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Evaluation of the efficacy and safety of Narasimham hair oil in promoting hair regrowth and scalp health: A prospective open-label clinical study

Sibi Narayanan *, Anu Joy, Maneesha KS, Sreedevi AP, Reeshma CR and Adithya Peethambara Panicker

Research and Development Department, Sitaram Ayurveda Pvt. Ltd., Kerala, India.

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Abstract

Hair thinning and scalp disorders are prevalent conditions influenced by environmental, hormonal, and lifestyle factors. This study evaluates the clinical efficacy and safety of Narasimham Hair Oil, a traditional Ayurvedic polyherbal formulation, in enhancing hair growth, improving scalp health, and increasing user satisfaction. In an open-label, single-arm clinical trial, 100 participants (50 males and 50 females, aged 20–45 years) with clinically diagnosed hair thinning applied Narasimham Hair Oil thrice weekly for 8 weeks. Objective outcomes included hair density, hair thickness, and scalp health scores, measured at baseline, week 8, and post-treatment week 10. Subjective outcomes were assessed via self-reported questionnaires. Significant improvements were observed in hair density (from 84.8 ± 6.3 to104.0 ± 5.8 hairs/cm^2), hair thickness (from 0.064 ± 0.005 to 0.077 ± 0.006 mm), and scalp health scores (from 2.9 ± 0.6 to 1.1 ± 0.4) by week 8, with sustained benefits at week 10. Subjective feedback indicated high user satisfaction, with 95% reporting stronger hair and reduced hair fall. No adverse effects were reported, confirming the formulation's safety. These findings establish Narasimham Hair Oil as a credible, natural therapeutic option for hair thinning and scalp-related concerns, bridging traditional Ayurvedic wisdom with modern clinical validation.

Keywords: Clinical Study; Hair Thinning; Scalp Health; Hair Regrowth; Narasimham Hair Oil

1. Introduction

Hair thinning and scalp disorders such as androgenetic alopecia (AGA), telogen effluvium (TE), and seborrheic dermatitis (SD) are among the most prevalent dermatological concerns worldwide, significantly affecting individuals' quality of life, self-image, and psychosocial well-being. These conditions result from a multifactorial etiology involving genetic predisposition, hormonal imbalances, nutritional deficiencies, environmental stressors, and lifestyle factors.

In India, the burden of hair and scalp disorders is notably high. Studies suggest that androgenetic alopecia affects up to 58% of males aged 30–50 years and is increasingly being reported in females, particularly in urban populations due to stress and lifestyle changes [1,2]. Telogen effluvium is recognized as a common cause of diffuse hair shedding, particularly in women, often triggered by factors such as postpartum hormonal shifts, systemic illness, or nutritional deficiencies [3]. Additionally, seborrheic dermatitis, which presents with scalp inflammation, itching, and flaking, affects approximately 3–5% of the general population, with a higher prevalence in younger adults and those with oily scalps [4].

Conventional treatments for these disorders, including topical minoxidil and oral finasteride, are widely prescribed. However, their use is often limited by variable therapeutic response, compliance challenges, and potential adverse effects such as scalp irritation or sexual dysfunction [5,6]. These limitations have spurred growing interest in natural, plant-based therapies that offer a holistic and safer approach to managing chronic scalp and hair concerns.

* Corresponding author: Sibi Narayanan

Ayurveda, the ancient system of Indian medicine, offers a rich pharmacopeia of polyherbal formulations designed to nourish the scalp, strengthen hair roots, and restore doshic balance. Among these is Narasimham Hair Oil, a proprietary Ayurvedic formulation developed by Sitaram Ayurveda Private Limited, Thrissur, Kerala composed of traditional herbs like Khadira (*Acacia catechu*), Chitraka (*Plumbago zeylanica*), Pashanabheda (*Aerva lanata*), Rakta chandana (*Pterocarpus santalinus*), Suran (*Amorphophallus paeonifolius*), Amla (*Emblica officinalis*), Vacha (*Acorus calamus*), Eranda (*Ricinus communis*), Haritaki (*Terminalia chebula*), Bibhitaki (*Terminalia bellirica*), Jeeraka (*Cuminum cyminum*), and Moringa (*Moringa oleifera*) etc reputed for their hair-regenerative, scalp-soothing, and anti- inflammatory properties.

