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"The Role of MEET Shilajeet Supplement in Supporting Minerals, Energy, Endurance and Testosterone: A Clinical Evaluation"

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ABSTRACT

Background: Shilajeet is a naturally occurring multi-component with humous rich blackish brown substance which is widely used in indigenous system of medicine for the cure of variety of diseases and to accelerate the process of rejuvenation. It serves as potent tonic and supplement on improving vitality, boosting stamina, strength and performance in healthy adults. **Methods:** A randomized, placebo-controlled clinical study trial was conducted with 50 healthy male subjects with age 18–45 years to evaluate the efficacy and safety of MEET Shilajeet supplement on improving vitality, boosting stamina, strength and performance in healthy adults (MEET Shilajeet-25 subjects, Placebo-25 subjects). **Results:** For 60-day trial durations, study outcomes efficacy and safety of MEET Shilajeet capsules. Subjects were administered MEET Shilajeet capsules twice daily rally for 60 days. The testosterone levels showed a difference of 10.60% between the MEET Shilajeet and Placebo group indicating that MEET Shilajeet group exhibited a noticeable improvement in the testosterone levels compared to the placebo proving its beneficial effect. Additionally, the SF-36 assessment revealed significant improvements in Vitality, Emotional Well-being, Social Functioning, and General Health for the MEET Shilajeet group, while the placebo group showed declines in these areas. **Conclusion:** This study reveals that MEET Shilajeet capsules had a substantial effect on during a 60-day period. The safety profile was favorable, with no significant adverse effects reported, indicating good tolerability of the treatment. As a result, studies should have well-defined goals and clinical safe and effective.

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INTRODUCTION

In recent years, the pursuit of holistic well-being has prompted an increased interest in natural supplements that have the potential to enhance various facets of human health. Among these, Shilajeet, a traditional Ayurvedic substance derived from the mountains, has gained attention for its purported health benefits.[1] With a rich composition of minerals, fulvic acid, and bioactive compounds, Shilajeet has been historically revered for its adaptogenic properties, claiming to contribute to energy enhancement, strength improvement, stress reduction, and increased endurance .[2]

The rationale behind conducting this study lay in the need to bridge the gap between traditional knowledge and contemporary scientific inquiry regarding the potential health benefits of MEET Shilajeet supplement.[3] While Shilajeet has been traditionally revered for its purported adaptogenic properties,[4] scientific evidence supporting its efficacy remains limited, particularly within the context of well-designed clinical trials. This randomized, placebo-controlled study was intended to provide a rigorous and evidence-based evaluation of Shilajeet's impact on key health parameters in healthy adults. The exploration of its effects on energy levels, strength, stress, and endurance was motivated by the current global interest in holistic approaches to health and well-being. This study's findings contributed valuable insights into the specific effects of Shilajeet and will serve as a foundation for informed decision-making

by individuals seeking natural supplements for health optimization. Additionally, the study aligned with the growing recognition of the importance of integrating traditional remedies into evidence-based healthcare practices, fostering a deeper understanding of their potential role in promoting overall health and vitality.

The word Shilajeet is composed of two parts "Shila" means rock and "jeet" means having won. So its literary meaning is "conqueror of mountains". Its Sanskrit meaning is "conqueror of mountains and destroyer of weakness". [5] The composition of Shilajeet shows variations from source to source and study to study. Broadly the composition of Shilajeet has been reported to have inorganic to organic materials like more than 85 minerals. [6] Ca, Fe, Mg, Al, Na, K, P, S, Li, C, Mn, Ni, Si, etc. elements and compounds- eighteen free amino acids, m–hydroxybenzoic acid, sterols, tri-terpenes, ellagic acid, three bencoumarins [7] benzoic acid, fulvic acid (Figure 1) and humic acid (Figure 2). [8]

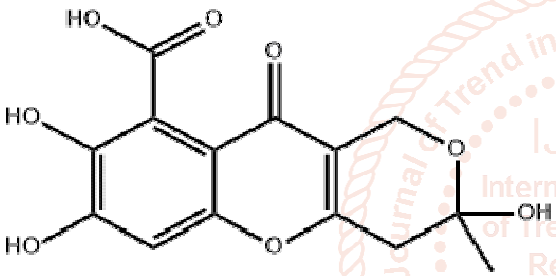

Figure 1: Fulvic Acid

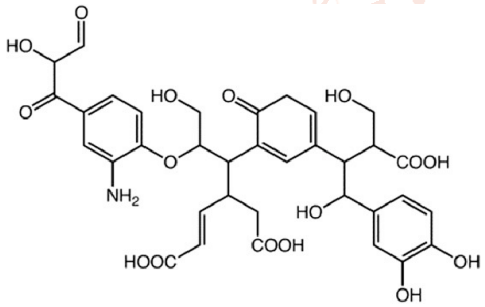

Figure 2: Humic Acid

Shilajeet was used as a drug in prehistoric periods. Shilajeet acts as an agent which enhances the property of other drugs. According to Ayurveda, Shilajeet arrests the process of ageing and produces rejuvenation which are two important aspects of an Ayurvedic rasayana. It is prescribed to treat fractures, osteoarthritis, spondolysis, chronic bronchitis, nervous disorders, epilepsy, anemia, angina, jaundice, menorrhagia and eczema. It has also been ascribed as a potent aphrodisiac property. It is useful for treating kidney stones, oedema, piles, internal antiseptic, adiposity, to reduce fat and anorexia. [9] Traditionally, Shilajeet is consumed by people from the north of India and Nepal and children usually take it with milk in their breakfast. The Sherpa claim to have Shilajeet as a part of their diet, they constitute a population of strong men with very high level of healthy longevity. The traditional uses include its action in genitourinary disorders, enlarged spleen, epilepsy and haemorrhoids. [10] Shilajeet is given alongwith milk to treat diabetes. It is used for applications of tongue and cheeks as paint, prepared by mixing Shilajeet in hot water. [11] It is also instilled as nasal drops and ear drops. [12]

This study aimed to rigorously investigate the efficacy and safety of MEET Shilajeet (standardized in Fulvic acid & Humic acid) through a randomized, placebo-controlled clinical trial. The primary focus was to evaluate its impact on key parameters, including energy levels, strength, stress levels, and endurance, in a cohort of healthy adults. This research was designed to provide valuable insights into the potential benefits of MEET Shilajeet supplement and contribute to the growing body of scientific knowledge surrounding natural interventions for health optimization. As the global interest in natural supplements continues to grow, this study held the promise of contributing evidence-based insights into the potential benefits of Shilajeet supplement on energy, strength, stress, and endurance in a population of healthy adults. The outcomes of this research not only had implications for individual well-being but also influenced future discussions on integrating traditional remedies into contemporary health practices.

MATERIALS AND METHODS:

Study Objectives:

Primary: To evaluate the efficacy of MEET Shilajeet supplement in healthy men on improvement of energy, strength, stress and endurance in adults.

Secondary: To evaluate the safety of MEET Shilajeet supplement in healthy men on improvement of energy, strength, stress and endurance in adults.

Study Design and Description

This was a randomized, placebo-controlled clinical study designed to evaluate the efficacy and safety of MEET Shilajeet capsules in adult subjects. Potential participants were screened based on predefined inclusion and exclusion criteria, and written informed consent was obtained prior to enrolment. The study spanned for 60 days and included two key site visits: the screening and baseline visit (V1) and the end-of-study visit (V2). Additionally, participants underwent periodic telephone follow-ups throughout the treatment period. During the screening and baseline visit, participants were assessed for eligibility, underwent a comprehensive medical evaluation, and were randomized into either the MEET Shilajeet or placebo group. Baseline assessments included

physical fitness tests, measurement of vital signs, serum testosterone and cortisol levels, and other health parameters. The investigational product was dispensed, and participants were provided with details for the subsequent visit.

