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Original Article

A Clinical Evaluation of the Safety and Efficacy of Melostacio Gold™ (Pistachio Extract) to Manage Stress and Improve Sleep Quality: A Randomized, Double-Blind, Parallel, Placebo-Controlled Trial in Adults

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ABSTRACT

Background and Objectives: Modern lifestyle nowadays leads adults towards chronic stress and poor sleep quality which impacts the health and well-being of an individual. While pharmacological interventions exist, their side effects have prompted interest in plant-based alternatives. Pistachio (*Pistacia vera*), known for its antioxidant and neuroprotective properties help in managing stress and improving sleep quality. This randomized, double-Blind, parallel, and placebo-Controlled trial was aimed at evaluating safety and efficacy of Melostacio Gold™ (Pistachio extract) to manage stress and improve sleep quality in adults. **Materials and Methods:** 40 subjects were selected and were randomly divided into two equal groups. The study group participants received Melostacio Gold™ (100 mg) orally in the form of capsules for 28 days and various parameters such as sleep quality, levels of serum markers, and quality of life were measured at four key time points: Screening, Baseline, Day 14, and Day 28. **Results:** The results revealed that AIS scores in the placebo group remained relatively stable while study group showed a significant reduction over time, from 16.95±1.96 at Visit 2 to 11.80±1.54 at Visit 4 (p<0.0001). The level of serum markers was also found to be decreasing from 35.81±4.54 at Visit 2 to 29.01±4.57 at Visit 4 (p<0.0001), indicating a marked decrease in stress levels. **Conclusion:** In conclusion, Melostacio Gold™ (Pistachio extract) was found to be safe and effective in improving sleep quality, reducing stress, and enhancing overall well-being.

Keywords: Pistachio, Stress, Sleep, Quality of Life, Natural supplement, Health.

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INTRODUCTION

Sleep is a critical process directly associated with overall health and well-being. It helps in restoring energy levels in the human body and also helps in normal physical and mental functioning. It is a basic need for human life, alongside food, water, and air.[1] Disturbance in sleep or disruption of sleep quality is associated with various disorders such as insomnia, obstructive sleep apnoea, hypersomnia, and parasomnias, significantly impacting quality of life and overall health and well-being.[2] Not getting enough sleep or struggling with sleep disorders is very common, and these issues can seriously affect people's health and even increase the risk of early death. Many factors including physical, psychological, and environmental factors can influence sleep quantity and quality, and causes sleep disturbance which disturbs the overall health and well-being.

In this study, the impact of sleep disturbance on Quality of Life (QoL) was measured by conducting a cross-sectional study on 225,541 adults. To assess the sleep quality; Pittsburgh Sleep Quality Index was used and the results findings concluded that poor sleep quality is directly associated with impaired QoL.[3]

Pistacia vera; a member of the Pistacia genus and Anacardiaceae family, is the only member species of this genus whose edible nuts are large enough to be commercially acceptable. It is native to Western Asia and Asia Minor, spanning regions from Syria to the Caucasus and Afghanistan.[4] Pistachios consist of protein, unsaturated fatty acids, dietary fibres, minerals such as magnesium, potassium, phosphorous, chromium, copper, manganese, iron, zinc and selenium, Vitamin E, Vitamin K, Vitamin B6 and several phytoconstituents such as phytosterols, lutein (xanthophyll carotenoid), g-tocopherol, and polyphenols.[5,6] Melatonin is responsible for regulating sleep-wake cycle, in this

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study various plant-based extracts were assessed for their activity in sleep promotions, among 25 plant-based extracts, *P. vera* extract was found to possess the most potent effect in melatonin receptor expressing cells, this effect was exhibited by *P. vera* extract because of high content of endogenous melatonin present in it.[7] Pistachios are rich in phenolic compounds which stops the formation of Reactive Oxygen Species (ROS) and provide protective effects.[8]

