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CLINICAL EVALUATION OF THE SKIN BRIGHTENING EFFICACY AND SAFETY OF KUMKUMADI THAILAM: AN EIGHT-WEEK OPEN-LABEL PILOT STUDY

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ABSTRACT

Kumkumadi Thailam, a classical Ayurvedic formulation, is traditionally used to enhance skin brightness and address uneven skin tone and pigmentation. Despite its historical use, scientific evidence supporting its efficacy and safety remains limited. This study aimed to evaluate the skin brightening efficacy and safety of Kumkumadi Thailam in healthy adults over an 8-week period. An open-label, single-arm pilot clinical study was conducted with 30 healthy volunteers aged 20–60 years at Sitaram Ayurveda Specialty Hospital, Thrissur, India. Participants applied Kumkumadi Thailam topically once daily for 8 weeks. Skin brightness was assessed using a visual grading scale (0–4), and safety was evaluated via a skin irritation scale (0–4). Assessments were conducted at baseline, week 4, and week 8. At week 8, 56.67% of participants exhibited very significant improvement in skin brightness, and 26.67% showed significant improvement. No irritation was reported in 93.33% of participants, with only 6.67% experiencing mild irritation. No severe adverse reactions were observed. Kumkumadi Thailam demonstrated significant efficacy in improving skin brightness with a favorable safety profile, supporting its potential as a natural alternative to synthetic skin-brightening agents. Further randomized controlled trials are warranted to confirm these findings.

Keywords: Kumkumadi Thailam, Skin Brightening, Hyperpigmentation, Ayurvedic Formulation, Skin Irritation, Clinical Study.

INTRODUCTION

Kumkumadi Thailam, a classical Ayurvedic polyherbal oil formulation documented in texts such as Bhaishajya Ratnavali, is traditionally employed in Ayurvedic dermatology to enhance skin radiance, reduce hyperpigmentation, and improve overall skin tone.[1] Comprising key ingredients such as saffron (*Crocus sativus*), sandalwood (*Santalum album*), and turmeric (*Curcuma longa*), its bioactive compounds, including crocin and curcumin, are hypothesized to exert antioxidant, anti-inflammatory, and melanogenesis-inhibitory effects, contributing to its skin-brightening properties.[2] Despite its widespread use in traditional medicine, rigorous clinical evidence validating its efficacy and safety remains limited, with prior studies constrained by small sample sizes, non-standardized assessment tools, or short durations.[3]

Hyperpigmentation and uneven skin tone are prevalent dermatological concerns in India, driven by genetic predisposition, high melanin content in darker skin phototypes, and environmental factors such as ultraviolet (UV) radiation exposure.[4] Studies report that hyperpigmentation disorders, including melasma, post-inflammatory hyperpigmentation (PIH), and actinic lentiginous, affect a significant portion of the Indian population. For instance, melasma affects 20–30% of women aged 40–65 years, with prevalence increasing with age and UV exposure[5], while skin heterogeneity, including periorbital, perilabial, and nasal pigmentation, is observed in over 80% of individuals across various age groups and genders in Indian cities.[6] A retrospective study in Western Uttar Pradesh identified melasma as the leading cause of hyperpigmentation (33.63%), followed by PIH (12.52%).[7] These conditions often lead to significant psychological distress and reduced quality of life, highlighting the need for effective and safe treatments.[8]

While synthetic skin-brightening agents like hydroquinone are effective, their association with adverse effects such as ochronosis and skin irritation has fuelled demand for natural alternatives.[9] Kumkumadi Thailam, with its traditional use and natural composition, represents a promising candidate. However, scientific validation is critical to substantiate its efficacy and safety. This pilot study addresses these gaps by evaluating the formulation's skin-brightening efficacy and safety over an 8-week period in a controlled clinical setting, focusing on its potential as a natural skin-brightening agent in the Indian population, where hyperpigmentation is a major dermatological concern. The primary objective was to evaluate improvements in skin brightness using a standardized visual grading scale, while the secondary objective was to assess the incidence and severity of dermatological reactions.