Selection of Study Population

Subjects were randomly assigned to treatment groups based on predefined inclusion and exclusion criteria.

Inclusion Criteria

To participate in this study, all subjects had to meet the following eligibility criteria:

1. Healthy male adult subjects age between 18–45 years.
2. Participants with a body mass index (BMI) of 18.5–29.9 kg/m^2.
3. Willingness to participate in an exercise program 2-3 times per week for a duration of 8 weeks.
4. Participants expressed a willingness to be available for the entire duration of the study period (8 weeks).
5. Participants expressed a willingness to actively participate in the study and provided written informed consent.

Exclusion Criteria

The study excluded individuals who met any of the following criteria:

1. Individuals currently undertaking resistance training exercises.
2. Presence of clinically significant medical conditions, including but not limited to cardiovascular, neurological, psychiatric, renal, immunological, endocrine (such as uncontrolled diabetes or thyroid disease), or hematological abnormalities.
3. Taking medications such as corticosteroids, antidepressants, anticholinergics, or any other drugs that could have influenced the study outcomes.
4. Severe pulmonary dysfunction, including uncontrolled bronchial asthma and/or chronic obstructive pulmonary disease (COPD).
5. History of orthopaedic conditions or surgeries that would interfere with exercise performance.
6. Completed any other clinical trial within 6 months prior to enrolment.
7. Consumed any dietary supplements or herbal drugs within 7 days prior to screening.
8. Known hypersensitivity to herbal drugs, nutritional supplements, or foods.
9. Active smokers or individuals with a history of high alcohol intake (defined as consuming 2 or more standard drinks per day).

Subject Discontinuation/Withdrawal Criteria

Participants may have discontinued from the study for conditions that made them unfit to continue, including serious adverse events, safety concerns regarding the development of a new medical condition, withdrawal of consent, or poor compliance with assessments. The study ended if serious adverse events, such as death, intervention-related hospitalization, or uncontrolled disease progression, occurred in 10% or more of the participants. A participant was withdrawn from the study for following reasons:

- Loss to follow-up

When a participant withdrew from the study before its completion, the reason for withdrawal was documented on the Case Report Form (CRF) as well as in the source document.

Treatments Administered

Subjects were administered either MEET Shilajeet capsule (500 mg) or a placebo (Microcrystalline cellulose 250 mg) twice daily for a duration of 60 days. The treatment regimen involved daily doses of 500 mg of MEET Shilajeet capsule, which was designed to evaluate its efficacy and safety compared to an in MEET Shilajeet placebo.

Efficacy and Safety Variables

Efficacy Assessment

The efficacy of MEET Shilajeet capsule was assessed using a comprehensive set of physical fitness tests, hormonal evaluations, and quality of life measures. The Queen's College Step Test and the 6-Minute Walk Test (6-MWT) evaluated cardiovascular endurance and aerobic capacity, providing insights into participants' physical fitness at baseline and after 60 days. The 30-Second Sit to Stand Test and Push-Up Test measured lower and upper body strength and endurance, while the Squat Test assessed overall lower body strength and flexibility. Additionally, serum testosterone and cortisol levels were monitored to understand the impact of the supplement on hormonal balance and stress response. The SF-36 questionnaire provided a subjective measure of participant's health-related quality of life across various domains, allowing for a holistic assessment of the intervention's effects on physical, mental, and social well-being. These assessments, conducted at both the baseline and final visits, enabled a thorough evaluation of the potential benefits of MEET Shilajeet supplementation over the study period (Figure 1).

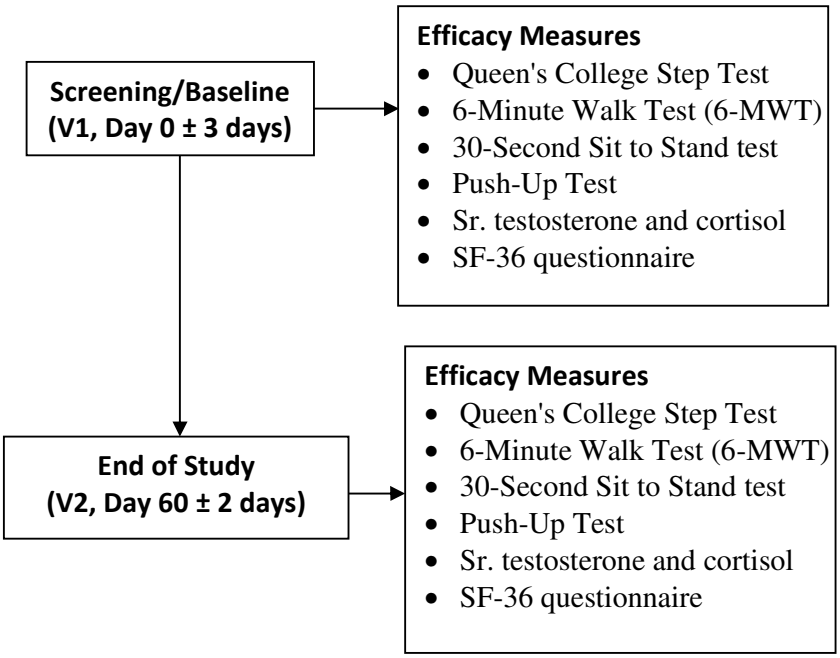

Figure 1: Flow Chart of Efficacy Assessments

➢ **Safety Assessment**

Safety assessment in this study included monitoring vital signs, conducting laboratory safety evaluations and documenting any treatment-related adverse events to ensure well-being of the participants throughout the trial. Vital signs, namely body temperature, pulse rate, respiratory rate and blood pressure were measured at both baseline and the end of the study to detect any deviations that could indicate adverse effects. In addition, laboratory safety parameters including haematology, liver function, kidney function, and Electrocardiogram (ECG) recordings were assessed at key time points. These comprehensive evaluations provided crucial insights into the physiological and cardiovascular impact of MEET Shilajeet supplementation, ensuring ongoing safety surveillance throughout the study (Figure 2).

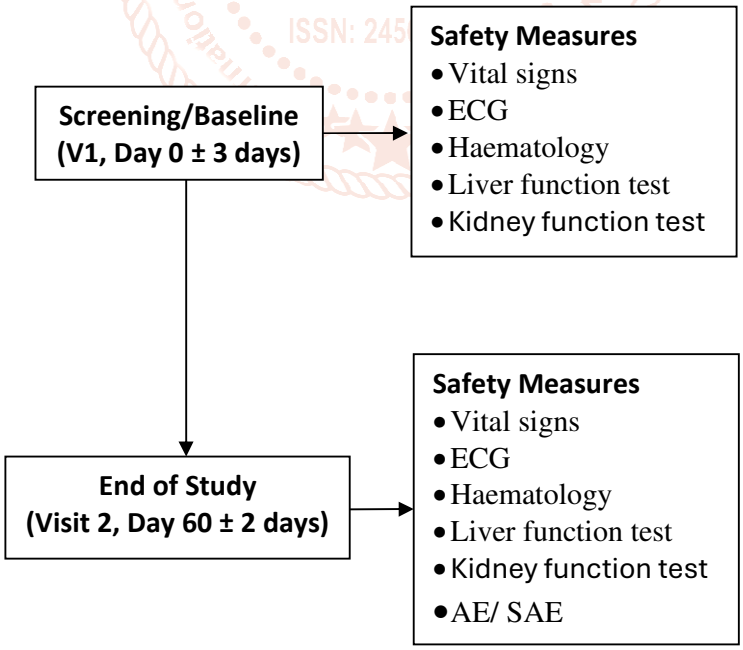

Figure 2: Flow Chart of Safety Assessments

RESULTS:

Analysis of Efficacy

Assessment of Aerobic Endurance by Queen's College Step Test

The assessment of aerobic endurance using the Queen's College Step Test showed significant improvements in the MEET Shilajeet group compared to the placebo group by the end of the study (Table 3). At baseline, there

were no significant differences between the groups in terms of height, weight, post-exercise heart rate or maximum aerobic capacity (VO_2max). The MEET Shilajeet group had a slightly higher mean VO_2max (62.64 ± 7.54 ml/kg/min) compared to the placebo group (59.58 ± 8.29 ml/kg/min), but this difference was not statistically significant (p = 0.135).

