nmol/L)	307.55 ± 62.26	243.22 ± 108.42	0.005	225.99 ± 110.85*	258.56 ± 97.55	<0.001

*Data is represented as Mean ± S.D (*mean change from screening). *The data was analyzed for within-group by using Student T dependent test and Wilcoxon Signed Rank test, and for between-group by using Student T independent test and Mann-Whitney U. Significant at < 0.05. * Significant p-values within a group.*

Assessment of Muscle Strength and Endurance

ShilAbsorb™ supplementation over a 60-day period resulted in clinically and statistically significant increases in muscle strength, in estimated 1RM for both leg and chest press exercises compared to placebo.

Muscle endurance, assessed by the number of repetitions performed at 50% estimated 1RM with chest and leg press, showed statistically significant improvement between groups (3.17% vs 1.6% in leg press; 7.65% vs. 4.8% in chest press between ShilAbsorb™ and placebo respectively). These findings suggest that ShilAbsorb™ may improve muscular strength performance when combined with resistance training (Fig. 2).



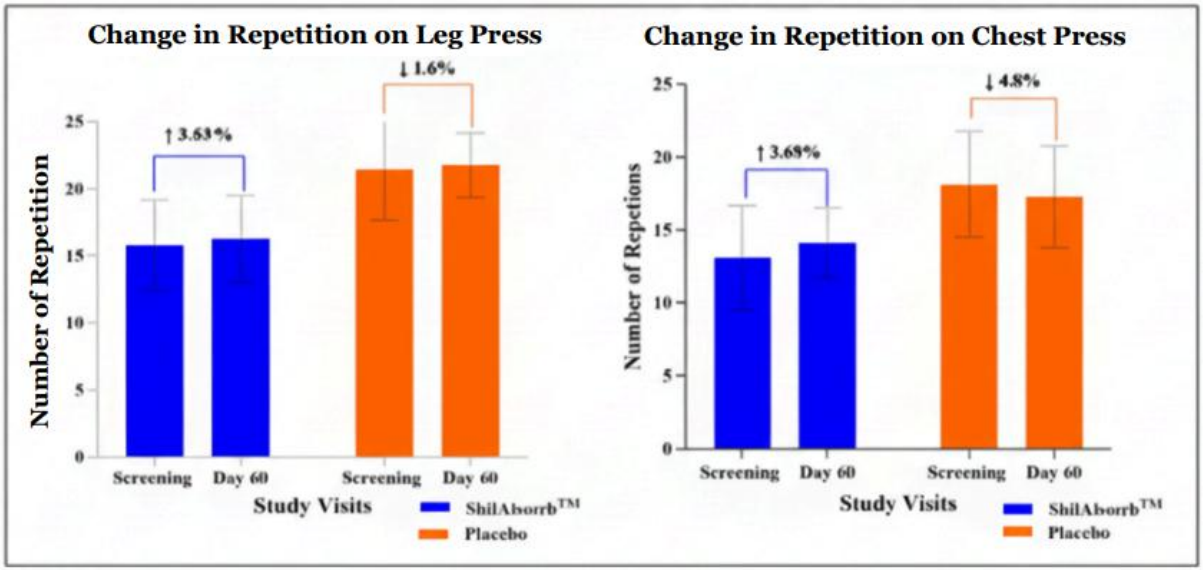


Figure 2: Changes in muscle strength (1RM) and endurance (repetitions at 50% 1RM) for chest and leg press. *Significant difference between groups, p<0.001.

Assessment of Perceived Exertion and Post-DOMS

Perceived exertion was assessed immediately post-1RM training, while soreness and pain scores were recorded 48 hours later to evaluate delayed onset muscle soreness. At baseline, scores were comparable between groups.

By Day 60, perceived exertion decreased significantly from 7.88 to 1.13 in the ShilAbsorb™ group, versus 7.50 to 4.53 in placebo ($p < 0.001$), indicating improved exercise tolerance. Similarly, soreness scores declined from 8.09 to 1.19 in ShilAbsorb™ and 8.27 to 5.23 in placebo. Pain scores reduced from 7.59 to 0.94 in ShilAbsorb™ compared to 8.00 to 5.17 in placebo ($p < 0.001$). These results suggest post-exercise recovery and reduced muscle discomfort with ShilAbsorb™.

Testosterone and Cortisol Levels

ShilAbsorb™ supplementation resulted in a significant 10.33% and 9.34% increase in free and total testosterone levels compared to placebo. The cortisol levels were significantly reduced by 26.5% in the ShilAbsorb™ group, suggesting a possible modulation of stress hormone response (Table 1).

Assessment of Creatine Kinase & Fitness Index

At baseline, creatine kinase levels across all time points were comparable between groups.

After 60 days, the ShilAbsorb™ group showed statistically significant reductions in CK levels pre-exercise, post-exercise, and 24-hour post-exercise than placebo, indicating reduced muscle damage and enhanced recovery following resistance training (Fig. 3).