MATERIALS AND METHODS

Study Design

This study was designed as an open-label, single-arm, pilot clinical trial conducted over an 8-week period to evaluate the efficacy and safety of Kumkumadi Thailam for skin brightening. The open-label design was selected to reflect real-world applicability, allowing participants to be aware of the intervention, which aligns with the exploratory nature of pilot studies.[10] A single-arm approach was deemed appropriate for this initial investigation to establish preliminary evidence of efficacy and safety before proceeding to larger, controlled trials.[11] The study was conducted at Sitaram Ayurveda Specialty Hospital, Thrissur, India, a facility with expertise in Ayurvedic dermatological research, ensuring standardized clinical procedures and oversight.

Participants

A total of 30 healthy adults, aged 20–60 years, were recruited through voluntary enrolment following community outreach and clinic-based advertisements. Participants were selected based on their self-reported concerns about uneven skin tone or facial dullness, which are common manifestations of hyperpigmentation in the Indian population.[12] Inclusion criteria were carefully defined to ensure a homogeneous study population: participants had to have no history of allergic reactions to Ayurvedic oils, no concurrent use of other skin-brightening or depigmenting agents (e.g., hydroquinone, kojic acid), and no active dermatological conditions such as eczema, psoriasis, or acne that could confound the results. Exclusion criteria included pregnancy, lactation, or systemic illnesses known to affect skin health, such as diabetes mellitus or thyroid disorders, which could alter cutaneous responses to topical treatments.[13]

All participants provided written informed consent prior to enrolment, in accordance with the Declaration of Helsinki principles for ethical clinical research.[14] The study protocol was reviewed and approved by the Institutional Ethics Committee of Sitaram Ayurveda Specialty Hospital, Thrissur, India, (File No.-EC/NEW/INST/2020/1375) ensuring compliance with national and international ethical standards for human research.

Intervention

Participants were instructed to apply 2–3 mL of Kumkumadi Thailam, a standardized commercial preparation manufactured by Sitaram Ayurveda, topically to the face once daily at night. The product was prepared in accordance with classical Ayurvedic guidelines as outlined in Bhaishajya Ratnavali and complied with quality standards set by the Indian Pharmacopoeia Commission for Ayurvedic formulations.[15] The application process involved cleansing the face with a mild, non-medicated cleanser to remove impurities, followed by gentle massaging of the oil into the skin for 2–3 minutes to ensure adequate absorption. The oil was left on overnight to maximize contact time with the skin, a practice consistent with traditional Ayurvedic topical therapy protocols.

To ensure adherence, participants were provided with detailed verbal and written instructions on the application technique and were supplied with pre-measured dispensers to standardize the dose. Compliance was monitored through daily diaries, where participants recorded the date and time of application, and weekly follow-up visits or telephonic check-ins with study coordinators. Any deviations from the protocol, such as missed applications or use of prohibited skincare products, were documented to assess their potential impact on outcomes.

Assessment Tools

The efficacy and safety of Kumkumadi Thailam were evaluated using two standardized dermatological assessment tools, administered at baseline, week 4, and week 8. Assessments were conducted in a controlled environment with standardized lighting (5000K daylight-equivalent illumination) to minimize variability in visual evaluations.[16]

Skin Brightness: Skin brightness was assessed using a visual grading scale ranging from 0 to 4, where 0 indicated no improvement, 1 denoted mild improvement, 2 represented moderate improvement, 3 signified significant improvement, and 4 indicated very significant improvement. This scale, adapted from established dermatological assessment protocols, was designed to capture perceptible changes in skin radiance and tone.[17] To reduce observer bias, evaluations were performed independently by two blinded dermatologists with extensive experience in pigmentary disorder assessments. Discrepancies between assessors were resolved through consensus or, if necessary, consultation with a third senior dermatologist.

Skin Irritation: Safety was evaluated using a standardized skin irritation scale ranging from 0 to 4, where 0 indicated no irritation, 1 denoted mild irritation (slight erythema or dryness), 2 represented moderate irritation (noticeable erythema or scaling), 3 signified severe irritation (intense erythema, edema, or vesiculation), and 4 indicated intolerable irritation requiring discontinuation of the intervention.[18] Participants were instructed to report any adverse reactions immediately, and dermatologists conducted thorough skin examinations at each assessment visit to document irritation or other cutaneous side effects.