Pistachios are also rich in tryptophan which is a precursor in the formation of melatonin, magnesium which helps in relaxation and improves sleep quality, and vitamin B acts as a cofactor in producing neurotransmitters that influence sleep patterns.[9] The findings of a 24-week randomized controlled trial suggested that pistachio supplementation can lead to noticeable improvements in key markers of inflammation and oxidative stress-such as hs-CRP, TNF-α, and TBARS-in people with metabolic syndrome. These positive changes suggest that pistachio consumption may play a helpful role in reducing the body's stress levels and supporting overall health.[10] *Pistacia vera* contains a variety of phenolic compounds, including tannins, which contribute to its antioxidant, anti-inflammatory, and neuroprotective properties. These compounds are believed to support overall health and may play a role in improving sleep quality.[11]

This randomized, double-Blind, parallel, and placebo-Controlled trial was aimed at evaluating safety and efficacy of Melostacio Gold™ (Pistachio extract) and to compare the result with placebo group (cyclodextrin) in managing stress and improving sleep quality in adults.

MATERIALS AND METHODS

Materials

The treatment regimen in this study involved the daily administration of Melostacio Gold™ (100 mg) orally in the form of capsules. Each capsule contained 100 mg of *P. vera* extract, and participants were instructed to take one capsule per day, preferably after dinner, ensuring a consistent daily dose of 100 mg.

Methods

Ethical approval

This study was done in compliance with ethical and regulatory guidelines. The study protocol no. BH/MG/24 (Version 1.1, dated December 11, 2024) and formal approval on 02 Jan 2025 was done by Institutional Ethics Committee (IEC). The current study has been officially registered with the Clinical Trials Registry-India (CTRI) under the registration number CTRI/2025/02/079862, dated 03 February 2025. The study was initiated on 14 Feb 2025.

Subject selection

Participants for the study were selected according to ethical guidelines and informed written consent was obtained from all subjects prior to the start of study. A detailed screening procedure was carried out so that only eligible subjects can participate in the study, and for this purpose, inclusion and exclusion criteria were established. The participants who passed the included criteria were included in the study while remaining who could not pass the criteria were excluded from the study.

Inclusion and exclusion criteria

Adults aged 18–54 years who were willing and able to provide written informed consent, with known hypertension or other cardiovascular diseases, free from psychiatric conditions, except mild stress and with no history of liver disease, kidney disease, epilepsy, or other relevant medical conditions were included in the study.

Subjects unwilling or unable to comply with study protocol or had participated in another clinical trial or received investigational product within past 90 days or anyone who had done withdrawal of written informed consent at any point or currently taking any medications, except oral contraceptives or pregnant females and patients with history of acute narrow-angle glaucoma, prostate hypertrophy, or cardiovascular, endocrine, renal, or other chronic diseases were excluded from the study.

Figure 1 shows the consort flow diagram of the study.

Efficacy Outcomes

Assessment of weight and BMI

Assessment of weight and BMI is an important parameter for the study, to monitor changes in the composition of the body and was conducted at each scheduled visit. Regular monitoring provided valuable insights into potential metabolic changes, weight fluctuations, or other physiological effects related to the intervention.

Assessment of Sleep Quality

The Athens Insomnia Scale (AIS) is a reliable tool to evaluate the severity of insomnia; it was used to assess the sleep quality of participants in this study. It comprises a total of eight items that assess various aspects of sleep such as difficulty in sleep induction, awakening at night etc. Each question was rated on a scale from 0 to 3, where higher scores reflected more severe sleep problems. Participants filled out the AIS at the beginning of the study, during follow-up, and at the final visit, to monitor how their sleep quality changed over time.

Assessment of serum biomarkers

The assessment of serum biomarkers, specifically cortisol and hs-CRP, at baseline and end of the study was conducted to

evaluate the physiological impact of the intervention on stress and inflammation. Elevated cortisol levels are often associated with chronic stress, similarly, hs-CRP is a sensitive marker of systemic inflammation and was often elevated in response to stress and poor sleep quality.