By the end of the study, the MEET Shilajeet group demonstrated a notable reduction in post-exercise heart rate (101.23 ± 12.96 bpm) compared to the placebo group (125.00 ± 15.69 bpm), with a highly significant p-value of 0.001. This significant reduction of -12.83% in heart rate indicated improved cardiovascular efficiency in the MEET Shilajeet group. Furthermore, the MEET Shilajeet group exhibited a substantial increase of 10.29% in VO_2max, with a mean of 68.81 ± 5.44 ml/kg/min, compared to 58.83 ± 6.59 ml/kg/min in the placebo group (p = 0.001), reflecting enhanced aerobic capacity.

Within-group comparisons further supported these findings (Table 4). The MEET Shilajeet group experienced a significant increase of 1.51% in weight (mean difference: -1.14 kg, p = 0.001), a significant reduction in post-exercise heart rate (mean difference: 15.59 bpm, p < 0.001), and a significant increase VO_2max (mean difference: -6.17 ml/kg/min, p < 0.001) from baseline to the end of the study. In contrast, the placebo group showed no significant changes in weight, post-exercise heart rate or VO_2max over the same period. These results indicate that the MEET Shilajeet intervention significantly improved aerobic endurance and cardiovascular efficiency in the study participants.

Table 3: Inter Group Comparison of Mean Change in Queen's College Step Test Parameters at Different Assessment Points

Variable	Placebo (Mean ± SD)	MEET Shilajeet (Mean ± SD)	P value
Baseline (Visit 1)			
Height (cm)	168.12 ± 7.61	170.28 ± 7.97	0.527
Weight (kg)	71.48 ± 10.89	74.36 ± 9.68	0.236
Post-exercise heart rate (bpm)	124.52 ± 20.27	116.72 ± 18.04	0.114
Maximum aerobic capacity (VO_2max)	59.58 ± 8.29	62.64 ± 7.54	0.135
End of Study (Visit 2)			
Height (cm)	167.87 ± 7.75	169.32 ± 6.07	0.569
Weight (kg)	72.26 ± 11.22	74.77 ± 7.95	0.381
Post-exercise heart rate (bpm)	125.0 ± 15.69	101.23 ± 12.96	0.001
Maximum aerobic capacity (VO_2max)	58.83 ± 6.59	68.81 ± 5.44	0.001
Percentage Difference			
Post-exercise heart rate (bpm)	1.00 ± 8.65	-12.83 ±9.17	0.001
Maximum aerobic capacity (VO_2max)	-0.72 ± 6.86	10.29 ±7.97	0.001

Table 4: Within the Group Comparison of Queen's College Step Test Parameters from Baseline to End of the Study

Variable	Comparison	Mean diff.	SD Value	95% Confidence Interval	P value
Placebo					
Weight (kg)	Baseline Vs End of study	-0.26	1.21	-0.786 to 0.264	0.363
Post-exercise heart rate (bpm)		-0.26	9.26	-4.265 to3.743	0.891
Maximum aerobic capacity (VO_2max)		0.71	4.25	-1.126 to 2.547	0.438
MEET Shilajeet					
Weight (kg)	Baseline Vs End of study	-1.14	1.28	-1.705 to 0.567	0.001
Post-exercise heart rate (bpm)		15.59	11.79	10.365 to 20.817	0.0
Maximum aerobic capacity (VO_2max)		-6.17	4.57	-8.191 to -4.142	0.0

Assessment of Aerobic Capacity and Endurance by 6-Minute Walk Test

The results from the 6-Minute Walk Test (6MWT) indicated notable differences in aerobic capacity and endurance between the placebo and MEET Shilajeet groups over the study period. At baseline, both groups were comparable across various parameters, including weight, blood pressure, heart rate, distance walked and predicted VO_2 peak. However, by the end of the study, significant changes were observed.

In the MEET Shilajeet group, there was a substantial increase in the total distance walked during the 6MWT by the end of the study, with a mean distance of 623.64 ± 115.41 meters, compared to 537.39 ± 49.84 meters in the

placebo group (p = 0.004). This increase in walking distance suggests improved endurance in the MEET Shilajeet group. Additionally, the MEET Shilajeet group demonstrated a decrease in weight (mean difference: -1.14 kg, p = 0.001), indicating potential weight loss during the study. The MEET Shilajeet group also showed an improvement in VO_2 peak (mean difference: -2.08 ml/kg/min, p = 0.017) from baseline to end of the study, indicating an improvement in aerobic capacity. The placebo group showed a decrease in VO_2 peak, from baseline to end of the study but this difference was less pronounced (Table 5).

Within-group comparisons revealed that the placebo group experienced a significant decrease in systolic blood pressure (mean difference: 7.57 mmHg, p = 0.015) and a modest decrease in total distance walked (mean difference: 31.30 meters, p = 0.025), along with a decline in VO_2 peak (mean difference: 1.02 ml/kg/min, p = 0.002). These results suggest that MEET Shilajeet group showed better performance in the 6MWT parameters exhibiting better maintenance and improvements in aerobic capacity as measured by VO_2 peak (Table 6).

Overall, the MEET Shilajeet intervention led to significant improvements in endurance as demonstrated by the increased walking distance and VO_2 peak.

Table 5: Between-Groups Comparison of Mean Change in Aerobic Capacity and Endurance Parameters at Different Assessment Points

Variable	Placebo (Mean ± SD)	MEET Shilajeet (Mean ± SD)	P value
Baseline (Visit 1)			
Weight (kgs)	71.48 ± 10.89	74.36 ± 9.68	0.236
Systolic blood pressure (mmHg)	127.20 ± 17.07	119.08 ± 13.93	0.076
Diastolic blood pressure (mmHg)	80.04 ± 11.99	74.12 ± 9.97	0.066
Heart rate (bpm)	102.64 ± 17.56	99.36 ± 14.12	0.515
End of test heart rate (bpm)	101.32 ± 16.96	103.24 ± 17.22	0.69
End of test total distance walked in six minutes (m)	569.60 ± 67.85	568.0 ± 82.26	0.564
End of test predicted distance (m)	668.52 ± 56.16	670.33 ± 60.35	0.808
End of test VO_2 peak ml/kg/min	20.91 ± 2.14	20.34 ± 2.70	0.19
End of Study (Visit 2)			
Weight (kgs)	72.26 ± 11.22	74.77 ± 7.95	0.381
Systolic blood pressure (mmHg)	118.83 ± 11.83	119.77 ± 9.94	0.633
Diastolic blood pressure (mmHg)	77.17 ± 10.92	75.45 ± 8.58	0.716
Heart rate (bpm)	100.48 ± 13.38	98.05 ± 12.42	0.946
End of test heart rate (bpm)	97.35 ± 10.76	97.27 ± 13.30	0.82
End of test total distance walked in six minutes (m)	537.39 ± 49.84	623.64 ± 115.41	0.004
End of test predicted distance (m)	663.52 ± 57.71	659.32 ± 55.84	0.601
End of test VO_2 peak ml/kg/min	19.77 ± 2.43	22.45 ± 8.79	0.323
Percentage Difference			
End of Test Total distance walked in six minutes (m)	-4.77 ± 9.52	8.62 ± 13.03	0.001
End of Test VO_2 peak ml/kg/min	-2.43 ± 9.52	4.60 ± 9.52	0.004

