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A PROSPECTIVE, OPEN-LABEL, SINGLE-ARM PHASE II CLINICAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF SCURF HERBAL OIL IN THE MANAGEMENT OF DANDRUFF AND HAIR FALL

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ABSTRACT

Introduction: Dandruff and hair fall are common scalp conditions that impact quality of life. Scurf Herbal Oil, a topical Ayurvedic formulation combining *Danthapala (Wrightia tinctoria)* and *Durdura (Datura metel)* infused in coconut oil, has been developed by Sitaram Ayurveda. This Phase II clinical trial aimed to evaluate the efficacy and safety of Scurf Herbal Oil in managing mild to moderate dandruff and hair fall. **Methodology:** A prospective, open-label, single-arm Phase II clinical trial was conducted over 6 weeks with 120 adult participants. Participants applied Scurf Herbal Oil topically to the scalp. The primary outcomes were reductions in dandruff severity and hair fall, assessed through clinical evaluations, ie Dandruff Severity Index scoring. **Results:** The trial demonstrated a 69% reduction in dandruff severity and a 67% decrease in hair fall by the end of 6 weeks. Participant satisfaction was high, with 87% reporting visible improvements and 90% expressing interest in continued use. No serious adverse events were reported, indicating an excellent safety profile. **Discussion:** The significant reductions in dandruff and hair fall suggest that Scurf Herbal Oil is an effective topical treatment for mild to moderate scalp conditions. The high participant satisfaction and absence of serious adverse events further support its potential as a safe, user-friendly alternative to conventional treatments. The herbal formulation's natural ingredients may contribute to its efficacy and tolerability. **Conclusion:** Scurf Herbal Oil is a promising natural alternative for managing dandruff and hair fall, with demonstrated efficacy and safety in this Phase II trial.

KEYWORDS: Dandruff, Hair fall, Khalitya, Darunaka, Scurf Herbal Oil.

1. INTRODUCTION

Dandruff and hair fall are widespread scalp disorders affecting individuals across diverse age groups and demographics globally, with significant prevalence in India. Dandruff is characterized by scalp flaking, itching, and irritation, while hair fall manifests as excessive hair shedding, often 50% of Indian adults, with contributing factors including nutritional deficiencies, hormonal imbalances, and environmental stressors.[1] These conditions, though not life-threatening, cause considerable psychological distress, negatively impacting self-esteem, confidence, and quality of life.

Conventional treatments, such as medicated shampoos, corticosteroids, antifungal agents, and oral medications, are widely used but linked to weakened hair follicles or scalp inflammation. In India, studies estimate that dandruff affects approximately 50–60% of the adult population, with higher incidence in urban areas due to pollution, stress, and lifestyle factors. Hair fall, similarly prevalent, is reported in nearly 40%.[2]

Prolonged use of synthetic products may result in side effects like scalp dryness, irritation, hormonal disruptions, or reduced efficacy over time.[3] As a result, there is increasing demand for natural and herbal alternatives that provide a safer, gentler approach to scalp care while maintaining therapeutic effectiveness.

Herbal remedies, rooted in traditional systems like Ayurveda, Unani, and Traditional Chinese Medicine, utilize plant-based ingredients with anti-microbial, anti-inflammatory, antifungal, antioxidant, and nourishing properties. These formulations aim to restore scalp health, reduce microbial activity, and strengthen hair follicles, addressing the underlying causes of dandruff and hair fall.[4] Scurf Herbal Oil, a topical herbal formulation, developed by Sitaram Ayurveda Private Limited, combines *Dathurapatra, Dathuraphala, and Dhantapala*, recognized for their scalp-soothing and hair-revitalizing effects. Designed to manage mild to moderate dandruff and hair fall, the oil aims to promote overall scalp and hair health. While anecdotal evidence and preliminary feedback suggest its benefits, rigorous scientific validation is necessary to establish its efficacy and safety.