Subjective Global Assessment (SGA) and Physician Global Assessment (PGA)

SGA and PGA were used together to get a well-rounded view of each participant's overall health and how they responded to the treatment. The SGA let participants share their own perspective, rating things like their sleep, stress, energy levels, and general well-being. In contrast, the PGA was completed by a doctor, who assessed the participant's health and treatment response using medical exams, vital signs, lab tests, and other clinical information.

Assessment of QOL – SF 36

The Short Form-36 (SF-36) was a comprehensive, standardized questionnaire that measured eight domains of health: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health perceptions. These domains provided a detailed understanding of how the intervention affected both physical and mental aspects of the participants' lives. In this study, the SF-36 was administered at baseline and at the end of the study to track changes in QOL over time.

Safety Outcomes

Physical Examinations

Physical examination included examination of head, neck, eyes, ears, nose, throat, chest, heart, lungs, abdomen, skin, extremities, and musculoskeletal system and was done at all visits.

Vital Signs

Vital signs such as systolic and diastolic blood pressure, pulse rate, respiratory rate, and body temperature were measured at each visit (baseline visit to final visit).

Laboratory Safety Parameters

Haematological evaluations, including CBC, were conducted to monitor parameters such as haemoglobin levels, white blood cell count, and platelet count, providing insights into overall blood health and identifying any potential haematological abnormalities. Biological assessments included an ECG to monitor cardiac health, LFT and RFT were performed to assess the impact of the intervention on hepatic and renal health. Additionally, the RBS test helped monitor glucose levels. These parameters were evaluated at baseline and again at the end of the treatment period, allowing for a comparative analysis to ensure that the intervention was safe and well-tolerated throughout the study.

Adverse Events assessment

Adverse events were accurately measured to assess the safety of Melostacio Gold™ supplementation and to ensure patients safety throughout the study period.

RESULTS

Demographic and Baseline Characteristics

The mean age of participants in the placebo group was 43.75±5.06 years, ranging from 36 to 51 years, while the study group had a slightly higher mean age of 45.9±6.09 years, with a range of 36 to 53 years. In terms of gender distribution, the placebo group comprised 15 males (75%) and 5 females (25%), whereas the study group had 12 males (60%) and 8 females (40%), indicating a balanced representation of both genders. The height of participants in the placebo group ranged from 152.90 cm to 179.50 cm, with a mean height of 167.27±8.31 cm. Similarly, the study group exhibited a comparable height range of 152.80 cm to 177.10 cm, with a mean height of 166.07±7.19 cm. The demographic and baseline characteristics of both groups were comparable to each other.

Efficacy Analysis

Assessment of Weight and BMI

The mean weight difference between groups ranged from 1.64 to 2.13 kg, while the BMI difference remained below 0.3 kg/m^2 throughout the study period. All comparisons yielded non-significant p-values ($p>0.05$), suggesting that the intervention had no notable effect on weight or BMI over the study duration.

Overall, the findings demonstrated that weight and BMI remained stable across visits, with no significant differences between the placebo and study groups, indicating that the intervention did not induce any major metabolic changes related to body composition.

Assessment of Sleep Quality Using Athens Insomnia Scale (AIS)

The assessment of sleep quality using the Athens Insomnia Scale (AIS) demonstrated a significant improvement in the study group, while the placebo group showed minimal changes. Between-group comparisons showed that the AIS score at visit 2 was significantly higher in study group compared to the placebo and ($p=0.0003$). However, at Visit 3, the study group exhibited a slight reduction in AIS score (13.60±2.19) compared to the placebo group (14.05±1.64, $p<0.466$). This reduction was more significant at Visit 4 (11.80±1.54 vs. 13.80±2.09, $p<0.0014$) (Figure 2). These results indicate that the intervention significantly improved sleep quality in the study group, whereas no significant improvement was observed in the placebo group.