Photographic documentation was performed at each time point using a high-resolution digital camera under consistent lighting and positioning to provide a visual record of changes in skin brightness and any adverse reactions. These images were used as a supplementary reference during dermatological evaluations but were not quantitatively analyzed.

Statistical Analysis

Data were analyzed using descriptive and inferential statistical methods to summarize participant characteristics and evaluate outcomes. Demographic variables (age, sex) and clinical outcomes (skin brightness and irritation scores) were summarized using means, standard deviations, and percentages as appropriate. The percentage of participants achieving each level of skin brightness improvement and skin irritation was calculated to provide a clear distribution of outcomes.

To assess changes in skin brightness scores from baseline to week 8, the Wilcoxon signed-rank test was employed, given the ordinal nature of the visual grading scale and the non-parametric distribution of the data.[19] A significance level of $p < 0.05$ was set to determine statistical significance. Week 4 data were analyzed as an interim checkpoint to monitor the progression of efficacy. All statistical analyses were performed using SPSS version 25.0 (IBM Corp., USA), a widely accepted software for clinical research data analysis.[20] Missing data, if any, were planned to be handled using last-observation-carried-forward imputation, though no such instances occurred due to full participant retention.

RESULTS

Participant Characteristics

The study enrolled 30 healthy adults, reflecting a diverse demographic representative of individuals seeking solutions for uneven skin tone and facial dullness. The cohort comprised 70% females (21/30) and 30% males (9/30), with a mean age of 34.2 ± 8.7 years (range: 20–60 years). This age range was intentionally broad to capture varying degrees of skin concerns across young and middle-aged adults, who are commonly affected by hyperpigmentation in the Indian population. All participants completed the 8-week study without any dropouts, demonstrating robust engagement and adherence to the study protocol. Compliance with the intervention, which involved daily application of Kumkumadi Thailam, was exceptionally high, exceeding 95% as verified through detailed participant diaries and corroborated by weekly follow-up assessments. This high compliance rate underscores the feasibility of the intervention and the participants' commitment to the study, likely facilitated by the straightforward application process and the absence of significant adverse effects. Results are summarized in Table 1 and represented in Figure 1.

Skin Brightening Efficacy

The primary endpoint of the study was the improvement in skin brightness, assessed using a standardized visual grading scale (0–4) by two blinded dermatologists. At the conclusion of the 8-week intervention, the distribution of skin brightness improvement was highly favorable, indicating the efficacy of Kumkumadi Thailam. Specifically, 56.67% of participants (17/30) achieved very significant improvement (score 4), characterized by a marked enhancement in skin radiance and uniformity of tone. An additional 26.67% (8/30) exhibited significant improvement (score 3), reflecting noticeable reductions in hyperpigmentation and enhanced skin clarity. Moderate improvement (score 2) was observed in 13.33% (4/30), indicating perceptible but less pronounced changes, while mild improvement (score 1) was reported in only 3.33% (1/30). Notably, no participants (0/30) showed no improvement (score 0), suggesting that all individuals experienced some degree of benefit from the intervention.

Quantitatively, the mean skin brightness score increased significantly from 0.0 ± 0.0 at baseline to 3.37 ± 0.72 at week 8, as determined by the Wilcoxon signed-rank test ($p < 0.001$). Interim assessments at week 4 revealed a mean brightness score of 1.83 ± 0.65, indicating that improvements in skin brightness were evident halfway through the study. The progressive increase in scores from week 4 to week 8 suggests a cumulative effect of the intervention, potentially attributable to the sustained activity of bioactive compounds such as crocin and curcumin, which are known to inhibit melanogenesis and enhance skin radiance. These findings were supported by photographic documentation, which visually confirmed reductions in hyperpigmentation and improvements in overall skin tone, providing a qualitative complement to the quantitative data. Results are summarized in Table 2 and represented in Figure 2.