This clinical study seeks to systematically evaluate the efficacy and safety of Scurf Herbal Oil in individuals with mild to moderate dandruff and hair fall. By employing standardized clinical and dermatological assessment methods, the study aims to provide robust data to support the use of this herbal oil as a viable natural alternative for managing prevalent scalp conditions in India and beyond.

2. Review of literature

2.1 Key Ingredients and Their Properties

2.1.1 Dhurdhoorapathra (*Datura metel* Leaves)

Dhurdhoorapathra, botanically known as *Datura metel*, is valued in traditional medicine for its leaves, which are rich in potent alkaloids such as hyoscyamine, scopolamine, and atropine.[5] These compounds confer antimicrobial, anti-inflammatory, and analgesic properties, making the leaves effective for scalp treatments. The juice extracted from *Datura metel* leaves acts as a carrier, delivering active constituents deep into scalp tissues to alleviate itching, inhibit microbial growth and reduce inflammation.[6]

2.1.2 Dhurdhooraphala (*Datura metel* Fruit)

The fruit of *Datura metel*, known as Dhurdhooraphala, contains similar alkaloids (hyoscyamine, scopolamine, and atropine), which contribute to its antimicrobial and anti-lice properties.[5] When used in powdered form, the fruit serves as a gentle exfoliant, removing dead skin cells and dandruff flakes from the scalp. It also detoxifies the scalp, fostering a clean, microbe-free environment that promotes overall scalp health.[7]

2.1.3 Danthapala (*Wrightia tinctoria* Leaves)

Wrightia tinctoria, commonly used in Ayurveda, is renowned for its leaves, which exhibit *kushtaghna* (skin disease alleviating) and *kapha-pitta shamaka* (balancing Kapha and Pitta doshas) properties.[8] Rich in flavonoids, triterpenoids, and indigo compounds, the leaves possess strong antimicrobial and anti-inflammatory effects, making them effective for treating scalp conditions such as psoriasis, eczema, and dandruff. Regular use reduces itching, scaling, and flakiness, promoting healthier scalp and hair.[9]

2.1.4 Kera Thaila (Coconut Oil)

Coconut oil, extracted from the endosperm of the coconut, is a cornerstone of Ayurvedic formulations due to its cooling, nourishing, and emollient properties.[10] Rich in lauric acid, capric acid, and antioxidants, it offers antifungal, antibacterial, and moisturizing benefits. Coconut oil penetrates the hair shaft, preventing protein loss and strengthening hair, while enhancing the delivery of herbal constituents to the scalp and hair follicles. It maintains scalp hydration, reducing dryness and scaling for a balanced scalp.[11]

Table No. 1: Ingredients of Scurf Oil.

Sl.	Sanskrit Name	Botanical Name	Part	Form
1	Dhurdhoorapathra	*Datura metel*	Leaf	Juice
2	Dhurdhooraphala	*Datura metel*	Fruit	Powder
3	Danthapala	*Wrightia tinctoria*	Leaf	
4.	Kera thaila	Coconut Oil	As Such	

2.2 Synergistic Effects of Ingredients

The combination of *Datura metel* (leaves and fruit), *Wrightia tinctoria*, and coconut oil creates a synergistic effect. *Datura metel* targets microbial infections and inflammation, *Wrightia tinctoria* promotes skin healing and soothes irritations, and coconut oil serves as a carrier and healing agent, enhancing absorption and supporting hair health. This classical oil formulation is particularly effective for Kapha-dominant conditions like dandruff and scalp congestion, improving scalp health, reducing dandruff, and promoting healthy hair growth.[12]

2.3 Literature Review on Dandruff and Hair Fall

2.3.1 Dandruff (Darunaka in Ayurveda)

Dandruff is a chronic, non-inflammatory scalp condition characterized by flaking of dead skin cells, distinct from the more severe seborrheic dermatitis.[13] Modern medical research attributes dandruff to factors such as overgrowth of *Malassezia furfur* (a lipophilic yeast), excessive sebum production, poor scalp hygiene, harsh shampoos, stress, dietary imbalances, and climate changes.[14] The yeast metabolizes sebum triglycerides into free fatty acids, irritating the skin and accelerating cell turnover, leading to visible flaking. Symptoms include flaky white or yellowish scales, itching, and scalp dryness, occasionally with redness or irritation.[15]

