

Original Research Article

Assessment of the efficacy and safety of Indulekha Svetakutaja hair oil in management of dandruff: a randomized, double-blind, placebo-controlled study

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ABSTRACT

Background: This study aimed to evaluate the efficacy and safety of Indulekha Svetakutaja Hair Oil in comparison with coconut oil in the management of dandruff through a randomized, double-blind, placebo controlled study.

Methods: A total of 110 subjects with clinically diagnosed moderate dandruff were randomly assigned into two groups: Group A (The Indulekha Svetakutaja Hair Oil group, n=55) and Group B (Placebo coconut hair oil group, n=55), where 50 subjects in each group completed the study. The treatment phase was for 4 weeks, followed by a regression phase of 2 weeks. Subjects applied the allotted oil on their scalp, massaged and kept it for a minimum of 30 mins or overnight thrice a week, then washed it with the provided neutral shampoo for a duration of 4 weeks. Dermatological assessments, instrumental measurements and subject self-assessment questionnaire were evaluated in comparison to baseline at weekly intervals throughout the study period.

Results: After 4 weeks of treatment, group A demonstrated a significantly greater reduction ($p<0.05$) in dandruff severity compared to group B. The Total Dandruff scores in Group A showed a significant reduction of 70.62 units while in Group B, it was noted to be 48.79 units. Nearly all participants (98%) in Group A reported a subjective perception improvement in dandruff symptoms compared to Group B.

Conclusions: Indulekha Svetakutaja Hair Oil is safe and effective in controlling dandruff and improving scalp and hair health, making it a promising therapeutic option for individuals with dandruff.

Keywords: Ayurveda, Dandruff, Fungal infection, Hair oil, Scalp health

INTRODUCTION

Dandruff, known as Darunaka in Ayurvedic literature, is a prevalent fungal infection that affects the scalp, resulting in symptoms such as scaling, itching, redness, and excessive shedding of dead skin cells. This condition leads to the formation of noticeable white flakes on the scalp, hair, and shoulders.^{1,2} Described in ancient Ayurvedic texts like Kshudrarogadhikaa, Darunaka, is predominantly ascribed to Vatakaphaj, representing a

disorder of the scalp that gives rise to itching, loss of lustre, weakening of roots, and hair fall.³

Dandruff commonly affects nearly half of the pre-pubertal population, irrespective of gender and ethnicity.⁴ The estimated prevalence of dandruff ranges between 50 to 70 percent in the overall population.^{2,5} This widespread condition not only causes discomfort but also leads to embarrassment and negatively impacts the quality of life for those affected.⁶ Despite the high prevalence, the

precise etiology of this skin condition remains uncertain. The central dandruff hypothesis remains that the lipophilic yeast *Malassezia furfur* is the causal agent of dandruff.⁷ However, it appears to be a multifaceted condition associated with various intrinsic and environmental factors, such as sebaceous secretions, skin surface fungal colonization, individual susceptibility and interactions between these factors, contributing to its pathogenesis as depicted in Figure 1.⁸

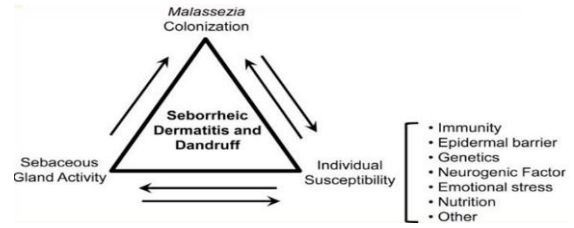


Figure 1: Predisposing factors and their interactions in the pathogenesis of dandruff.