Assessment of Serum Biomarkers

The assessment of serum stress and inflammatory markers revealed significant improvements in the study group compared to the placebo group. Between-group comparisons further confirmed these findings. At Visit 2, serum cortisol levels were significantly higher in the study group (35.81±4.54) compared to the placebo group (32.07±5.38; p=0.023). However, by Visit 4, cortisol levels had significantly decreased in the study group, resulting in a lower mean value (29.01±4.57) compared to the placebo group (32.24±5.26; p=0.045). For hs-CRP, baseline (Visit 2) values were comparable between the groups (p=0.575), but by Visit 4, the study group showed a significantly lower hs-CRP level (1.95±0.71) compared to the placebo group (2.59±0.72, p<0.007) (Table 1). These results suggest that the intervention led to a significant reduction in both stress while the placebo group experienced no significant changes.

Assessment of Subjective Global Assessment (SGA) and Physician Global Assessment (PGA)

The assessment of SGA and PGA scores demonstrated significant improvements in the study group compared to the placebo group. Between-group comparisons further confirmed these findings. At Visit 3, SGA and PGA scores were comparable between the two groups (p=0.547 and p=0.886, respectively). However, by Visit 4, the study group demonstrated lower SGA (2.0±1.08) compared to the placebo group (2.70±1.17, p=0.324) and lower PGA (1.95±0.83) compared to the placebo group (2.45±0.83, p=0.063), but the results were not statistically significant (Figure 3). These results indicate that the intervention in the study group led to a significant improvement in both subjective and physician-assessed global outcomes, whereas the placebo group showed minimal or no significant changes.

Evaluation of SF-36 Score

The evaluation of SF-36 scores revealed notable differences between the placebo and study groups across multiple health domains from screening to the end of the study. Between-group comparisons as shown in Table 2, indicated significant improvements in the study group for several domains. By the end of the study, the study group exhibited statistically significant enhancements in physical functioning (p=0.022), role limitations due to emotional problems (p=0.022), vitality (p=0.004), pain (p=0.044), and general health (p=0.028) compared to the placebo group. Overall, the study group showed greater improvements across multiple health domains compared to the placebo group.