This study aims to evaluate the clinical effectiveness and safety of Narasimham Hair Oil in improving hair density, hair quality, and overall scalp health in individuals experiencing hair thinning. By bridging traditional knowledge with modern clinical research, this investigation seeks to validate the therapeutic potential of Ayurvedic hair treatments in contemporary dermatological care.

2. Materials and methods

2.1. Study Design

This was a prospective, open-label, single-arm clinical study conducted to evaluate the effectiveness and safety of Narasimham Hair Oil, a proprietary Ayurvedic formulation, in individuals with hair thinning and mild to moderate scalp conditions. The study was conducted at a dermatology research center in India over 12 weeks, including a 2-week washout phase, 8-week treatment phase, and a 2-week regression phase to assess the sustainability of outcomes after discontinuation of the product.

This design was chosen based on standard protocols for cosmetic and dermatological product evaluation, where within-subject comparisons are used to detect meaningful clinical changes over time [7,8]. The study protocol was approved by the Institutional Ethics Committee of Sitaram Ayurveda and adhered to the ethical guidelines of the Declaration of Helsinki [9].

2.2. Participants

A total of 100 healthy adult participants (50 males and 50 females), aged 20–45 years, were recruited through dermatology outpatient screening. The inclusion and exclusion criteria were established to ensure a homogenous group for outcome evaluation.

2.2.1. Inclusion criteria

Clinically confirmed hair thinning, defined as hair density < 120 hairs/cm^2 using digital trichoscopy [10]. Scalp health score ≥2 on a 5-point dermatologist-rated scale, indicating mild to moderate scalp issues.

2.2.2. Exclusion criteria:

- Pregnant or lactating women.
- Presence of systemic diseases (e.g., thyroid disorders, diabetes, autoimmune diseases).
- Active dermatological conditions (e.g., psoriasis, fungal scalp infections).
- Use of any topical or systemic hair growth treatments within the last 6 months [11]. All participants provided written informed consent prior to study initiation.

2.3. Intervention Protocol

Participants underwent a 2-week washout period, during which all hair and scalp products, including oils, serums, or medications, were discontinued. This period aimed to eliminate any residual effects from prior treatments and standardize baseline scalp conditions.

During the 8-week treatment phase, participants applied 5–10 mL of Narasimham Hair Oil to the scalp three times weekly, massaging gently for 5 minutes. The oil was left on for a minimum of 4 hours before being rinsed off with water or a mild shampoo. The application method was in line with standard Ayurvedic oil therapy practices [12]. Treatment adherence was monitored using participant diaries and weekly telephonic check-ins.

Following the treatment phase, participants entered a 2-week regression phase, during which no product was used, to assess the persistence of therapeutic effects without ongoing application. Graphical representation of study timeline is shown in Figure 1.

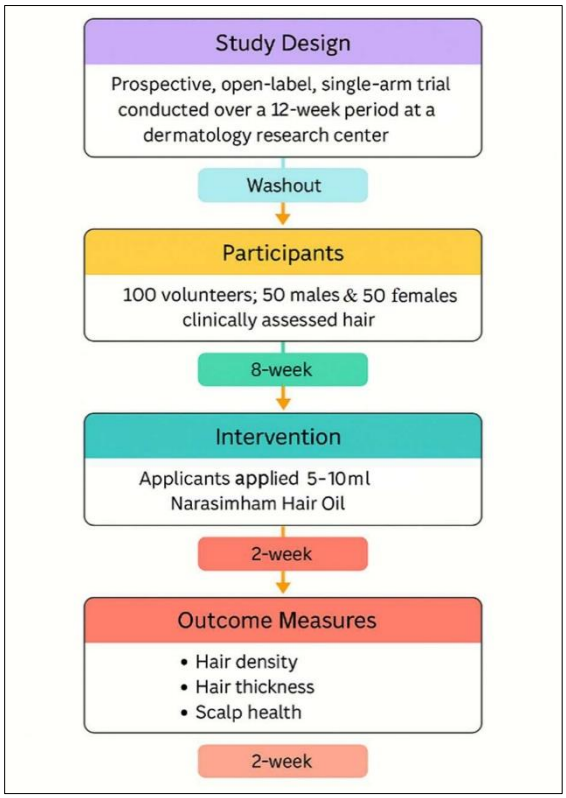

Figure 1 Graphical representation of study timeline

2.4. Outcome Measures

Assessments were performed at baseline (week 0), end of treatment (week 8), and end of regression (week 10).