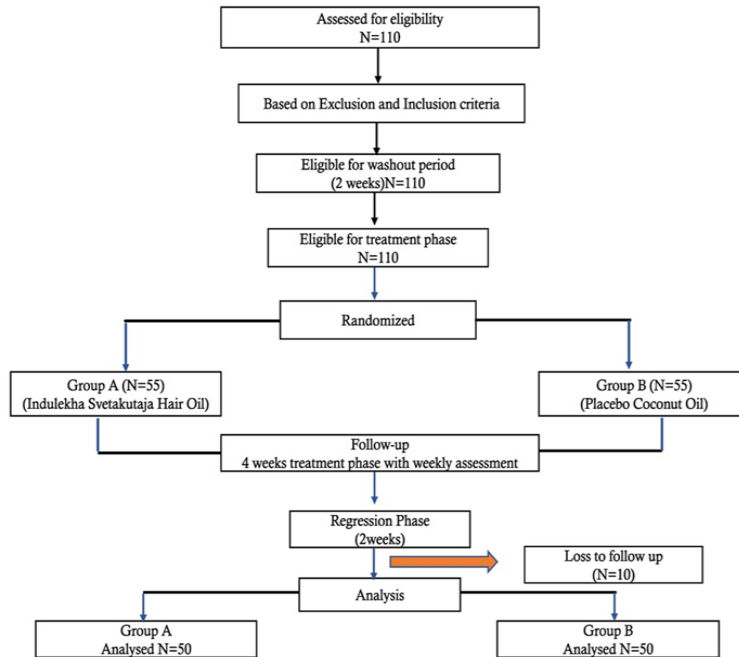


Figure 2: Study flow chart.

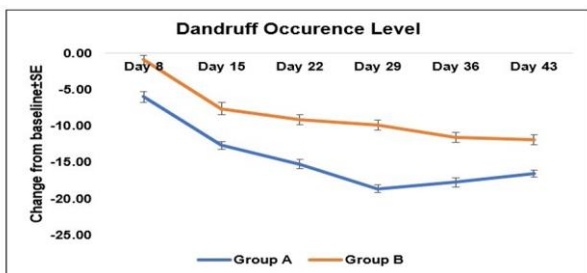


Figure 3: Change in dandruff occurrence level at various time points compared to baseline.

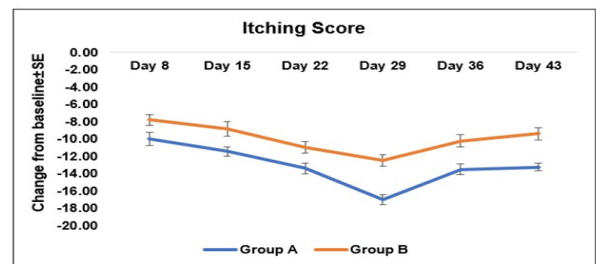


Figure 5: Change in itching score at various time points compared to baseline.

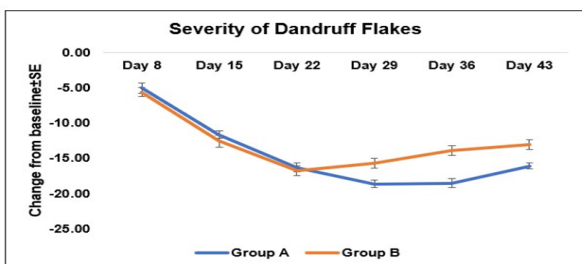


Figure 4: Change in severity of dandruff Flakes at various time points compared to baseline.

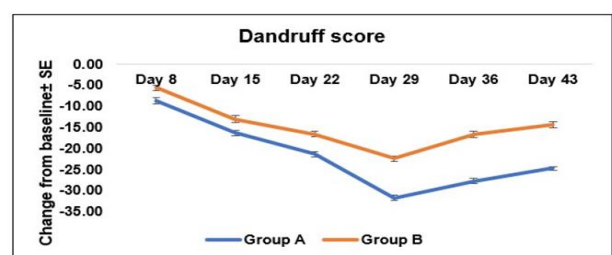


Figure 6: Change in dandruff score at various time points compared to baseline.