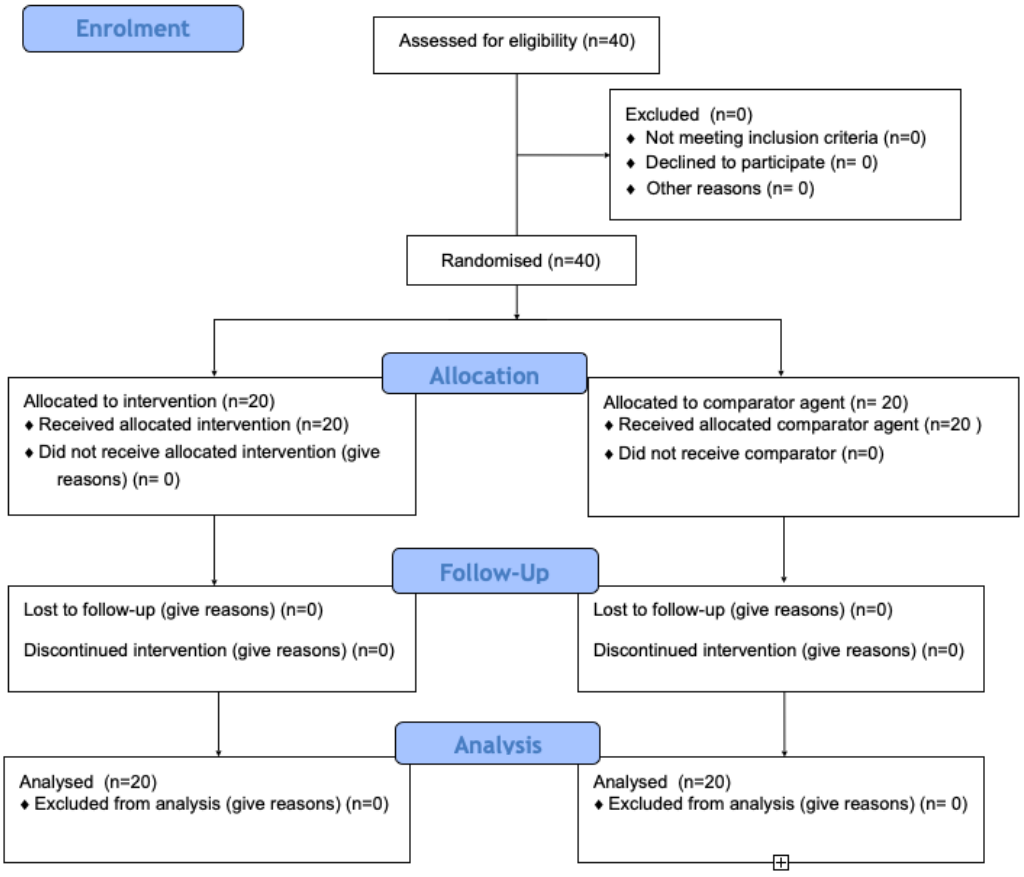

Figure 1: CONSORT Flow diagram of the study.

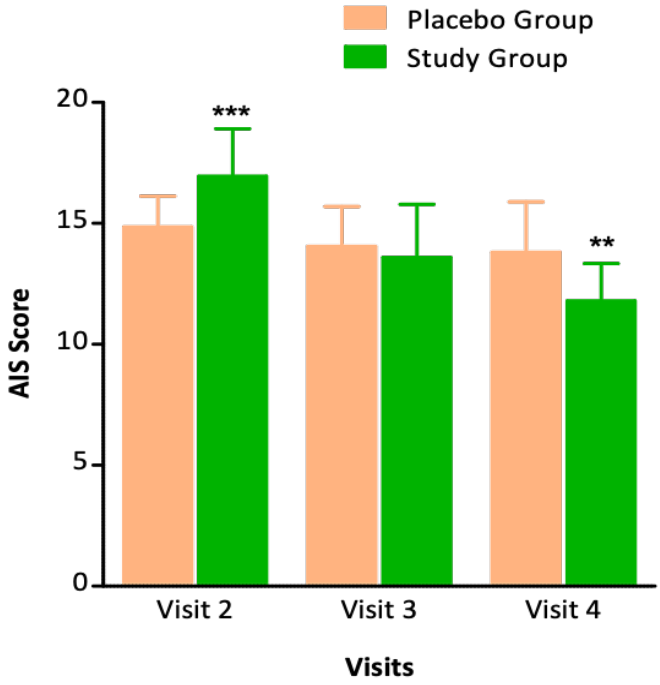

Figure 2: Between groups comparison of AIS Score at different visits. Comparisons were performed using unpaired t test. Comparison: Placebo Group vs Study Group, **p=<0.01, and ***p=<0.001.

Table 1: Between groups comparison of serum markers at different visits.

Visits	Placebo Group (n=20) Mean±SD	Study Group (n=20) Mean±SD	Mean Diff.	95% CI	P value
Serum Cortisol (mcg/dL)					
VISIT 2	32.07±5.38	35.81±4.54	3.74±1.57	6.927 to 0.553	0.023*
VISIT 4	32.24±5.26	29.01±4.57	3.23±1.56	-0.075 to -6.385	0.045*
hs-CRP (mg/dL)					
VISIT 2	2.68±0.68	2.55±0.72	0.13±0.22	0.323 to -0.573	0.575
VISIT 4	2.59±0.72	1.95±0.71	0.64±0.23	-0.182 to -1.098	0.007**

Note: Between groups comparison of serum biomarkers were performed using unpaired t-test at different study visits. Placebo Group vs Study Group, *p=<0.05 and **p=<0.01

Safety Analysis

Physical Examination

All study subjects underwent comprehensive physical examinations at each visit. No abnormalities were detected during the screening examination or at the end of the study.