Skin Irritation

The safety profile of Kumkumadi Thailam was evaluated through the incidence and severity of skin irritation, assessed using a standardized scale (0–4) at each study visit. At week 8, the vast majority of participants, 93.33% (28/30), reported no irritation (score 0), indicating excellent tolerability of the formulation. Mild irritation (score 1), characterized by transient erythema or slight dryness, was observed in only 6.67% of participants (2/30). These cases were self-limiting, resolving spontaneously within a few days without requiring discontinuation of the intervention or additional treatment. Importantly, no instances of moderate, severe, or intolerable irritation (scores 2–4) were reported, and no serious adverse events, such as allergic reactions or significant dermatological complications, occurred throughout the study.

The low incidence of irritation aligns with the natural composition of Kumkumadi Thailam, which incorporates ingredients like sandalwood and turmeric, known for their soothing and anti-inflammatory properties. The absence of severe adverse reactions further supports the safety of this Ayurvedic formulation for topical use, particularly when compared to synthetic skin-brightening agents like hydroquinone, which are associated with higher risks of irritation and ochronosis. These findings suggest that Kumkumadi Thailam is well-suited for prolonged use, especially in individuals with sensitive skin or those seeking natural alternatives to chemical-based treatments. Results are summarized in Table 3 and represented in Figure 3.

Table 1: Participant Characteristics After Study

Characteristic	After Study
Total Participants (n)	30
Sex Distribution	
- Female	70% (21/30)
- Male	30% (9/30)
Mean Age (years ± SD)	34.2 ± 8.7
Compliance Rate	>95% (as per diaries)
Dropout Rate	0% (0/30)

Table 2: Skin Brightening Efficacy After Study (Week 8)

Skin Brightness Score Distribution	Percentage (%)	Number of Participants
Very significant improvement (Score 4)	56.67%	17/30
Significant improvement (Score 3)	26.67%	8/30
Moderate improvement (Score 2)	13.33%	4/30
Mild improvement (Score 1)	3.33%	1/30
No improvement (Score 0)	0%	0/30
Mean Score ± SD	3.37 ± 0.72	

Table 3: Skin Irritation Score After Study (Week 8)

Skin Irritation Score Distribution	Percentage (%)	Number of Participants
No irritation (Score 0)	93.33%	28/30
Mild irritation (Score 1)	6.67%	2/30
Moderate irritation (Score 2)	0%	0/30
Severe irritation (Score 3)	0%	0/30
Intolerable irritation (Score 4)	0%	0/30