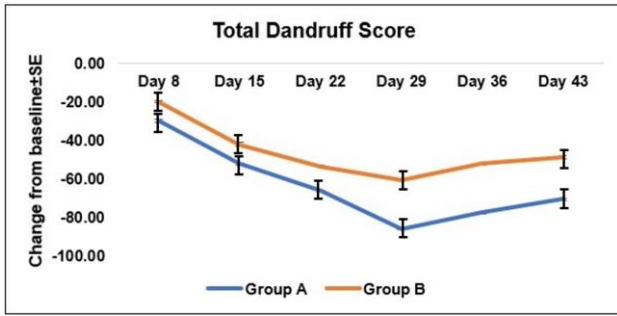


Figure 7: Change in total dandruff score at various time points compared to baseline.

Currently the market is saturated with numerous anti-dandruff products that claim to effectively reduce dandruff and provide relief. However, the extensive range of available options present a challenge for individuals seeking an effective, sustainable treatment with no side effects. In recent times, there has been a growing interest in investigating herbal remedies for managing dandruff. These remedies are perceived safe and often associated with fewer side effects when compared to synthetic alternatives.⁹

In India, it is a customary practice to prepare hair oils infused with various medicinal ingredients that are believed to promote hair growth. The Charaka Samhitha describes the importance of oiling the hair and scalp to maintain good hair health and prevent hair loss.¹⁰ Recent studies highlight various natural remedies, both individually and in combination, exhibit efficacy in combating dandruff. These findings validate the Ayurvedic approach to dandruff treatment, emphasizing the significance of herbal formulations in addressing this condition. Plethora of herbs have been employed for hair treatments, but lack of sound scientific information limits their usage with confidence.^{11,12}

This study aims to evaluate the anti-dandruff efficacy and safety of Indulekha Svetakutaja Hair Oil in reducing dandruff severity following a specified treatment duration of 4 weeks and observing its effect over 2 weeks of regression phase.

METHODS

This study was approved by an Independent Ethics Review Board, conducted in accordance with current standards for Good Clinical Practices. Each subject provided a written informed consent prior to participating in any study-related activities. The study was registered on the Clinical Trial Registry of India (CTRI) website at <http://ctri.nic.in/> (CTRI number: CTRI/2021/09/036884).

Study design

This was a double-blind, randomized study consisting of two test groups with an allocation ratio of 1:1: Group A (Indulekha Svetakutaja Hair Oil) and Group B (Placebo Coconut hair oil). Svetakutaja Indulekha hair oil is an

Ayurvedic proprietary oil formulated with a unique blend of herbal ingredients known for their therapeutic properties. It is specifically designed for treating dandruff and dandruff-related hair and scalp problems. The ingredients of the hair oil are: Svetakutaja, Nimba, Amalaki, Brahmi, Bringha, Kumari, Palandu, Baheda, Nalikera, Rosemary Oil and Prakratik Sugandh, which have been used traditionally in Ayurveda for their hair-nourishing and scalp-soothing properties. Commercially available marketed benchmark coconut oil was used as a placebo and a comparator in the study.

Subjects were selected to group A or B by randomization and were retained in the study for 8-9 weeks: a 2–3 weeks pre-treatment washout phase, followed by a treatment phase of 4 weeks, and concluded with a regression phase lasting for 2 weeks. The subjects were screened on the study inclusion-exclusion criteria, Ayurvedic Dashvida Pariksha and Prakriti Analysis questionnaire along with dermatological assessment for dandruff severity was performed. Those subjects who had moderate dandruff (adherent and non-adherent dandruff score ≥ 40) and met all other inclusion and exclusion criteria continued onto the pre-treatment washout phase of the study. Subjects underwent two weeks of wash out period during which they were provided with neutral shampoo to use at home and were instructed not to use it more than thrice a week. After two weeks of washout period, baseline assessments were performed and subjects were given their respective test products after randomization.

During the test phase, subjects in group A applied the allocated test oil (Indulekha Svetakutaja Hair Oil) and Subjects in Group B applied the allocated (Placebo coconut Hair Oil) to their hair and were instructed to keep it minimum for 30 minutes or overnight three times a week at home, followed by washing with a neutral shampoo (no anti-dandruff active) for a period of 4 weeks. Dandruff was assessed using dermatological parameters such as dandruff occurrence level, both adherent and non-adherent dandruff, total dandruff score, severity of dandruff flakes, itching score, etc., at baseline and at weekly intervals over the entire study duration.