Assessment of Vital Signs

The assessment of vital signs, as presented in Table 3, showed that all measured parameters remained within normal physiological ranges across all study visits in both the placebo and study groups. No significant within-group variations were observed over time for temperature, heart rate, respiratory rate, SBP), and DBP, as indicated by p-values above 0.05. In the placebo group, the mean temperature remained stable, ranging from 37.12°C to 37.16°C (p=0.934), while in the study group, it ranged from 37.13°C to 37.19°C (p=0.782). Heart rate also showed minimal fluctuations, with values between 72.95 and 74.45 bpm in the placebo group (p=0.721) and 74.90 to 75.95 bpm in the study group (p=0.523). Respiratory rate was consistently within the normal range, varying between 17.20 and 17.70 bpm in the placebo group (p=0.620) and 16.70 to 17.0 bpm in the study group (p=0.225). Similarly, SBP and DBP remained within normal limits, with SBP ranging from 115.0 to 115.95 mmHg (p=0.895) in the placebo group and 116.35 to 117.40 mmHg (p=0.848) in the study group, while DBP fluctuated between 75.35 and 75.95 mmHg (p=0.973) in the placebo group and 75.80 to 77.50 mmHg (p=0.649) in the study group.

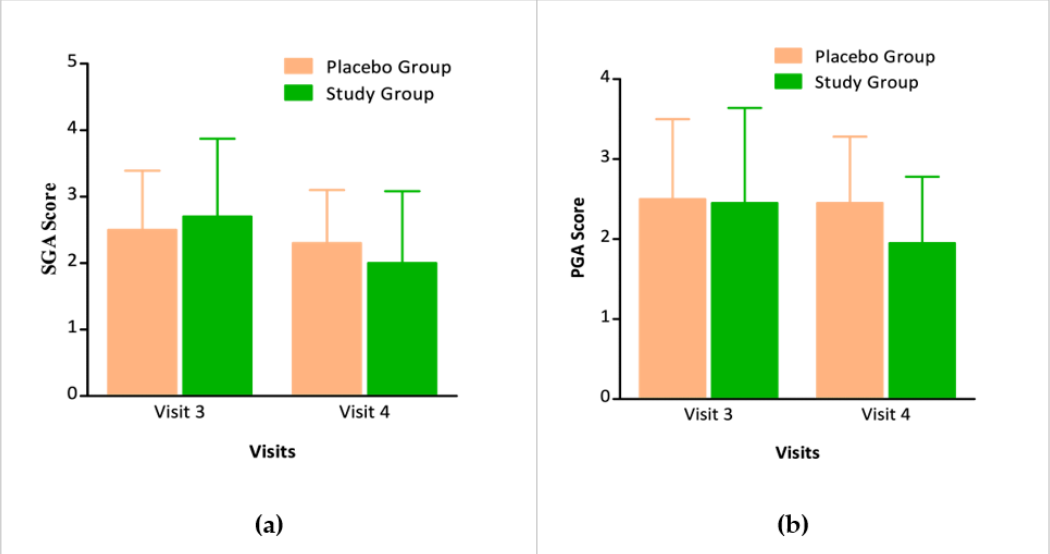

Figure 3: Between groups comparison of (a) SGA, and (b) PGA scores at different visits. Comparisons were performed using unpaired *t* test. Comparison: Placebo Group vs Study Group.

Table 2: Between groups comparison of mean change in SF36 scores at screening to end of the study.