Table 6: Within the Group Comparison of Aerobic Capacity and Endurance Parameters from Baseline to End of the Study

Variable	Comparison	Mean diff.	SD Value	95% Confidence Interval	P value
Placebo					
Weight (kgs)	Baseline Vs End of study	-0.26	1.21	-0.786 to 0.264	0.363
Systolic blood pressure (mmHg)		7.57	17.0	0.213 to 14.918	0.015
Diastolic blood pressure (mmHg)		2.57	13.19	-3.137 to 8.268	0.284
Heart rate (bpm)		2.35	17.23	-5.104 to 9.780	0.573
End of test heart rate (bpm)		3.91	15.09	-2.611 to 10.437	0.273
End of test total distance walked in six minutes (m)		31.30	59.95	5.381 to 57.227	0.025
End of test predicted distance (m)		1.65	3.65	0.0735 to 3.231	0.065

End of testVO2 peak ml/kg/min		1.02	1.71	0.284 to 1.760	0.002
MEET Shilajeet					
Weight (kgs)	Baseline Vs End of study	-1.14	1.28	-1.705 to -0.567	0.001
Systolic blood pressure (mmHg)		-0.14	12.09	-5.498 to 5.225	0.945
Diastolic blood pressure (mmHg)		-1.18	9.13	-5.228 to 2.865	0.944
Heart rate (bpm)		2.50	12.72	-3.140 to 8.140	0.571
End of test heart rate (bpm)		6.59	16.08	-0.540 to 13.721	0.097
End of test total distance walked in six minutes (m)		-49.09	75.02	-82.352 to -15.830	0.006
End of test predicted distance (m)		3.01	2.84	1.750 to 4.269	0.0
End of testVO2 peak ml/kg/min		-2.08	6.79	-5.088 to 0.936	0.017

Assessment of Lower Extremity Muscle, Upper Body and Lower Body Strength and Endurance

The assessment of lower extremity muscle, upper body and lower body strength and endurance revealed significant differences between the placebo and MEET Shilajeet groups by the end of the study. At baseline, both groups were relatively similar across all parameters, including the 30-Second Sit to Stand Test, Push-up Test, and Squat Test, with no significant differences noted.

However, by the end of the study, the MEET Shilajeet group showed significant improvements in several key areas. The Push-up Test results significantly improved by 38.57% in the MEET Shilajeet group compared to the baseline and significantly better with an average of 22.59 ± 12.02 push-ups, compared to 16.48 ± 5.65 in the placebo group ($p = 0.002$) indicating a significant increase in upper body strength and endurance for those in the MEET Shilajeet group. Similarly, the Squat Test results also demonstrated a trend toward improved lower body strength and endurance, with the MEET Shilajeet group performing an average of 34.86 ± 11.53 squats, compared to 25.87 ± 6.67 in the placebo group. There was 22% significant increase in the number of completed squats in MEET Shilajeet group compared to the 5% reduction in the placebo group (p=0.003) (Table 7).

Within-group comparisons further highlighted the MEET Shilajeet group's progress. The MEET Shilajeet group showed a significant improvement in the 30-Second Sit to Stand Test, with a mean difference of -3.77 ($p < 0.001$), indicating enhanced lower extremity strength and endurance. Additionally, there were significant improvements in the Push-up Test (mean difference: -3.59, $p = 0.026$) and Squat Test (mean difference: -5.95, $p < 0.001$) within the MEET Shilajeet group, reflecting substantial gains in both upper and lower body strength and endurance over the course of the study (Table 8).

In contrast, the placebo group showed no significant improvements in these measures from baseline to the end of the study, indicating that the observed enhancements in the MEET Shilajeet group were likely due to the intervention. These results suggests that the MEET Shilajeet intervention had a positive impact on both upper and lower body strength and endurance, contributing to improved physical performance in these areas.

Table 7: Between-Groups Comparison of Lower Extremity Muscle, Upper Body and Lower Body Strength and Endurance Parameters at Different Assessment Points

Variable	Placebo (Mean ± SD)	MEET Shilajeet (Mean ± SD)	P value
Baseline (Visit 1)			
30 Second sit to stand Test	13.92±3.32	14.12 ± 4.40	0.573
Push up test	17.20 ±6.01	19.64 ± 10.70	0.808
Squat test	27.36 ± 6.75	28.76 ± 9.89	0.573
End of Study (Visit 2)			
30 Second sit to stand Test	14.35 ± 2.44	17.91 ± 5.73	0.074
Push up test	16.48 ±5.65	22.59 ± 12.02	0.002
Squat test	25.87 ± 6.67	34.86 ± 11.53	0.074
Percentage Difference			
30 Second sit to stand Test	4.70 ± 19.20	28.55 ± 22.34	0.003
Push up test	-4.29 ± 17.47	38.57 ± 77.33	0.001
Squat test	-5.06 ± 14.50	22.69 ± 23.01	0.003

Table 8: Within the Group Comparison of Lower Extremity Muscle, Upper Body and Lower Body Strength and Endurance Parameters from Baseline to End of the Study

Variable	Comparison	Mean diff.	SD Value	95% Confidence Interval	P value
Placebo					
30 Second sit to stand Test	Baseline Vs End of study	-0.26	2.61	-1.392 to 0.870	0.614
Push up test		1.13	3.90	-0.556 to 2.817	0.275
Squat test		1.61	4.41	-0.297 to 3.515	0.090
MEET Shilajeet					
30 Second sit to stand Test	Baseline Vs End of study	-3.77	2.88	-5.048 to -2.497	0.0
Push up test		-3.59	6.80	-6.606 to -0.576	0.026
Squat test		-5.95	4.97	-8.159 to -3.750	0.0

Assessment of Serum Levels of Testosterone and Cortisol

The testosterone levels showed a difference of 10.60% between the MEET Shilajeet and Placebo group indicating that MEET Shilajeet group exhibited a noticeable improvement in the testosterone levels compared to the placebo proving its beneficial effect. At baseline, the mean testosterone levels were comparable between the placebo group (4.95 ± 1.64 ng/mL) and the MEET Shilajeet group (4.69 ± 1.81 ng/mL), with a non-significant p-value of 0.648. By the end of the study, there was an increase in mean testosterone levels in the MEET Shilajeet group (5.06 ± 1.42 ng/mL) whereas the placebo group exhibited a slight decrease in the value (4.93 ± 1.73 ng/mL). The clinical significance measured using the effect size was calculated comparing the mean serum testosterone levels in the two groups at visit 2 and was found to be 0.1 indicating a very small effect size suggesting a small but noticeable difference was found between the MEET Shilajeet and placebo.

Similarly, cortisol levels were also compared between the groups at baseline (8.92 ± 2.98 µg/dL for placebo and 8.83 ± 2.70 µg/dL for MEET Shilajeet, p = 0.892). While cortisol levels decreased slightly in both groups, the reduction in the MEET Shilajeet group (from 8.83 ± 2.70 µg/dL to 7.53 ± 3.86 µg/dL) was more pronounced than in the placebo group (from 8.92 ± 2.98 µg/dL to 8.74 ± 4.56 µg/dL); however, this change also did not reach statistical significance (p = 0.467). Within-group comparisons showed a mild increase in the testosterone level from baseline to end of study (mean difference: -0.36, p=0.445) in the MEET Shilajeet group and a mild decrease in the cortisol levels from baseline to the end of the study (mean difference: 1.44, p=0.080) (Table 10).