Instrumental measurement (TEWL) was also performed to assess the skin barrier function. The subject's hair and scalp quality were evaluated with the subject self-assessment questionnaire. Subjects were restricted to use only the provided oil and shampoo and were not permitted to use any hair care products, treatments or styling products. They were also restricted from undergoing any chemical treatment or hair cut during the entire study period. The detailed study flow is presented in Figure 2.

Study population

Healthy male and female subjects from 18 to 42 years of age who suffered from dandruff were recruited from the general population. Potential subjects were initially

screened using ayurvedic Dashavida Pariksha and Prakriti Analysis questionnaire and then assessed by the dermatologist using adherent and non-adherent dandruff scale to quantitate total dandruff severity. To be eligible to participate in the test phase of the study, subjects were required to have a total dandruff score ≥ 40 at the baseline visit before initiation of treatment.

Subjects were excluded if they had a clinical hair and scalp condition that may impact the dandruff condition; use of anti-inflammatory, steroids or anti-fungal medications; history of serious illness that may require regular systemic medications; use of any other medicated or anti-dandruff oil/ hair care products within last 2 month. In this study, 110 subjects were recruited into test phase and 100 subjects completed the whole study. There was no adverse event reported in this study.

Statistical analysis

A sample size of 50 subjects in each group was sufficient to detect statistical significance with 80% power and 95% confidence interval. Continuous data are presented as mean and standard deviation while, for categorical data, the frequency and percentage are presented. Based on the normality of the data, Paired t-test or Wilcoxon-Signed Rank test was used to compare the parameters with respect to baseline whereas unpaired t-test or Mann-Whitney U-test was used to compare the parameters among the test groups.

RESULTS

Herbal hair oil is one of the most well recognized hair treatments. Herbal hair oil not only moisturizes scalp but also reverses dry scalp and dry hair condition. It provides numerous essential nutrients required to maintain normal function of sebaceous glands and promotes natural hair growth. The results of the present study indicate a reduction in dandruff levels for all participants who used Svetakutaja Indulekha hair oil regularly for 4 weeks. Every subject using Svetakutaja Indulekha Hair Oil expressed extreme satisfaction with the product. The demographic characteristics of the subjects is outlined in table 1.

Table 1: Demographic characteristics of the subjects.

Characteristics	Value
Males (N, %)	27 (27%)
Females (N, %)	73 (73%)
Age range	18-42

The Anti dandruff activity was carried out by measuring various dermatological parameters such as hair quality, visible flakes, visual scalp condition, dandruff occurrence level, severity of dandruff flakes, adherent dandruff, non-adherent dandruff, itching score, dandruff score, occurrence level, total dandruff score.

Instrumental measurement such as TEWL was also taken into consideration along with subject self-assessment as represented in table 2 and 3. A significant anti-dandruff benefits were observed for group A in comparison with group B during the entire study period.

Visible flakes

A 1-10 scale was used by trained evaluator to score the number of visible flakes after combing the hair. The mean values of visible flakes significantly decreased from 7.77 units to 1.69 units in group A with regular usage for 4 weeks, in group B also there was a decrease which was found to be lesser in comparison to Group A.

Dandruff occurrence level

This scale grades dandruff levels from 0-5. For the scoring the scalp was divided into 4 sections in each half and the dandruff for each section were graded separately for all the parameters. Within 1 week of regular use of group A hair oil, there was a significant reduction in dandruff occurrence level when compared to baseline where as in 2 weeks of continuous usage there was a significant reduction in dandruff occurrence level in comparison to group B as shown in Figure 3.