Health Domain	Score (Mean±SD)		Mean diff.	95% CI	P value
	Placebo Group	Study Group			
Screening					
Physical functioning	78.25±13.40	75.0±15.22	3.25±4.54	5.93 to -12.43	0.478
Role limitations due to physical health	76.25±24.97	77.50±17.95	1.25±6.88	15.18 to -12.68	0.857
Role limitations due to emotional problems	80.0±19.94	78.33±16.31	1.67±5.76	10.0 to -13.33	0.774
Vitality (energy/fatigue)	63.50±6.90	64.25±9.36	0.75±2.60	6.02 to 4.52	0.775
Emotional well-being	69.80±8.56	71.0±10.61	1.20±3.05	7.374 to -4.974	0.696
Social functioning	83.13±13.62	84.38±18.53	1.25±5.14	11.660 to -9.163	0.809
Pain	87.38±13.24	84.25±17.07	3.13±4.83	6.659 to -12.910	0.522
General health	68.75±9.02	67.71±8.75	1.04±2.81	4.647 to -6.732	0.713
End of Study					
Physical functioning	70.50±19.46	83.25±13.70	12.75±5.32	23.530 to 1.974	0.022*
Role limitations due to physical health	73.75±23.61	86.25±22.18	12.50±7.24	27.170 to -2.169	0.093
Role limitations due to emotional problems	81.67±17.01	93.33±13.68	11.67±4.88	21.550 to 1.790	0.022*
Vitality (energy/fatigue)	65.0±9.32	73.0±6.77	8.0±2.58	13.220 to 2.785	0.004**
Emotional well-being	73.20±7.58	76.20±8.26	3.0±2.51	8.08 to 2.08	0.239
Social functioning	81.25±14.90	90.0±12.57	8.75±4.36	17.580 to -0.077	0.052
Pain	84.25±10.48	91.75±12.20	7.50±3.60	14.780 to 0.217	0.044*

Assessment of Hematological Parameters

In the study group, within-group comparisons of CBC parameters from baseline (Visit 1) to the end of the study (Visit 4) showed no statistically significant changes across all measured parameters, including haemoglobin, RBC count, haematocrit, platelet count, total leukocyte count, differential counts, and red cell indices (MCV, MCH, MCHC). All *p*-values were >0.05, indicating stability in haematological profiles over the study period. These results indicate that the investigational product did not induce any clinically relevant haematological changes over the study duration, supporting its safety profile in terms of hematopoietic function.

Assessment of Liver and Kidney Functions

The assessment of liver and kidney function parameters in both the placebo and study groups revealed no significant changes from baseline (Visit 1) to the end of the study (Visit 4). Within-group comparisons indicated minimal variations in serum AST, ALT, bilirubin, creatinine, and BUN levels over the study period. In the placebo group, the mean difference for AST was 0.66 (p=0.282), ALT was 0.02 (p=0.947), and bilirubin was 0.02 mg/dL (p=0.607), all of which were statistically non-significant. Similarly, in the study group, AST showed a negligible mean change of 0.05 (p=0.764), ALT changed by 0.40 (p=0.057), and bilirubin by 0.09 (p=0.178). Serum creatinine and BUN levels remained stable across both groups, with non-significant changes observed (p>0.05).

Assessment of Serum Biochemical Parameters

The assessment of serum biochemical parameters demonstrated that all measured values remained within the normal physiological range throughout the study. Within-group comparisons from screening to the end of the study indicated no statistically significant changes in the placebo group, except for uric acid, which showed a slight but significant reduction (p=0.005). In the study group, a similar decrease in blood glucose level (p=0.026) was observed, along with a significant increase in serum potassium level (p=0.0067). These results suggest that the intervention was well tolerated and did not cause any notable metabolic disturbances.

Assessment of Serum Cholesterols

Between-group comparisons at different study visits showed no significant differences in total cholesterol, LDL cholesterol, or triglycerides levels between the placebo and study groups at both Visit 1 and Visit 4. However, a significant increase in HDL cholesterol levels was observed in the study group at Visit 4 compared to the placebo group (p=0.007). These findings indicate that all cholesterol parameters remained within their respective normal reference ranges, supporting the overall metabolic stability and safety of the intervention.

Adverse Events assessment

No adverse events with supplementation were observed throughout the study.

DISCUSSION

The findings demonstrated that weight and BMI remained stable across visits, with no significant differences between the placebo and study group. The results indicated that the intervention significantly improved sleep quality in the study group, whereas no significant improvement was observed in the placebo group. In a study conducted by Shivaprasad HN *et al.*, it was found that pistachio is rich in melatonin and can improve sleep quality

Table 3: Mean changes in vital sign parameters throughout the study visit.