Table 9: Between-Groups Comparison of Mean Change in Serum Levels of Testosterone and Cortisol at Different Assessment Points

Variable	Placebo (Mean ± SD)	MEET Shilajeet (Mean ± SD)	P value
Baseline (Visit 1)			
Testosterone (ng/mL)	4.95 ± 1.64	4.69 ± 1.81	0.648
Cortisol (ug/dL)	8.92 ± 2.98	8.83 ± 2.70	0.892
End of Study (Visit 2)			
Testosterone (ng/mL)	4.93 ± 1.73	5.06 ± 1.42	0.555
Cortisol (ug/dL)	8.74 ± 4.56	7.53 ± 3.86	0.467
Percentage Difference			
Testosterone (ng/mL)	-2.13 ± 44.49	8.47 ± 70.20	0.838
Cortisol (ug/dL)	-5.10 ± 50.45	-22.96 ± 46.95	0.204

Table 10: Within the Group Comparison of Serum Levels of Testosterone and Cortisol from Baseline to End of the Study

Variable	Comparison	Mean diff.	SD Value	95% Confidence Interval	P value
Placebo					
Testosterone (ng/mL)	Baseline Vs End of study	-0.10	1.61	-0.80 to 0.59	0.922
Cortisol (ug/dL)		-0.18	3.75	-1.80 to 1.44	0.795
MEET Shilajeet					
Testosterone (ng/mL)	Baseline Vs End of study	-0.36	1.48	-1.02 to 0.29	0.445
Cortisol (ug/dL)		1.44	3.84	-0.26 to 3.14	0.080

Assessment of SF-36 Score

The SF-36 (Short Form-36) health survey provides a comprehensive evaluation of eight health domains: Physical Functioning, Role Limitations due to Physical Health, Role Limitations due to Emotional Problems, Vitality (Energy/Fatigue), Emotional Well-being, Social Functioning, Pain, and General Health. The study compared these domains between MEET Shilajeet treatment group and a placebo group, as well as within each group over the study period.

In the between-groups comparison, significant differences were observed between the MEET Shilajeet and placebo groups at the end of the study. Notably, the MEET Shilajeet group showed marked improvements in several domains. The Vitality (Energy/Fatigue) scores in the MEET Shilajeet group increased substantially, with a mean difference of 19.42 compared to the placebo group ($p < 0.001$). Similarly, Emotional well-being saw a significant enhancement in the MEET Shilajeet group, with a mean difference of 17.23 ($p < 0.001$). Social functioning also improved significantly in the MEET Shilajeet group, with a mean difference of 27.03 ($p < 0.001$). Additionally, the MEET Shilajeet group experienced a significant reduction in Pain scores, with a mean difference of 11.35 ($p = 0.003$). General Health scores in the MEET Shilajeet group also improved significantly, with a mean difference of 10.54 ($p = 0.001$). These results highlight the efficacy of the MEET Shilajeet treatment in enhancing the overall quality of life compared to the placebo (Table 11).

The within-group analysis further emphasized the differences in outcomes for both groups from baseline to the end of the study. In the placebo group, there was a significant decline in several domains. Vitality (Energy/Fatigue) decreased notably, with a mean decline of 8.91 (-11.0%, $p = 0.001$). Emotional Well-being, Social Functioning and General Health scores also saw significant reductions, with mean declines of 8.0 (-9.62%, $p = 0.002$), 11.96 (-14.66%, $p = 0.031$), and 5.07 (-5.56%, $p = 0.138$), respectively. Additionally, the Pain scores in the placebo group increased significantly, with a mean difference of 11.30 (11.47%, $p = 0.002$), indicating worsening conditions (Table 12).

Conversely, the MEET Shilajeet treatment group exhibited significant improvements across most domains. The Vitality (Energy/Fatigue) scores increased by 9.77 (11.94%, $p < 0.001$), while Emotional Well-being saw a significant rise with a mean increase of 9.46 (11.40%, $p < 0.001$). Social Functioning improved significantly in the MEET Shilajeet group, with a mean increase of 13.64 (16.44%, $p< 0.001$). General Health also improved in the MEET Shilajeet group, with a mean increase of 6.43 (7.14%, $p = 0.002$). These improvements in the MEET Shilajeet group contrast sharply with the declines observed in the placebo group, highlighting the effectiveness of the treatment.

The results revealed that the MEET Shilajeet treatment group experienced significant improvements in various aspects of health and well-being, particularly in Vitality, Emotional Well-being, Social Functioning, and General Health. In contrast, the placebo group showed decline in these domains, reinforcing the benefits of the MEET Shilajeet treatment in enhancing quality of life.

Table 11: Between-Groups Comparison of Mean Change in Eight Health Domains at Baseline and at End of the Study

Health Domain	Score (mean ± SD)		Mean diff.	95% CI	P value
	Placebo Gr. (n = 23)	MEET Shilajeet (n = 22)			
Baseline (V1)					
Physical functioning	99.78 ± 1.04	100.0 ± 0.0	-	-	-
Role limitations due to physical health	97.83 ± 10.43	100.0 ± 0.0	-	-	-
Role limitations due to emotional problems	100.0 ± 0.0	100.0 ± 0.0	-	-	-
Vitality (energy/fatigue)	81.09 ± 2.11	81.82 ± 2.91	-0.73 ± 0.75	-2.253 to 0.791	0.338
Emotional well-being	83.13 ± 4.51	82.91 ± 4.48	0.22 ± 1.34	-2.483 to 2.926	0.870
Social functioning	81.52 ± 13.52	82.95 ± 11.92	-1.43 ± 3.81	-9.113 to 6.248	0.708
Pain	98.59 ± 6.78	100.0 ± 0.0	-	-	-
General health	91.12 ± 7.36	90.15 ± 7.107	0.97 ± 2.16	-3.382 to 5.327	0.655
End of Study (V2)					
Physical functioning	99.78 ± 1.04	100.0 ± 0.0	-	-	-

Role limitations due to physical health	97.83 ± 10.43	100.0 ± 0.0	-	-	-
Role limitations due to emotional problems	100.0 ± 0.0	100.0 ± 0.0	-	-	-
Vitality (energy/fatigue)	72.17 ± 9.98	91.59 ± 6.43	19.42 ± 2.52	-24.49 to -14.34	< 0.001
Emotional well-being	75.13 ± 8.44	92.36 ± 6.86	17.23 ± 2.30	-21.87 to -12.59	< 0.001
Social functioning	69.57 ± 18.40	96.59 ± 8.78	27.03 ± 4.33	-35.76 to -18.29	< 0.001
Pain	87.28 ± 16.22	98.64 ± 3.51	11.35 ± 3.54	-18.49 to -4.219	0.003
General health	86.05 ± 12.48	96.59 ± 6.52	-10.54 ± 2.99	-16.57 to -4.510	0.001
Note: The asterisks (*) indicate statistically significant results. Statistical comparison was performed by unpaired t-test: Placebo vs MEET Shilajeet					

Table 12: Within the Group Mean Difference in SF-36 Scores from Screening to End of the Study