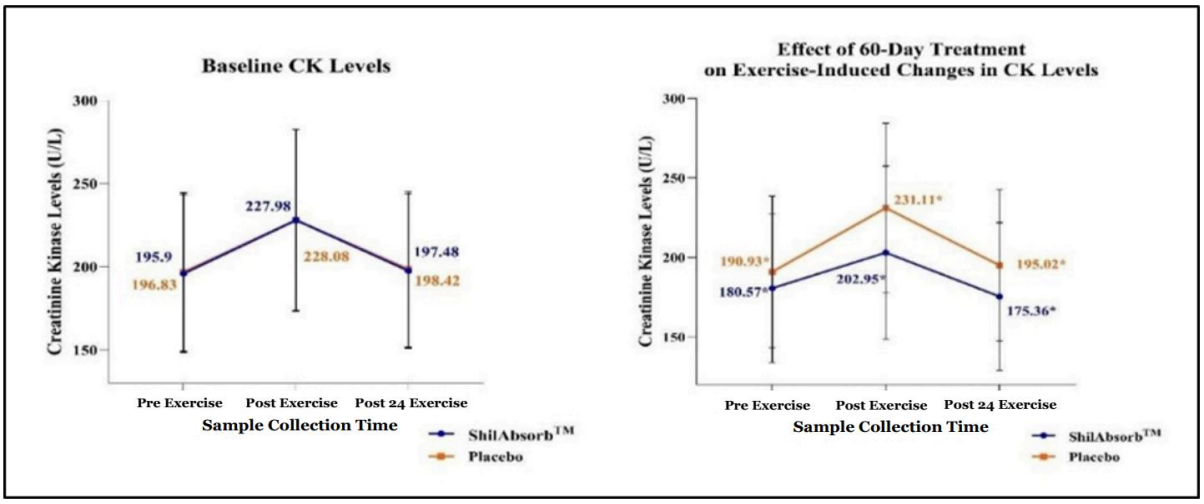


Figure 3: Creatine Kinase (CK) levels pre-exercise, post-exercise, and 24-hour post-exercise at Day 60. *Significant difference between groups, p<0.05.

The Fitness Index was calculated using the Harvard Step Test to evaluate cardiorespiratory endurance. ShilAbsorb™ supplementation resulted in a significant improvement in cardiorespiratory endurance compared to placebo. Notable increases in fitness index were observed at days 30 and 60, indicating enhanced endurance, with values reaching the high-average range by day 60. The differences between groups were statistically significant at both time points. (Fig. 4).

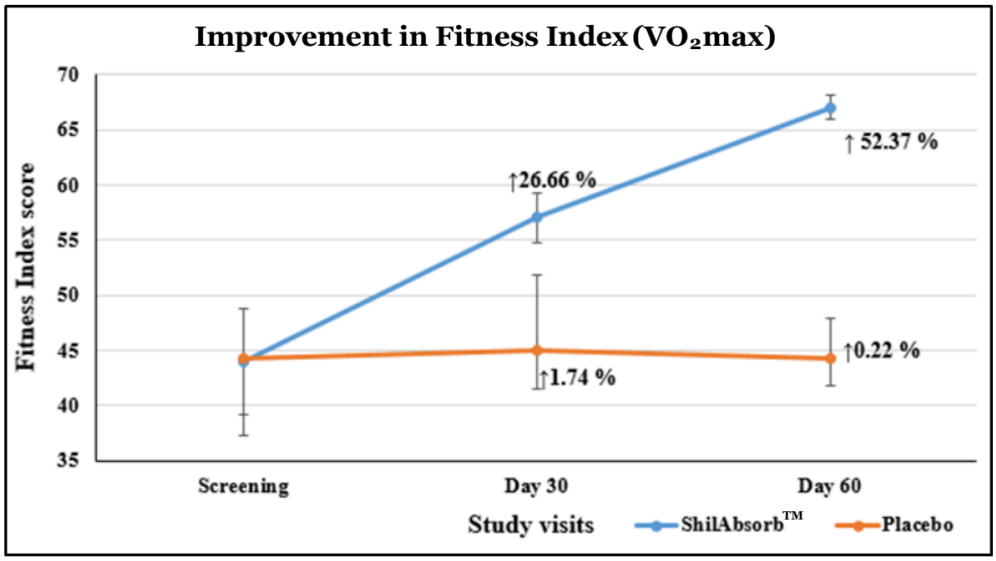


Figure 4: Fitness Index scores from the Harvard Step Test at baseline, Day 30, and Day 60. *Significant difference between groups, p<0.05.

Safety Assessment

No clinically significant changes were observed in haematological parameters (complete blood count) or vital signs in either the ShilAbsorb™ or placebo groups over the 60 days, indicating overall safety.

There were zero adverse events, and tolerability was excellent in both groups throughout the study. All participants showed high compliance throughout the study.