Severity of the dandruff flakes

Most prevalent type of flakes noted in each section was graded in this parameter using a 0-5 scale. An average score for each section based on the most prevalent type of flakes was used. The severity of the dandruff reduced to 18.58 units in group A where as in group B it was found to be 15.68 units on comparison to the baseline as shown in Figure 4.

Non-adherent dandruff scale

Again 0-5 grading photo numerical scale was used to grade dandruff which were based on the visibility of loose flakes in the hair shafts, near the scalp but not attached to the scalp. In group A non-adherent dandruff also showed noticeable difference as early as week 1 which was found to be progressive.

Adherent dandruff scale

A photo numerical scale ranging from 0 to 5 was employed to grade visibly attached dandruff on the scalp. Over the course of four weeks, the mean value of adherent dandruff exhibited a significant reduction, where the decrease was noted to be 19.12 in group A after 4 weeks of treatment. In contrast, for group B, the decrease was noted to be 15.4 units over the same time frame.

Itching score

Subjects were asked to report the itching sensation on their scalp using a 0-5 scale, and their responses were recorded as the itching score. After regular usage of products for four weeks, the itching score of group A subjects demonstrated a significant reduction of 17.02 units, compared to 12.5 units reduction in the group B as shown in Figure 5.

Dandruff scores

The dandruff score was calculated by combining both adherent and non-adherent dandruff parameters which were based on 0-5 dermatological evaluation scale.

With regular usage of test products for 4 weeks, both adherent and non-adherent dandruff score demonstrated a significant reduction of 31.74 units in group A when

compared to group B where the reduction was by 22.47 units as shown in Figure 6.

Total dandruff score

Group A demonstrated a significant and substantial improvement in mean values of Total Dandruff score, a composite measure encompassing various factors such as dandruff occurrence level, severity of dandruff flakes, itching score and the overall dandruff. At baseline, group A total Dandruff score was 113.3±8.4, which decreased to 27.3±.35 by the end of the treatment phase. In contrast, group B started with an identical baseline mean value to group A of 113.5±10.5, however at the end of treatment phase group B showed a mean value of 52.9±8.8. Group A demonstrated a 70.62 units reduction, surpassing the 48.79 units reduction observed in group B during regression phase. Group A consistently demonstrated statistical significance (p<0.05) at all time points as shown in Figure 7.

Table 2: Mean values of various parameters assessed at various time points throughout the study.