Health Domain	Score (mean ± SD)		Mean diff.	95% CI	P value
	Baseline	End of Study			
Placebo (n = 23)					
Physical functioning	99.78 ± 1.04	99.78 ± 1.04	-	-	-
Role limitations due to physical health	97.83 ± 10.43	97.83 ± 10.43	-	-	-
Role limitations due to emotional problems	100.0 ± 0.0	100.0 ± 0.0	-	-	-
Vitality (energy/fatigue)	81.09 ± 2.11	72.17 ± 9.98	-8.91	4.124 to 13.70	0.001
Emotional well-being	83.13 ± 4.51	75.13 ± 8.44	-8.0	3.423 to 12.58	0.002
Social functioning	81.52 ± 13.52	69.57 ± 18.40	-11.96	1.209 to 22.70	0.031
Pain	98.59 ± 6.78	87.28 ± 16.22	-11.30	4.460 to 18.15	0.002
General health	91.12 ± 7.36	86.05 ± 12.48	-5.074	-1.754 to 11.90	0.138
MEET Shilajeet (n = 22)					
Physical functioning	100.0 ± 0.0	100.0 ± 0.0	-	-	-
Role limitations due to physical health	100.0 ± 0.0	100.0 ± 0.0	-	-	-
Role limitations due to emotional problems	100.0 ± 0.0	100.0 ± 0.0	-	-	-
Vitality (energy/fatigue)	81.82 ± 2.91	91.59 ± 6.43	9.77	-13.16 to -6.387	< 0.0001***
Emotional well-being	82.91 ± 4.48	92.36 ± 6.86	9.46	-13.15 to -5.760	< 0.0001***
Social functioning	82.95 ± 11.92	96.59 ± 8.781	13.64	-20.24 to -7.031	0.0003***
Pain	100.0 ± 0.0	98.64 ± 3.51	-1.36	-0.1940 to 2.921	0.0829
General health	90.15 ± 7.11	96.59 ± 6.52	6.437	-10.12 to -2.751	0.0016**
Note: Statistical analysis was performed by paired t-test. Baseline vs End of Study					

Analysis of Safety

Haematology

The haematological analysis provided insights into the effects of MEET Shilajeet capsules on key blood parameters, comparing the Placebo and MEET Shilajeet groups at different assessment points and evaluating changes within each group from baseline to the end of the study.

At baseline (Visit 1), the haematological parameters between the Placebo and MEET Shilajeet groups were closely matched, showing no statistically significant differences. For instance, haemoglobin (Hb %) levels were 13.75 ± 1.45 in the Placebo group and 14.09 ± 1.79 in the MEET Shilajeet group, with a p-value of 0.509, indicating no significant difference. Similarly, red blood cell (RBC) counts were identical in both groups at 5.24 ± 0.65 million/cu mm (p = 0.915). White blood cell (WBC) counts showed a slight variation, with 6399.20 ± 1726.90 cells/cu mm in the Placebo group and 6211.60 ± 1603.05 cells/cu mm in the MEET Shilajeet group, but

this difference was not statistically significant (p = 0.415). Platelet counts and lymphocyte percentages were also comparable between the two groups, with no significant differences observed (p = 0.930 and p = 0.318, respectively). By the end of the study (Visit 2), the comparison between the groups continued to show no statistically significant differences in any of the haematological parameters. Haemoglobin levels were nearly identical, with 13.47 ± 1.22 in the Placebo group and 13.46 ± 1.76 in the MEET Shilajeet group (p = 0.658). RBC counts remained similar between the groups, with 5.05 ± 0.66 million/cu mm in the Placebo group and 5.10 ± 0.71 million/cu mm in the MEET Shilajeet group (p = 0.683). WBC counts showed a small reduction in both groups, with 6165.51 ± 2367.32 cells/cumm in the Placebo group and 5709.02 ± 1981.36 cells/cumm in the MEET Shilajeet group (p = 0.447). Platelet counts slightly increased in both groups, with no significant difference (p = 1.000), and lymphocyte percentages remained statistically comparable (p = 0.208) (Table 13).

The analysis of changes within each group from baseline to the end of the study revealed that the Placebo group experienced no significant changes in any of the haematological parameters. For example, the difference in haemoglobin levels from baseline to the end of the study was only 0.14, with a p-value of 0.626, indicating no significant change. Similarly, the RBC count showed a minimal mean difference of 0.12 (p = 0.153), and the changes in WBC and platelet counts were also not significant. In the MEET Shilajeet group, most haematological parameters remained stable from baseline to the end of the study. The haemoglobin level showed a slight decrease with a mean difference of 0.34, which approached statistical significance (p = 0.051) (Table 14). However, other parameters, including RBC, WBC, platelet counts, and lymphocyte percentages, did not show significant changes, with p-values well above the threshold for significance.

Overall, the haematological analysis suggests that treatment with MEET Shilajeet Capsules did not significantly impact the blood parameters of participants compared to the placebo, indicating a stable haematological profile and suggesting that the capsules did not adversely affect these key health indicators over the course of the study.

Table 13: Between-Groups Comparison of Hematological Parameters at Different Assessment Points

Variable	Placebo (Mean ± SD)	MEET Shilajeet (Mean ± SD)	P value
Baseline (Visit 1)			
Haemoglobin (Hb %)	13.75 ± 1.45	14.09 ± 1.79	0.509
Red Blood Cells (RBC) (Million/cumm)	5.24 ± 0.65	5.24 ± 0.65	0.915
White Blood Cells (Cells/cumm)	6399.20 ± 1726.90	6211.60 ± 1603.05	0.415
Platelet count (lakhs/cumm)	274200.0 ± 81572.05	275800.0 ± 55416.60	0.93
Lymphocyte (%)	32.05 ± 7.10	34.17 ± 6.37	0.318
End of Study (Visit 2)			
Haemoglobin (Hb %)	13.47 ± 1.22	13.46 ± 1.76	0.658
Red Blood Cells (RBC) (Million/cumm)	5.05 ± 0.66	5.10 ± 0.71	0.683
White Blood Cells (Cells/cumm)	6165.51 ± 2367.32	5709.02 ± 1981.36	0.447
Platelet count (lakhs/cumm)	290565.22 ± 68590.24	294940.91 ± 71985.65	1.0
Lymphocyte (%)	34.17 ± 6.37	31.86 ± 7.28	0.208

Table 14: Within the Group Comparison of Hematological Parameters from Baseline to End of the Study

Variable	Comparison	Mean diff.	SD Value	95% Confidence Interval	P value
Placebo					
Haemoglobin (Hb %)	Baseline Vs End of study	0.14	0.92	-0.26 to 0.54	0.626
Red Blood Cells (RBC) (Million/cumm)		0.12	0.43	-0.06 to 0.31	0.153
White Blood Cells (Cells/cumm)		166.23	1392.56	-435.96 to 768.42	0.338
Platelet count (lakhs/cumm)		21608.70	71608.62	-52574.59 to 9357.19	0.136
Lymphocyte (%)		0.49	7.87	-2.92 to 3.89	0.976
MEET Shilajeet					
Haemoglobin (Hb %)	Baseline Vs	0.34	0.70	0.03 to 0.65	0.051
Red Blood Cells (RBC)		0.13	0.32	-0.01 to 0.28	0.118

(Million/cumm)	End of study				
White Blood Cells (Cells/cumm)		335.53	1618.37	-382.02 to 1053.07	0.445
Platelet count (lakhs/cumm)		-18940.91	66513.23	-48431.22 to 10549.41	0.276
Lymphocyte (%)		-0.43	6.82	-3.45 to 2.59	0.922

ECG, Serum Biochemistry, Kidney and Liver Function Tests

There were no significant changes in ECG parameters observed between the MEET Shilajeet treatment group and the placebo group throughout the study. Similarly, within-group analyses showed no notable differences in ECG results from baseline to the end of the study in either group. The analysis of serum biochemistry, kidney, and liver function tests provided insights into the physiological effects of the treatment with MEET Shilajeet capsules compared to the placebo group. At baseline (Visit 1), there were no significant differences between the two groups across the measured parameters, including albumin, total protein, alkaline phosphate (ALP), alanine transaminase (ALT), aspartate transaminase (AST), bilirubin, serum creatinine, serum uric acid, blood urea, serum calcium, serum sodium, and serum potassium, indicating that both groups were comparable at the baseline.