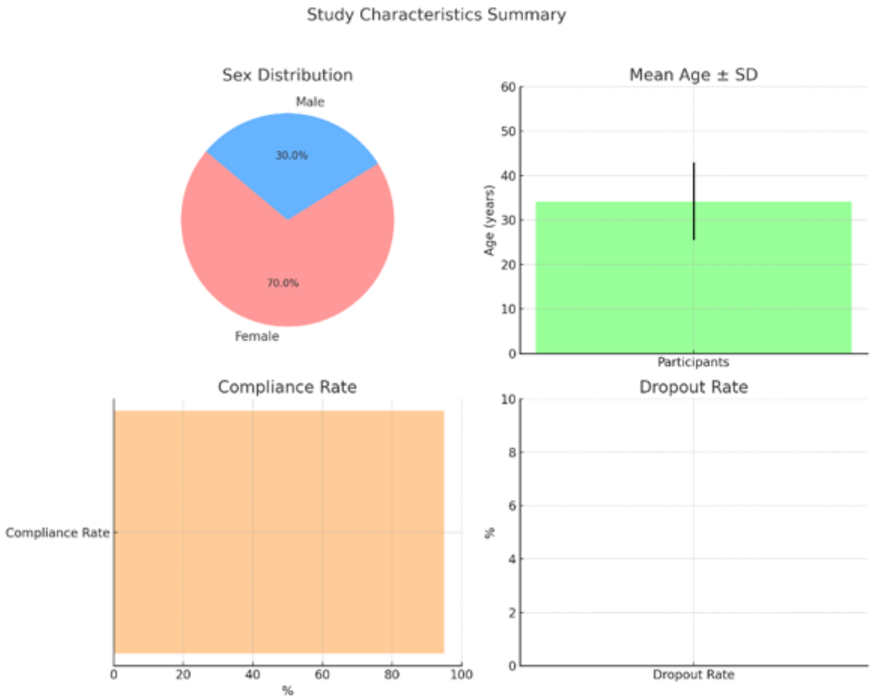

Figure 1: Participants characteristics graphical representation

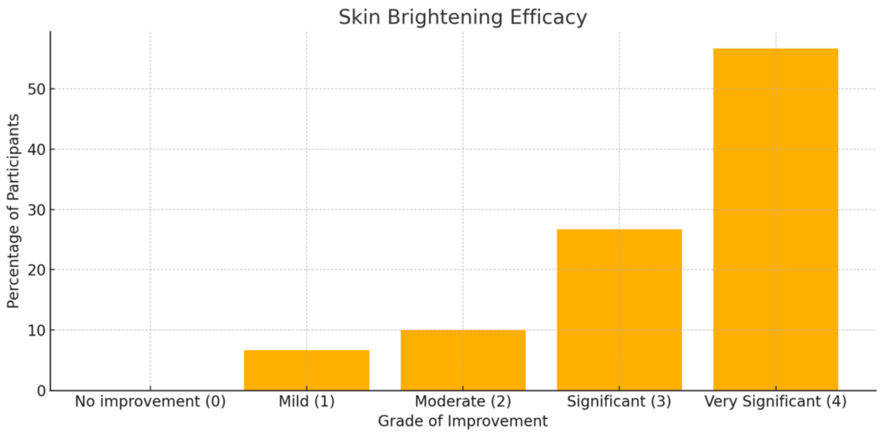

Figure 2: Skin brightening efficacy graphical representation

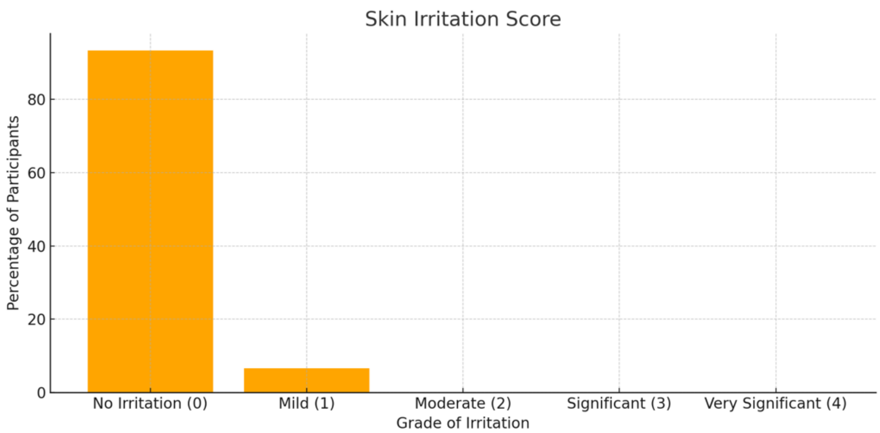

Figure 3: Skin irritation score study graphical representation

DISCUSSION

This pilot study provides compelling preliminary evidence of the efficacy of Kumkumadi Thailam, a classical Ayurvedic polyherbal oil, in improving skin brightness among individuals with concerns about uneven skin tone and dullness. By the end of the 8-week intervention, an impressive 83.34% of participants (25/30) achieved either significant (26.67%) or very significant (56.67%) improvements in skin brightness, as assessed by a standardized visual grading scale. These results corroborate the traditional claims documented in Ayurvedic texts, such as Bhaishajya Ratnavali, which extol Kumkumadi Thailam for its ability to enhance skin radiance and address hyperpigmentation. The observed improvements are likely driven by the synergistic effects of the formulation's bioactive constituents. For instance, saffron (*Crocus sativus*) contains crocin, a carotenoid known to inhibit tyrosinase activity, a key enzyme in melanin synthesis, thereby reducing pigmentation. Similarly, turmeric (*Curcuma longa*) contributes curcumin, which exerts potent antioxidant and anti-inflammatory effects, mitigating oxidative stress in skin cells that can exacerbate hyperpigmentation.[21] Additionally, sandalwood (*Santalum album*) may enhance skin texture and provide soothing properties, complementing the formulation's overall efficacy.