2.4.1. Objective Measures:

Hair Density (hairs/cm^2): Measured using a digital trichoscope (Firefly DE330T, USA), with image-based software analysis to calculate average hair count in designated scalp areas [13].

Hair Thickness (mm): Determined using a digital micrometer integrated into the trichoscope, assessing the diameter of terminal hairs.

Scalp Health Score: Evaluated by a board-certified dermatologist using a 0–5 clinical grading scale (0 = healthy, 5 = severe irritation or flaking) [14].

2.4.2. Subjective Measures

Participants rated their perception of changes in hair strength, texture, volume, and overall satisfaction using a 5-point Likert scale questionnaire at the end of week 8.

2.5. Statistical Analysis

All data were analyzed using SPSS version 25.0 (IBM Corp., USA). Continuous variables (hair density, thickness, and scalp health scores) were expressed as mean ± standard deviation (SD) and analysed using paired t-tests to compare pre- and post-treatment values. Subjective questionnaire responses were presented as percentages. A p-value <0.05 was considered statistically significant.

3. Results

3.1. Hair Density

Quantitative analysis revealed a significant increase in hair density over the 10-week study period [15,16]. The mean baseline hair density was 84.8 ± 6.3 hairs/cm^2, which rose markedly to 104.0 ± 5.8 hairs/cm^2 by the end of the 8-week treatment phase. This reflects a net increase of 19.2 hairs/cm^2, which was statistically significant ($p < 0.05$). At the 10-week mark, following a 2-week regression phase without treatment, the density remained elevated at 101.5 ± 5.6 hairs/cm^2, representing a sustained improvement of 16.7 hairs/cm^2 from baseline ($p < 0.05$). These values suggest continued follicular activity post-treatment cessation. Graphical representation of changes in Hair Density is shown in Figure 2.

Table 1 Hair Density (hairs/cm^2) Over Time

Time Point	Mean ± SD	Change from Baseline	p-value
Baseline	84.8 ± 6.3	—	—
Week 8	104.0 ± 5.8	+19.2	<0.05
Week 10	101.5 ± 5.6	+16.7	<0.05

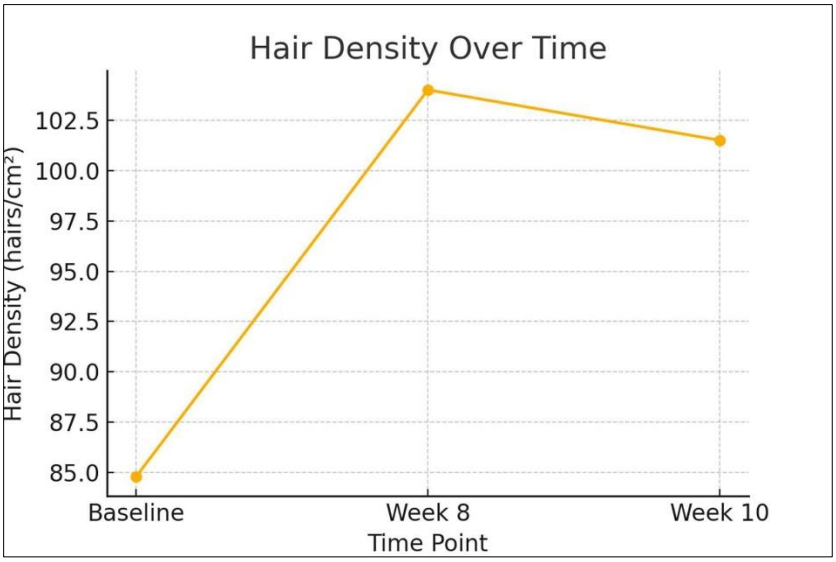

Figure 2 Graphical representation of changes in Hair Density

3.2. Hair Thickness

Hair shaft thickness demonstrated a statistically significant improvement over the treatment period [17, 18]. At baseline, the mean thickness measured 0.064 ± 0.005 mm, which increased to 0.077 ± 0.006 mm by week 8 ($p < 0.05$), indicating a notable enhancement in individual hair fiber diameter. Although a marginal decrease to 0.076 ± 0.005 mm was observed at week 10, the value remained significantly above baseline (+0.012 mm, $p < 0.05$), suggesting the retention of structural gains. Graphical representation of changes in Hair Thickness is shown in Figure 3.