DISCUSSION

This randomized, double-blind, placebo-controlled trial demonstrated that 60-day supplementation with ShilAbsorb™, a proprietary multi-herbal formulation, significantly enhanced muscle hypertrophy (arm, chest, thigh circumferences), strength (1RM chest and leg press), endurance, and fatigue resistance in resistance-trained males compared to placebo. These improvements were accompanied by better post-exercise recovery, enhanced cardiorespiratory endurance and favorable hormonal modulation, with no reported adverse events, confirming the safety and tolerability of the formulation.

One of the key findings of the study was the significant increase in skeletal muscle percentage and circumference measurements (arm, chest, thigh) in the ShilAbsorb™ group. This aligns with existing literature suggesting that certain bioactive compounds can enhance nutrient bioavailability and muscle protein synthesis (MPS).[11] While the exact mechanism of ShilAbsorb™ was not the primary focus of this study, previous research on similar formulations indicates that they may improve amino acid uptake and stimulate mTOR signaling, a critical pathway for muscle growth.[11,12]

The greater reduction in fat percentage (though not statistically significant) alongside increased muscle mass suggests an improvement in metabolic efficiency, possibly due to enhanced mitochondrial function and nutrient partitioning. Given that muscle hypertrophy is highly dependent on protein synthesis and nitrogen retention, the observed changes in body composition may be attributed to improved protein absorption and utilization rather than direct anabolic effects.

Participants receiving ShilAbsorb™ demonstrated significant improvements in 1RM strength (leg press and chest press) and greater endurance, completing more repetitions under heavier loads with reduced perceived exertion and DOMS. These performance improvements may be attributed to enhanced ATP production via mitochondrial bioenergetics, reduced oxidative stress and inflammation, improved glycogen resynthesis, likely resulting from superior nutrient uptake.

Importantly, reductions in post-exercise CK levels in the ShilAbsorb™ group suggest lower exercise-induced muscle damage and enhanced recovery capacity.[13,14] These findings point to the formulation's ability to support cellular repair mechanisms, mitigate fatigue, and improve exercise tolerance.

A notable finding was the significant increase in both total and free testosterone along with a reduction in cortisol levels. This shift toward a more anabolic

hormonal profile is essential for muscle recovery, adaptation, and growth. Cortisol, a catabolic hormone, is known to inhibit protein synthesis and delay recovery when elevated post-exercise.[15]

The observed hormonal modulation may be driven by adaptogenic constituents of the formulation, such as Shilajit and Ashwagandha, which are known to influence the hypothalamic-pituitary-gonadal and hypothalamic-pituitary-adrenal axes.[16,17] This adaptogenic modulation may enhance stress resilience, support recovery, and promote long-term muscular adaptations.

ShilAbsorb™ supplementation led to a significant improvement in cardiorespiratory fitness, as reflected by the Harvard Step Test fitness index. These enhancements may be explained by improved oxygen utilization, mitochondrial biogenesis, and metabolic flexibility all critical components of endurance performance.[18]

The combination of botanicals in ShilAbsorb™ may have produced synergistic effects. Ginger has been shown to reduce exercise-induced pain and inflammation via COX pathway modulation, with meta-analyses supporting its efficacy in DOMS reduction and strength recovery.[19] *Tribulus terrestris* has demonstrated testosterone-enhancing and muscle performance benefits in trained males,[20,21] while *Mucuna pruriens* exerts HPA and HPG axis modulating effects, increasing testosterone and reducing cortisol and prolactin.[22,23] Collectively, these adaptogenic and ergogenic effects appear to contribute to the formulation's multifaceted performance-enhancing properties.

Unlike traditional gym supplements (whey protein, BCAAs, creatine), which typically target isolated anabolic or energetic pathways,[24] ShilAbsorb™ appears to provide broader physiological modulation. Its multi-targeted approach spanning hormonal balance, mitochondrial bioenergetics, anti-inflammatory action, and enhanced protein metabolism positions it as a comprehensive strategy for improving muscle performance, recovery, and overall fitness.

Throughout the 60-day supplementation period, no adverse events were reported, and hematological parameters remained stable. This confirms the favorable safety profile of ShilAbsorb™, supporting its potential for routine use among fitness enthusiasts and athletes.

A major strength of this trial is its robust design and focus on resistance-trained males. However, the 60-day duration may not reflect long-term outcomes. Future studies should assess extended use, include females and older adults, and explore broader health parameters for enhanced generalizability.

CONCLUSION

ShilAbsorb™ gummies may enhance muscle performance and recovery by proposed mechanisms such as protein metabolism, mitochondrial efficiency, and hormonal balance. The observed benefits align with pathways such as mTOR activation and improved amino acid utilization. These results suggest a multi-targeted physiological effect, though further research is needed to confirm underlying mechanisms and long-term benefits.

DECLARATIONS

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Author Contributions

Study Concept: D.M.; Study Design: S.A.; Interpretation of Data, Drafting, and Critical Revision of Manuscript: S.H.R.* All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

Darshani Mohan, Subhashree Aparimita, and Supriya Raut are employees of Mosaic Wellness Pvt Ltd. No other conflicts of interest are declared.

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