By the end of the study (Visit 2), the results continued to show no significant differences between the placebo and MEET Shilajeet groups for most parameters, with a few notable observations. In the MEET Shilajeet group, a statistically significant reduction was observed in AST levels ($p = 0.022$) from baseline to the end of the study. However, other liver function tests, such as ALT and bilirubin, did not show significant changes, indicating that this reduction in AST may not reflect a clinically relevant effect. Similarly, in the placebo group, significant changes were noted in serum sodium ($p = 0.003$) and serum potassium ($p = 0.005$) levels from baseline to the end of the study, though these changes remained within the normal physiological range (Tables 15 and 16).

Overall, the serum biochemistry, kidney, and liver function parameters remained stable throughout the study, suggesting that MEET Shilajeet capsules did not negatively impact these critical physiological functions. The observed variations in certain parameters were minor and within the expected range for normal biological variability, further supporting the safety profile of the treatment.

Table 15: Between-Groups Comparison of Serum Biochemistry, Kidney and Liver Function Parameters at Different Assessment Points

Variable	Placebo (Mean ± SD)	MEET Shilajeet (Mean ± SD)	P value
Baseline (Visit 1)			
Albumin (g/dL)	4.49 ± 0.23	4.52 ± 0.19	0.954
Total protein (g/dL)	7.11 ± 0.39	7.19 ± 0.44	0.443
Alkaline phosphate (ALP) (U/L)	90.0 ± 25.32	79.77 ± 21.27	0.184
Alanine transaminase (ALT) (U/L)	20.54 ± 12.81	24.70 ± 16.93	0.594
Aspartate transaminase (AST) (U/L)	19.59 ± 10.42	20.24 ± 8.16	0.332
Bilirubin (mg/dL)	0.57 ± 0.33	0.57 ± 0.28	0.764
Serum creatinine (mg/dL)	1.07 ± 1.18	0.91 ± 0.22	0.42
Serum uric acid (mg/dL)	5.99 ± 1.26	5.60 ± 1.27	0.336
Blood urea (mg/dL)	19.04 ± 4.80	18.63 ± 3.82	0.938
Serum calcium (mg/dL)	9.30 ± 0.44	9.31 ± 0.53	0.668
Serum sodium (mg/dL)	141.16 ± 3.02	141.36 ± 2.68	0.632
Serum potassium (mg/dL)	4.11 ± 0.37	4.13 ± 0.25	0.938
End of Study (Visit 2)			
Albumin (g/dL)	4.37 ± 0.26	4.37 ± 0.22	0.794
Total protein (g/dL)	7.19 ± 0.43	7.25 ± 0.47	0.503
Alkaline phosphate (ALP) (U/L)	95.64 ± 30.76	82.72 ± 16.23	0.216
Alanine transaminase (ALT) (U/L)	19.84 ± 7.40	25.99 ± 21.22	0.376
Aspartate transaminase (AST) (U/L)	20.28 ± 8.81	24.84 ± 12.26	0.051
Bilirubin (mg/dL)	0.51 ± 0.20	0.52 ± 0.27	0.699
Serum creatinine (mg/dL)	0.85 ± 0.15	0.90 ± 0.13	0.26
Serum uric acid (mg/dL)	5.68 ± 1.07	5.45 ± 1.35	0.407
Blood urea (mg/dL)	18.67 ± 4.16	20.15 ± 5.12	0.601

Serum calcium (mg/dL)	9.21 ± 0.30	9.28 ± 0.52	0.74
Serum sodium (mg/dL)	138.48 ± 2.35	138.59 ± 2.20	0.972
Serum potassium (mg/dL)	4.40 ± 0.39	4.49 ± 0.46	0.485

Table 16: Within the Group Comparison of Serum Biochemistry, Kidney and Liver Function Parameters from Baseline to End of the Study

Variable	Comparison	Mean diff.	SD Value	95% Confidence Interval	P value
Placebo					
Albumin (g/dL)	Baseline Vs End of study	0.11	0.23	0.01 to 0.20	0.061
Total protein (g/dL)		-0.10	0.36	-0.25 to 0.06	0.101
Alkaline phosphate (ALP) (U/L)		-6.06	12.24	-11.35 to -0.76	0.013
Alanine transaminase (ALT) (U/L)		0.87	8.38	-2.75 to 4.49	0.951
Aspartate transaminase (AST) (U/L)		-0.58	9.64	-4.75 to 3.59	0.218
Bilirubin (mg/dL)		0.02	0.21	-0.07 to 0.11	0.939
Serum creatinine (mg/dL)		0.25	1.26	-0.30 to 0.80	0.531
Serum uric acid (mg/dL)		0.33	1.01	-0.11 to 0.76	0.097
Blood urea (mg/dL)		0.51	3.09	-0.83 to 1.84	0.394
Serum calcium (mg/dL)		0.08	0.46	-0.12 to 0.28	0.404
Serum sodium (mg/dL)		2.83	4.42	0.92 to 4.74	0.003**
Serum potassium (mg/dL)		-0.30	0.45	-0.50 to -0.11	0.005**
MEET Shilajeet					
Albumin (g/dL)	Baseline Vs End of study	0.13	0.18	0.05 to 0.21	0.004**
Total protein (g/dL)		-0.08	0.39	-0.25 to 0.09	0.039*
Alkaline phosphate (ALP) (U/L)		-2.50	10.69	-7.23 to 2.24	0.223
Alanine transaminase (ALT) (U/L)		0.31	17.08	-7.26 to 7.89	0.770
Aspartate transaminase (AST) (U/L)		-3.87	9.91	-8.26 to 0.53	0.022*
Bilirubin (mg/dL)		0.02	0.17	-0.06 to 0.10	0.685
Serum creatinine (mg/dL)		-0.01	0.09	-0.05 to 0.03	0.696
Serum uric acid (mg/dL)		0.30	0.88	-0.10 to 0.69	0.095
Blood urea (mg/dL)		-1.90	4.58	-3.93 to 0.13	0.108
Serum calcium (mg/dL)		0.01	0.31	-0.13 to 0.15	0.851
Serum sodium (mg/dL)		2.45	3.08	1.09 to 3.82	0.004**
Serum potassium (mg/dL)		-0.35	0.41	-0.53 to -0.17	0.001***

Individual Patient Changes

Throughout the study, detailed laboratory evaluations were performed to assess individual changes in various parameters in response to MEET Shilajeet treatment. Analysis of these evaluations revealed that all patients remained within the normal ranges for haematological parameters, serum biochemistry, kidney and kidney function markers. No deviations outside of the established normal ranges were observed, indicating that MEET Shilajeet treatment did not adversely affect these laboratory measures in any individual participant.

Individual Clinically Significant Abnormalities

During the study period, there were no instances of clinically significant abnormalities detected among the participants. This finding emphasizes the favourable safety profile associated with MEET Shilajeet capsule, indicating that the study population did not experience any notable deviations from normal health parameters.

Physical Examination

Throughout the study, the physical examination outcomes were consistently reassuring, with no abnormalities detected among any of the study participants. This underscores the overall good health and well-being of the subjects, indicating the absence of any evident physical anomalies or concerns associated with the investigational products. The lack of abnormal physical examination findings further reinforces the positive safety profile observed with MEET Shilajeet capsules in this study, bolstering its suitability for clinical application.

Vital Signs

The analysis of vital signs throughout the study period revealed that both the placebo and MEET Shilajeet groups exhibited stable physiological parameters, with minor fluctuations that did not indicate significant clinical concerns. At baseline (Visit 1), there were no significant differences between the two groups in temperature, pulse rate, respiratory rate, and systolic blood pressure. However, diastolic blood pressure was notably lower in the MEET Shilajeet group compared to the placebo group ($p = 0.041$).

By the end of the study (Visit 2), the only statistically significant difference observed between the groups was in body temperature, where the MEET Shilajeet group had a slightly higher temperature compared to the placebo group ($p = 0.022$) (Table 17). The pulse rate, respiratory rate, and blood pressure measurements did not show significant differences between the groups at the end of the study, indicating that the intervention did not significantly affect these vital parameters.