Parameters	Sample size (n=50)	Timepoints						
		Baseline	Day 8	Day 15	Day 22	Day 29	Day 36	Day 43
Hair quality	Group A	3.3±0.99	3.38±0.97 *	3.74±0.72 **	3.94±0.42 **	3.98±0.32 **	3.96±0.28 **	3.96±0.28 **
	Group B	3.82±0.75	3.9±0.65 *	3.94±0.59 *	3.98±0.51 *	3.98±0.51 *	3.94±0.55 *	3.96±0.53 *
Visible flakes	Group A	7.77±0.74	6.45±0.82 **	4.8±0.75 **	2.96±0.83 **	1.57±0.67 **	1.69±0.62 **	1.62±0.67 **
	Group B	7.69±0.65	7.15±0.6 *	5.65±0.65 *	3.85±0.72 *	3.5±0.61 *	4.01±0.57 *	4.41±0.62 *
Visual scalp condition	Group A	1.56±0.88	1.56±0.88	1.36±0.75 *	1.22±0.58 *	1.18±0.52 *	1.18±0.52 *	1.2±0.57 *
	Group B	1.92±1	1.92±1	1.77±0.97 *	1.66±0.94 *	1.62±0.92 *	1.62±0.92 *	1.62±0.92 *
Dandruff occurrence level	Group A	25.1±3.01	19.1±4.52 *	12.4±2.79 **	9.86±2.95 **	6.48±2.3 **	7.36±3.28 **	8.56±0.99 **
	Group B	25.5±3.7	24.6±3.31 *	17.8±4.86 *	16.4±3.63 *	15.64±3.22 *	13.9±3.11 *	13.58±2.79 *
Severity dandruff flakes	Group A	24.4±3.64	19.4±4.98 *	12.8±3.69 *	8.12±3.4 *	5.82±2.21 **	5.9±2.29 **	8.36±0.75 **
	Group B	25.3±3.75	19.7±4.79 *	12.7±2.94 *	8.52±2.95 *	9.62±2.81 *	11.4±3.91 *	12.2±2.87 *
Non-adherent dandruff	Group A	16.5±2.55	13.6±2.05 **	11.9±3.12 **	9.92±3.29 **	3.82±3.03 **	6.64±2.51 **	8.28±1.21 **
	Group B	16.6±3.68	16.4±5.57 *	14.47±4.78 *	12.7±3.88 *	9.5±3.05 *	13.04±3.25 *	14.14±3.16 *
Adherent dandruff	Group A	25.2±2.85	19.3±4.69 *	13.4±3.53 *	10.3±3.6 **	6.08±2.27 **	7.24±2.58 **	8.62±1.5 **
	Group B	26.2±2.86	20.8±5.1 *	15.3±5.17 *	13.5±4.32 *	10.8±2.71 *	13.1±3.14 *	14.3±3.04 *
Itching score	Group A	22.1±6.17	12.1±3.49 *	10.6±3.44 *	8.66±4.21 *	5.06±3.61 **	8.56±1.21 **	8.82±1.3 **
	Group B	19.8±4.35	12.02±2.71 *	11±3.56 *	8.88±4.15 *	7.34±3.98 *	9.6±1.73 *	10.4±2.28 *
Dandruff score (adherent+ non-adherent dandruff)	Group A	41.6±1.76	32.9±5.28 **	25.3±6.14 **	20.2±6.73 **	9.90±4.64 **	13.9±4.52*	16.9±2.17 **
	Group B	42.8±3.13	37.2±8.92 *	29.7±9.46 *	26.2±7.6 *	20.3±5.33 *	26.1±5.43*	28.4±5.47*

Continued.

Parameters	Sample	Timepoints						
Occurrence level (w.r.t adherent dandruff)	Group A	79.8±17.4	48.4±22.1 **	21.5±9.36 **	13.2±5.97 **	5.48±3.74 **	7.32±4.58 **	9.23±2.05 **
	Group B	84.3±19.1	64.9±19.9 *	35.7±18.5 *	28.8±14.9 *	21.13±7.6 *	23.4±8.95 *	24.9±9.51 *
Total dandruff score	Group-A	113.3±8.4	83.4±13.2 **	61.1±12.9 **	46.9±11.9 **	27.3±9.35 **	35.7±7.85 **	42.6±3.01 **
	Group-B	113.5±10.5	93.4±14.5 *	71.3±15.2 *	59.9±12.8 *	52.9±8.8*	61.1±11.4 *	64.7±10.69 *
Tewameter	Group-A	14.7±7.51	12.8±4.13 *	12.2±3.66 *	11.5±3.34 *	10.7±3.36 *	12.1±4.15 *	12.2±3.75 *
	Group-B	14.4±3.73	13.8±4.52 *	12.5±3.87 *	11.8±4.53 *	12.0±3.81*	12.3±3.52 *	13.1±3.37 *

*Significant in comparison to baseline, **Significant in comparison to placebo regime (group B) (p<0.05).

Table 3: Subjects assessment based on questionnaire.

Questions	Day 8 (%)	Day 15 (%)	Day 22 (%)	Day 29 (%)	Day 36 (%)	Day 43 (%)
The product is effective in reducing dandruff	39 (78)	38 (76)	41 (82)	49 (98)	43 (86)	42 (84)
The product makes my hair soft	49 (98)	49 (98)	49 (98)	49 (98)	-	-
The product makes my hair look shiny	41 (82)	45 (90)	46 (92)	45 (90)	-	-
The product does not dry my hair	48 (96)	47 (94)	45 (90)	46 (92)	-	-
The product makes my hair nourished	46 (92)	48 (96)	47 (94)	47 (94)	-	-
The product keeps my hair and scalp healthy	46 (92)	46 (92)	47 (94)	47 (94)	-	-
The product prevents dandruff recurrence on scalp	43 (86)	42 (84)	37 (74)	45 (90)	-	-
The product provides a relief from the itching	25 (50)	30 (60)	47 (94)	48 (96)	-	-
The product is efficient against adherent dandruff	44 (88)	44 (88)	47 (94)	49 (98)	45 (90)	44 (88)
The product is efficient against non-adherent dandruff	44 (88)	44 (88)	47 (94)	49 (98)	44 (88)	44 (88)