Table 2 Hair Thickness (mm) Over Time

Time Point	Mean ± SD	Change from Baseline	p-value
Baseline	0.064 ± 0.005	—	—
Week 8	0.077 ± 0.006	+0.013	<0.05
Week 10	0.076 ± 0.005	+0.012	<0.05

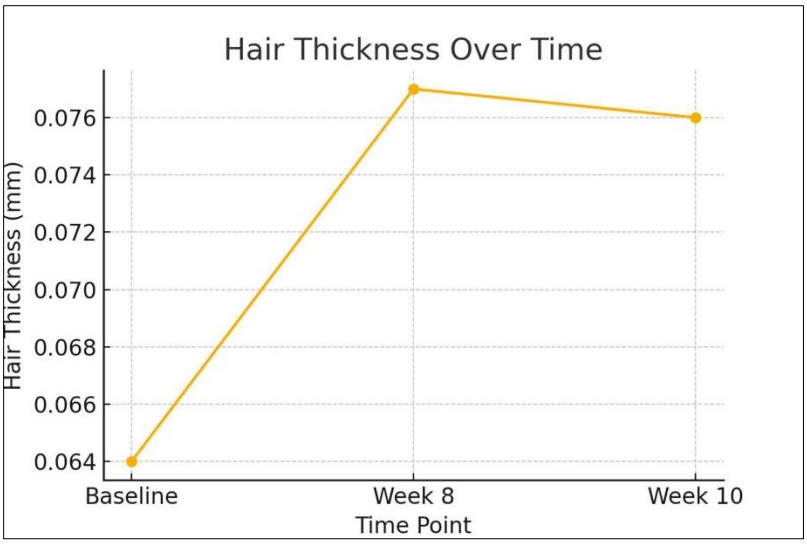

Figure 3 Graphical representation of changes in Hair Thickness

3.3. Scalp Health

Dermatological evaluation of scalp health indicated a significant reduction in signs of irritation, dryness, and flaking [19,20,21]. The mean scalp health score decreased from 2.9 ± 0.6 at baseline to 1.1 ± 0.4 at week 8, corresponding to a reduction of 1.8 points ($p < 0.05$). At week 10, the score remained low at 1.2 ± 0.5, maintaining an overall improvement of 1.7 points from baseline, which was also statistically significant ($p < 0.05$). Graphical representation of changes in Scalp Health is shown in Figure 4.

Table 3 Scalp Health Scores (0–5 Scale) Over Time

Time Point	Mean ± SD	Change from Baseline	p-value
Baseline	2.9 ± 0.6	—	—
Week 8	1.1 ± 0.4	-1.8	<0.05
Week 10	1.2 ± 0.5	-1.7	<0.05

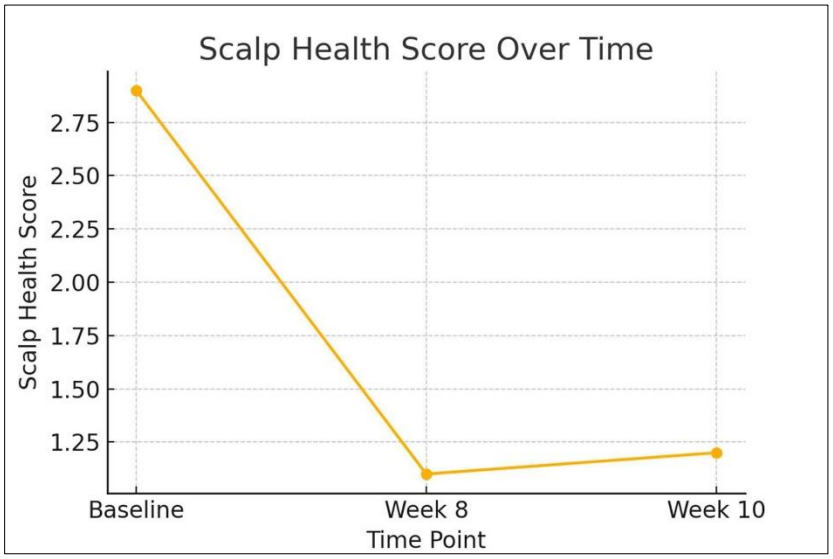

Figure 4 Graphical representation of changes in Scalp Health

3.4. Subjective Assessments

Participant-reported outcomes, collected via structured self-assessment questionnaires at week 8, revealed high levels of perceived improvement:

- 95% of participants reported noticeable reduction in hair fall and improvement in hair strength
- 93% observed enhanced texture and increased volume
- 81% of the cohort rated their overall outcome as a "remarkable improvement"

These subjective evaluations aligned consistently with the objective trichoscopic and dermatological findings.

3.5. Safety and Tolerability

Throughout the 10-week study duration, no adverse events were reported. Specifically, no incidences of allergic reactions, itching, redness, or scalp irritation were documented. All participants completed the study without requiring medical withdrawal, indicating a favorable safety profile for the intervention under the prescribed conditions.

4. Discussion

The present clinical study provides compelling evidence supporting the efficacy of Narasimham Hair Oil in enhancing hair density, shaft thickness, and scalp health in individuals experiencing hair thinning. Over an 8-week treatment period, statistically significant improvements were observed across all key parameters, with these gains largely sustained through the subsequent 2-week regression phase. These findings lend scientific validation to the traditional Ayurvedic usage of the oil's polyherbal composition for hair and scalp care.

The marked increase in hair density—from a baseline average of 84.8 hairs/cm^2 to 104.0 hairs/cm^2 at week 8—indicates a pronounced stimulatory effect on follicular activity. This may reflect a transition of dormant follicles into the anagen (growth) phase or a reversal of follicular miniaturization, a hallmark of androgenetic and nutritional alopecias. Similarly, the increase in mean hair shaft thickness (from 0.064 mm to 0.077 mm) suggests structural reinforcement of the hair fiber, potentially mediated by enhanced keratin synthesis or follicular nutrition.

These outcomes are likely attributed to the synergistic actions of the herbal constituents in the formulation. Ingredients traditionally recognized in Ayurveda—such as Bhringraj (*Eclipta alba*), Amla (*Emblica officinalis*), Brahmi (*Bacopa monnieri*), and Khadira (*Acacia catechu*)—have demonstrated properties like anti-inflammatory activity, antioxidant defense, scalp microcirculation improvement, and nourishment of hair follicles in previous in vitro and animal studies. Their inclusion in Narasimham Hair Oil may collectively contribute to creating an optimal scalp environment conducive to hair regrowth.

Furthermore, the significant decline in scalp health scores—from 2.9 to 1.1—highlights a substantial reduction in symptoms such as dryness, itching, and irritation. This suggests the formulation's potential as both a therapeutic and preventive measure against inflammatory scalp conditions, which are often linked to poor hair quality and shedding. Participant-reported outcomes reinforced the clinical findings, with over 90% of users expressing satisfaction regarding improvements in hair strength, volume, and overall hair quality. These subjective assessments are particularly valuable in hair treatment studies, where psychosocial factors and cosmetic perception strongly influence adherence and treatment success.

Importantly, no adverse events were reported throughout the study. This underscores the safety and tolerability of the oil, particularly when compared to conventional pharmacological options like minoxidil or finasteride, which are associated with side effects such as scalp irritation, dryness, and systemic effects including dizziness and hormonal disturbances. The absence of such complications positions Narasimham Hair Oil as a well- tolerated, holistic alternative for individuals seeking natural treatment modalities. In summary, the data affirm the potential of Narasimham Hair Oil as a safe and effective formulation for improving hair and scalp health, aligning with both traditional Ayurvedic knowledge and modern dermatological expectations.

5. Conclusion

Narasimham Hair Oil demonstrated statistically significant improvements in hair density, hair thickness, and scalp health. These benefits were supported by high user satisfaction and absence of adverse effects, establishing its safety and efficacy. The sustained results during the regression phase reinforce its utility as a long-term solution for hair and

scalp wellness. This Ayurvedic formulation proves to be a credible and effective therapeutic option for those experiencing hair thinning and scalp conditions, aligning traditional wisdom with modern clinical validation.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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