Within-group comparisons from baseline to the end of the study revealed a significant decrease in systolic blood pressure in the placebo group ($p = 0.015$), suggesting a potential placebo effect or natural variation over time. Other vital sign parameters, including temperature, pulse rate, respiratory rate, and diastolic blood pressure, remained stable within both groups, with no significant changes observed (Table 18).

Overall, the data suggest that the treatment with MEET Shilajeet capsules was well-tolerated, with no adverse effects on vital signs, and any observed differences were minimal and within normal physiological ranges. The stability of these parameters further supports the safety profile of the intervention.

Table 17: Between-Groups Comparison of Mean Change in Vital Signs at Different Assessment Points

Variable	Placebo (Mean ± SD)	MEET Shilajeet (Mean ± SD)	P value
Baseline (Visit 1)			
Temperature (ºC)	37.02 ± 0.40	37.05 ± 0.27	0.474
Pulse rate (bpm)	80.52 ± 10.72	81.27 ± 9.60	0.733
Respiratory rate (bpm)	16.32 ± 2.78	15.80 ± 2.08	0.618
Systolic blood pressure (mmHg)	127.20 ± 17.07	119.08 ± 13.93	0.076
Diastolic blood pressure (mmHg)	80.04 ± 11.99	73.52 ± 8.84	0.041
End of Study (Visit 2)			
Temperature (ºC)	36.99 ± 0.25	37.16 ± 0.19	0.022
Pulse rate (bpm)	80.52 ± 10.72	81.27 ± 9.60	0.733
Respiratory rate (bpm)	15.96 ± 2.12	16.0 ± 2.02	0.927
Systolic blood pressure (mmHg)	118.83 ± 11.83	119.77 ± 9.94	0.633
Diastolic blood pressure (mmHg)	77.17 ± 10.92	75.45 ± 8.58	0.716

Table 18: Within the Group Comparison of Vital Signs from Baseline to End of the Study

Variable	Comparison	Mean diff.	SD Value	95% Confidence Interval	P value
Placebo					
Temperature (ºC)	Baseline Vs End of study	0.05	0.45	-0.14 to 0.25	0.302
Pulse rate (bpm)		3.30	13.40	-2.49 to 9.10	0.188
Respiratory rate (bpm)		0.39	2.69	-0.77 to 1.56	0.416
Systolic blood pressure (mmHg)		7.57	17.00	0.21 to 14.92	0.015
Diastolic blood pressure (mmHg)		2.57	13.19	-3.14 to 8.27	0.284
MEET Shilajeet					
Temperature (ºC)	Baseline Vs End of study	-0.11	0.38	-0.28 to 0.06	0.129
Pulse rate (bpm)		0.91	11.07	-4.00 to 5.82	0.754
Respiratory rate (bpm)		0.14	2.21	-0.84 to 1.12	0.837
Systolic blood pressure (mmHg)		-0.14	12.09	-5.50 to 5.22	0.945
Diastolic blood pressure (mmHg)		-1.86	8.71	-5.72 to 2.00	0.613

Efficacy Conclusions

The efficacy conclusions of this study demonstrate that MEET Shilajeet capsules significantly enhance energy, strength, and endurance among participants. Analysis of the efficacy subset, which included participants adhering to the study protocol and meeting all inclusion criteria, revealed substantial improvements in key performance metrics. Notable enhancements were observed in aerobic capacity, as indicated by increased VO_2

max and VO_2 peak and longer distances walked during the 6-Minute Walk Test. Additionally, participants showed significant gains in lower extremity muscle strength and endurance, as measured by improvements in the 30-Second Sit-to-Stand Test, push-up test, and squat test. There was 10.60% difference in the testosterone level at the end of study between the MEET Shilajeet and placebo group. The impact of treatment was further validated by the positive shifts in performance outcomes and overall physical endurance. Additionally, the SF-36 assessment revealed that participants in the MEET Shilajeet treatment group experienced significant improvements in various aspects of health and well-being, particularly in Vitality (11.94%), Emotional Well-being (11.40%), Social Functioning (16.44%), and General Health (7.14%). These results underscore the efficacy of MEET Shilajeet Capsules in boosting physical performance and endurance, with minimal adverse effects reported.

Safety Conclusions

The safety assessment of this study, based on the analysis of serum biochemistry, kidney and liver function tests, and vital signs, indicates that the administration of MEET Shilajeet capsules was well-tolerated by participants. Across all measured parameters, including albumin, total protein, liver enzymes (ALP, ALT, AST), bilirubin, serum creatinine, serum uric acid, blood urea, serum electrolytes, and vital signs such as temperature, pulse rate, respiratory rate, and blood pressure, there were no clinically significant adverse changes observed in either the placebo or MEET Shilajeet groups. Minor fluctuations in some parameters, such as a slight increase in temperature in the MEET Shilajeet group and a decrease in systolic blood pressure in the placebo group, were noted, but these changes remained within normal physiological ranges and did not indicate any safety concerns. Overall, the findings demonstrate that the MEET Shilajeet capsules were safe and did not pose any significant risk to the participants' health over the course of the study.

ADVERSE EVENTS (AEs)

In the course of the study, there were five reported adverse events. In total, four subjects reported gastritis among which two subjects were febrile. One subjected reported to have dizziness. List of adverse events by patients is displayed in Table 19.

Table 19: Listing of Adverse Events by Patient

Sl.no	Adverse Event	Severity	Concomitant Medication
1	Gastritis	Mild	No
2	Dizziness and Febrile	Mild	No
3	Gastritis and Febrile	Mild	No
4	Gastritis and Febrile	Mild	No
5	Gastritis	Mild	No

DISCUSSION AND OVERALL CONCLUSIONS

This study evaluated the efficacy and safety of MEET Shilajeet Capsules, focusing on their impact on energy, strength, and endurance. The results indicated that the MEET Shilajeet treatment group experienced notable improvements across various physical performance measures and health-related quality of life metrics compared to the placebo group.

In terms of efficacy, the study demonstrated significant enhancements in muscle strength and endurance. Participants receiving MEET Shilajeet Capsules showed improvements in strength tests, including the 30-Second Sit-to-Stand Test, push-up test, and squat test, indicating increased lower and upper body strength. Aerobic capacity, as measured by the 6-Minute Walk Test, also improved in the MEET Shilajeet group, with significant increases in the total distance walked and improvements in VO_2 peak compared to the placebo group. The testosterone levels showed a difference of 10.60% between the MEET Shilajeet and Placebo group indicating that MEET Shilajeet group exhibited a noticeable improvement in the testosterone levels compared to the placebo proving its beneficial effect. These findings suggest that the MEET Shilajeet treatment effectively supports physical fitness and endurance.

The SF-36 assessment further reinforced these results, showing that the MEET Shilajeet treatment group experienced significant gains in Vitality, Emotional Well-being, Social Functioning, and General Health. In contrast, the placebo group exhibited declines in these domains, highlighting the MEET Shilajeet treatment's positive impact on overall quality of life. These improvements underscore the potential benefits of MEET Shilajeet Capsules in enhancing not only physical performance but also overall well-being.

Safety assessments revealed that the treatment was well-tolerated, with no significant adverse effects reported. The study was conducted as a single-center

trial, and while this design provided detailed insights into the efficacy of the treatment, future multicenter studies could further validate these findings and assess broader applicability.

Overall, the results suggest that MEET Shilajeet Capsules offer a promising intervention for enhancing physical performance and quality of life. The observed benefits in strength, endurance, and well-being, combined with a favorable safety profile, support their potential use in improving physical fitness and overall health. Further research is warranted to confirm these findings and explore the broader implications of this treatment.

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