n=Number of subjects, %= Percentage of subjects in agreement.

Scalp barrier function

In the study Tewameter was used to understand the impact of test products on the scalp barrier function. It was noticed that the TEWL values decreased over time indicating improved barrier function.

Subjects assessments

Subjects who regularly used Group A hair oil reported improvement in the condition, 49 (98%) experienced a significant reduction in both adherent and non-adherent dandruff levels, along with softer hair. Additionally, 48 (96%) reported a decrease in itching, while 46 (94%) noted that their hair appeared nourished, contributing to an overall enhancement in scalp and hair health as depicted in Table 3.

DISCUSSION

Herbal hair oil is one of the most well recognized hair treatments. It not only moisturizes scalp but also reverses dry scalp and dry hair condition. It provides numerous

essential nutrients required to maintain normal function of sebaceous glands and promotes natural hair growth.¹³ Hydration levels also play an important role in shaping the microbiome of the scalp surface this is in accordance with a study conducted by Saxena R et al.¹⁴ The present study demonstrates that the Polyherbal Hair Oil, (Svetakutaja Indulekha hair oil) is very effective in the management of dandruff. Even today, the debate on whether dandruff has to be treated as a disease or a disorder continues. The spectrum of dandruff is difficult to define because it blurs with seborrhoeic dermatitis and some other scaly conditions. However, dandruff is non-inflammatory in nature. The real cause for dandruff formation from the normal physiological spectrum of scaling is yet to be understood, despite an incomplete understanding of its origin, one of the associated etiological factors is Malassezia sp. colonization.⁴ Few ingredients in the Indulekha Svetakutaja Hair Oil, Svetakutaja (*W. tinctoria*) and nimba has demonstrated antifungal properties. Additionally, preliminary research on cell lines suggests that extracts of Svetakutaja may reduce the proliferation of keratinocytes. The combination of antifungal activity and the ability to inhibit keratinocyte proliferation in Svetakutaja makes it

highly effective in managing dandruff also localized immune response triggered by nimba provides extended protection against dandruff relapse over an extended period as suggested by similar study conducted by JR Krishnamoorthy et al.¹⁵ Amla is rich in vitamin C, tannins and minerals such as phosphorus, iron and calcium which provides nutrition to hair.^{16,17} Brahmi, with its alkaloids, enhances protein kinase activity, calming and soothing the scalp, balancing sebum levels, and preventing dandruff.^{17,18} Bhringraj possess anti-inflammatory properties that can provide relief to the scalp, reducing itchiness and irritation, which can indirectly aid in managing dandruff.¹⁹ Collectively, these ingredients make Svetakutaja Indulekha Hair Oil a comprehensive solution for dandruff management, addressing various aspects of its complex nature.

CONCLUSION

The findings of the present study in the management of dandruff are highly promising. This polyherbal solution has demonstrated its effectiveness in combating dandruff, reducing itchiness and improving overall scalp and hair health. It stands out as a clinically proven and safe option for regular use. The unique combination of herbal ingredients, characterized by antimicrobial, anti-inflammatory, and nourishing properties, offers a holistic approach to addressing the complexities of dandruff. The comprehensive assessment of dermatological parameters throughout the study, along with statistical verification, adds credibility to the observed positive outcomes. The encouraging results from this study provide a strong foundation for further research and exploration in this field, aiming to develop innovative and holistic solutions for dandruff management.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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