In Ayurveda, dandruff is termed *Darunaka*, a condition primarily involving vitiated Vata and Kapha doshas. Symptoms include *Kandu* (itching), *Twak Parushya* (roughness), *Rookshata* (dryness), *Sravana* (discharge), and *Twak Patana* (flaking).[16] Causes (*Nidana*) include a *Ruksha* (dry) and *Sheeta* (cold) diet, stress, and improper hair care practices. Ayurvedic management emphasizes *Snehana* (oleation), *Shiro-abhyanga* (therapeutic head massage), and *Shirodhara* (medicated oil pouring), using herbs like *Wrightia tinctoria* and *Datura metel* in medicated oils to restore scalp balance.[17]

2.3.2 Hair Fall (Khalitya in Ayurveda)

Hair fall manifests in forms such as androgenetic alopecia, telogen effluvium, alopecia areata, scarring alopecia, and hair loss due to nutritional deficiencies.[18] Modern causes include hormonal imbalances (e.g., sensitivity to dihydrotestosterone), stress, thyroid dysfunction, nutrient deficiencies (iron, biotin, zinc), chronic illnesses, medication side effects, fungal infections, and dandruff-related scalp issues.[19]

In Ayurveda, hair fall is known as *Khalitya*, primarily involving aggravated Pitta dosha, with contributions from Vata and Kapha. Pitta burns hair follicles, causing *Bhramsa* (destruction) of hair roots, while Vata dries the roots and Kapha blocks hair pores, impeding growth.[20] Management includes internal *Rasayana* (rejuvenative) therapies and dosha-balancing herbs, alongside external applications of medicated oils (*Tailas*). Severe cases may require *Shirodhara*, *Nasya*, or *Raktamokshana* to pacify doshas and promote hair regeneration.[21]

3. Study Design and Methodology

This investigation was structured as an open-label, single-arm, Phase II clinical trial, aimed at assessing the efficacy and safety of Scurf Herbal Oil for treating mild to moderate dandruff and non-pathological hair fall. The open-label nature of the study means both investigators and participants were aware of the treatment being administered, allowing for real-world usability insights but also carrying a risk of bias.

The trial was divided into two main phases:

- Screening Phase (Weeks 0–2): During this phase, participants underwent clinical evaluation to determine their eligibility. This process ensured a homogeneous study population in line with the inclusion and exclusion criteria.
- Treatment Phase (Weeks 3–6): Participants who met eligibility requirements received the study intervention. Regular evaluations were scheduled throughout this period to monitor progress, ensure compliance, and detect any adverse events.

3.1 Inclusion Criteria

To ensure that participants were representative of the intended treatment population and to maintain safety, the study applied specific eligibility requirements:

- Age 18–50 years: The age range reflects a population where dandruff and hair fall are commonly reported, yet minimizes age-related variability.
- Mild to moderate dandruff**:** Participants needed a clinical confirmation to standardize the severity across subjects.
- Self-reported hair fall: Hair loss not due to underlying diseases (like alopecia areata or thyroid disorders) ensured that observed improvements could be linked to the intervention.
- No other scalp treatments during the study period: This prevented confounding effects from concurrent product usage.

3.2 Exclusion Criteria

To safeguard participants and preserve data integrity, individuals with the following characteristics were excluded:

- Severe or chronic scalp disorders: Conditions like psoriasis or seborrheic dermatitis could interfere with the assessment of dandruff and hair fall outcomes.
- Known hypersensitivity: Allergic reactions to herbal components could pose risks and affect study continuity.
- Pregnancy or lactation: Hormonal changes during these periods can influence hair fall, introducing variability.
- Recent corticosteroid or systemic treatment usage: These could mask or mimic therapeutic outcomes, skewing results.