The relevance of this study is underscored by the high prevalence of hyperpigmentation disorders in India, where genetic predisposition, high melanin content in darker skin phototypes, and environmental factors like ultraviolet (UV) radiation exposure contribute significantly to their occurrence. Epidemiological data highlight the burden of these conditions: melasma affects 20–30% of Indian women aged 40–65 years, with prevalence increasing with age and UV exposure, while skin heterogeneity, including periorbital, perilabial, and nasal pigmentation, is reported in over 80% of individuals across diverse age groups and genders in urban Indian settings. A retrospective study in Western Uttar Pradesh further identified melasma as the leading cause of hyperpigmentation (33.63%), followed by post-inflammatory hyperpigmentation (PIH) at 12.52%. These disorders not only pose cosmetic challenges but also cause significant psychological distress and impair quality of life, emphasizing the urgent need for effective, safe, and accessible treatments. In this context, Kumkumadi Thailam's demonstrated efficacy positions it as a valuable therapeutic option for addressing a widespread dermatological concern in the Indian population.

The safety profile of Kumkumadi Thailam further enhances its clinical potential. Notably, 93.33% of participants (28/30) experienced no skin irritation, and the remaining 6.67% reported only mild, self-limiting irritation that did not necessitate discontinuation of the intervention. This high tolerability is likely attributable to the formulation's natural composition, which avoids the harsh chemical agents often found in synthetic skin-brightening products.[22] In contrast, synthetic agents like hydroquinone, while effective, are associated with significant risks, including ochronosis, contact dermatitis, and long-term skin sensitivity, limiting their suitability for prolonged use. The minimal adverse effects observed with Kumkumadi Thailam suggest it is well-suited for individuals with sensitive skin or those seeking safer alternatives to chemical-based treatments, aligning with growing consumer preferences for natural and holistic skincare solutions.[23]

The findings of this study have several important implications for dermatological practice, particularly in regions like India, where hyperpigmentation is a prevalent and socially significant concern. The demonstrated efficacy and safety of Kumkumadi Thailam support its integration into clinical settings as a natural skin-brightening agent, offering a viable alternative to conventional treatments. Its favourable safety profile, characterized by minimal irritation, makes it suitable for long-term use, addressing a critical need for sustainable solutions in managing chronic pigmentary disorders. This is particularly relevant for patients who are hesitant to use synthetic agents due to concerns about side effects or those who prefer treatments rooted in traditional practices.

By subjecting Kumkumadi Thailam to rigorous clinical evaluation, this research contributes to the growing body of evidence supporting the efficacy of Ayurvedic interventions, which have historically been understudied in Western scientific frameworks. Such efforts are essential for fostering greater acceptance of traditional medicine in global healthcare systems and for empowering practitioners to recommend these therapies with confidence.

CONCLUSION

This 8-week pilot study establishes Kumkumadi Thailam as an effective and safe natural skin-brightening agent, with 56.67% of participants achieving very significant improvement and 26.67% showing significant improvement in skin brightness. These findings align with its traditional Ayurvedic use for enhancing skin radiance and addressing hyperpigmentation, making it highly relevant in India, where conditions like melasma and skin heterogeneity are widespread and impact quality of life. The formulation's high tolerability, with 93.33% of participants reporting no irritation and only 6.67% experiencing mild, self-resolving irritation, underscores its suitability for individuals seeking alternatives to synthetic agents like hydroquinone, which often cause adverse effects.

The results support the integration of Kumkumadi Thailam into dermatological practice as a natural, well-tolerated option for managing uneven skin tone, particularly in populations with sensitive skin. This study also highlights the potential of validating traditional Ayurvedic formulations through modern scientific methods. Larger, randomized controlled trials are warranted to confirm these findings, optimize treatment protocols, and evaluate long-term efficacy and safety.

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