Visits	Visit 1 Mean±SD	Visit 2 Mean±SD	Visit 3 Mean±SD	Visit 4 Mean±SD	*P* value
Placebo Group					
Temperature (^{0}C)	37.12±0.26	37.12±0.26	37.15±0.27	37.16±0.24	0.934
Heart rate (bpm)	73.80±4.74	74.45±5.35	73.15±4.55	72.95±3.36	0.721
Respiratory rate (bpm)	17.20±1.58	17.25±1.16	17.35±1.14	17.70±1.30	0.620
SBP (mmHg)	115.95±4.80	115.0±3.83	115.25±4.02	115.45±3.27	0.895
DBP (mmHg)	75.70±4.62	75.35±3.88	75.50±4.35	75.95±4.01	0.973
Study Group					
Temperature (^{0}C)	37.13±0.24	37.12±0.27	37.13±0.25	37.19±0.24	0.782
Heart rate (bpm)	74.90±3.45	75.95±2.58	74.95±3.30	75.55±3.07	0.523
Respiratory rate (bpm)	16.70±1.53	16.75±1.33	16.75±1.07	17.0±1.12	0.225
SBP (mmHg)	116.80±4.05	117.40±3.79	117.05±3.63	116.35±3.76	0.848
DBP (mmHg)	75.80±4.58	77.50±3.71	76.70±4.32	76.65±4.07	0.649

Note: Vital signs data at Screening (Visit 1) were compared to different study visits using the one-way ANOVA test. Comparison: VISIT 1 vs VISIT 2, VISIT 3 and VISIT 4.

mainly by reducing the time period to sleep.[11] The results obtained from this current research also tells the same. The assessment of serum stress and inflammatory markers revealed significant improvements in the study group compared to the placebo group. The evaluation of SF-36 scores revealed notable differences between the placebo and study groups across multiple health domains from screening to the end of the study. No adverse events with supplementation were observed throughout the study.

CONCLUSION

The results of the study are indicative of the efficacy and safety of Melostacio Gold™ (Pistachio extract) in improving sleep quality, reducing stress, and enhancing overall well-being. The values measured by AIS were indicating towards improvement in sleep parameters. This closely aligns with the sleep promoting effect exhibited by pistachio due to presence of melatonin and magnesium. Reduction in the levels of serum cortisol and hs-CRP helps in mitigating stress, thus pistachio-derived bioactive compounds were also able to show stress-mitigating properties. Enhancement in QoL was also noticed by SF-36 assessment. Above all, Melostacio Gold™ was well-tolerated by subjects, and showed no adverse effects, and hence can be safe for regular consumption. All these findings suggest that this pistachio supplement could serve as a promising functional dietary intervention for stress reduction, sleep enhancement, and metabolic health improvement.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

AIS: Athens Insomnia Scale; **BMI:** Body Mass Index; **SGA:** Subjective Global Assessment; **PGA:** Physician Global Assessment; **QoL:** Quality of Life.

AUTHOR CONTRIBUTIONS

Conception and design: Dr. H N Shivaprasad; Srivalli Susmitha Ghatti; Gaurav Soni, D Manohar, Data collection: Madhu Krishnamani; D Manohar, Data analysis and interpretation: Dr. Srivalli Susmitha Ghatti, Manuscript drafting: T Sravani; Dr. H N Shivaprasad, Final approval: Dr. H N Shivaprasad.

SUMMARY

This randomized, double-blind, placebo-controlled trial evaluated the safety and efficacy of Melostacio Gold™ (Pistachio extract) in managing stress and improving sleep quality among adults. Forty participants were randomly assigned to receive either Melostacio Gold™ or placebo for 28 days. Assessments of sleep quality, serum stress markers, and quality of life were conducted at baseline, day 14, and day 28. The study group demonstrated a significant reduction in Athens Insomnia Scale (AIS) scores and serum stress markers compared to placebo, indicating improved sleep quality and reduced stress levels. The findings suggest that Melostacio Gold™ is a safe and effective plant-based intervention for enhancing sleep and reducing stress in adults.

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