3.3 Intervention

The treatment protocol involved daily application of Scurf Herbal Oil, designed to address dandruff and promote hair health. Participants from Sitaram Ayurveda were instructed to apply the oil to the scalp each morning before bathing, gently massage it in to improve absorption, leave it on for 30 minutes to maximize effectiveness, and then wash their hair with a mild shampoo.

3.4 Assessment criteria

Table No. 2: Dandruff Severity Index (DSI).

Sr. No	Severity Level	Description
1	0 - No dandruff	Scalp appears clean and healthy
2	1 - Very mild	Occasional flaking in a small area; no inflammation or itching
3	2 - Mild	Sparse flakes visible on hair and scalp; no itching or erythema

4	3 - Moderate	Noticeable flaking and occasional itching; scattered inflammation
5	4 - Severe	Heavy flaking covering large parts of scalp; redness and moderate itching
6	5 - Very severe	Persistent thick flakes; intense itching; significant redness and scaling

3.5 Assessment Schedule

To monitor progress and evaluate outcomes, assessments were carried out at four key points:

1. Baseline (Day 0): Initial evaluations established a reference for clinical comparison.
2. Day 14: Early signs of effectiveness and tolerability were observed.
3. Day 28: Midpoint assessment allowed tracking of progressive changes.
4. Day 42 (Final): End-of-treatment results measured overall effectiveness.

4. RESULTS

A total of 120 participants completed the study. Assessments demonstrated statistically and clinically significant improvements in both dandruff severity and hair fall rates from baseline to the end of the study.

Table No. 3: Dandruff Severity Reduction.

Sr. No	Time Point	Mean DSI Score	% Reduction from Base line
1	Base line	6.2	-
2	Day 14	4.3	30.6%
3	Day 28	2.5	59.7%
4	Day 42	1.9	69.4%

Table No. 4: Hair Fall Rate Reduction.

Sr. No	Time Point	Mean DSI Score	% Reduction from Base line
1	Base line	5.4	-
2	Day 14	4.0	25.9%
3	Day 28	2.5	53.7%
4	Day 42	1.8	66.7%

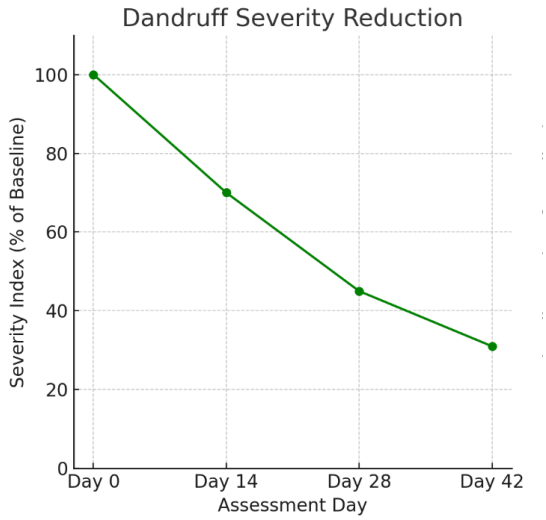

Figure 1: Dandruff Severity Reduction.

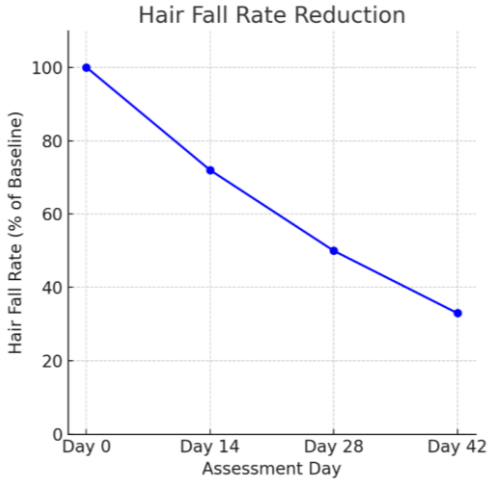

Figure 2: Hair Fall Rate Reduction.

Average improvements were as follows.

- Dandruff Severity Index: 69% reduction
- Hair Fall Grading**:** 67% reduction

Participants reported high levels of satisfaction, and no significant adverse effects were observed, indicating good tolerance of the herbal formulation.

All 120 participants completed the study, reflecting strong engagement and suggesting high tolerability of the product. The findings demonstrated significant efficacy, with the Dandruff Severity Index (DSI) showing a 69% average reduction by Day 42, and early improvements observed as soon as Day 14, indicating fast-acting properties. Additionally, hair fall was reduced by an average of 67%, with many participants reporting stronger hair strands and less breakage. Baseline DSI scores, ranging from 4 to 5 (severe dandruff), decreased to 1 or 2 in most groups post-treatment, confirming a mean reduction of over 69% and validating the product's clinical efficacy. These objective improvements were supported by positive subjective feedback from participants.

4.1 Participant Feedback

The study recorded high levels of participant satisfaction, with 87% reporting visible improvements in scalp condition, including reduced flaking and itching. Additionally, 81% appreciated the product's sensory attributes, such as its texture and scent, highlighting its user-friendly qualities. A notable 90% of participants expressed interest in continuing usage after the study, a strong indicator of the product's acceptability. This feedback underscores both the therapeutic efficacy and appealing formulation of the product.

4.2 Safety and Tolerability

The product exhibited an excellent safety profile, with no serious adverse events reported throughout the study. Only three participants experienced mild itching, which resolved spontaneously without intervention. The absence of allergic or dermatological complications suggests the oil is well-suited for sensitive users. These findings highlight the potential of herbal solutions to provide gentle, side-effect-free alternatives to conventional treatments.

5. DISCUSSION

The results of this Phase II clinical trial demonstrate that Scurf Herbal Oil is a highly effective and safe topical treatment for managing mild to moderate dandruff and hair fall. The observed 69% reduction in dandruff severity and 67% reduction in hair fall by the end of the 6-week treatment period are both statistically and clinically significant, underscoring the therapeutic potential of this Ayurvedic proprietary formulation. These findings align with the traditional use of its key ingredients—*Datura metel*, *Wrightia tinctoria*, and coconut oil—which have been historically recognized for their antimicrobial, anti-inflammatory, and nourishing properties. The synergy of these components likely contributes to the oil's ability to address the multifactorial etiology of dandruff and hair fall, including microbial overgrowth, scalp inflammation, and weakened hair follicles.

The rapid onset of improvement, with a 30.6% reduction in dandruff severity and a 25.9% reduction in hair fall by Day 14, suggests that Scurf Herbal Oil acts quickly to alleviate symptoms. This early efficacy is particularly noteworthy, as rapid symptom relief is a critical factor in patient adherence and satisfaction. The progressive improvement observed at Days 28 and 42 indicates sustained therapeutic effects, which may be attributed to the oil's ability to restore scalp health and strengthen hair follicles over time. The high participant satisfaction rate (87% reporting visible improvements and 90% expressing intent to continue use) further supports the product's acceptability and real-world applicability. These outcomes compare favorably to conventional treatments, such as antifungal shampoos or corticosteroids, which often achieve similar reductions in dandruff severity (50–70%) but may require longer treatment durations or cause side effects like scalp dryness or irritation.

The absence of serious adverse events and the minimal occurrence of mild, self-resolving itching in only three participants highlight the excellent safety profile of Scurf Herbal Oil. This is a significant advantage over synthetic treatments, which can lead to adverse effects such as hormonal disruptions or reduced efficacy with prolonged use. The natural composition of the oil, particularly the use of coconut oil as a carrier, likely enhances its tolerability by maintaining scalp hydration and minimizing irritation. These findings are consistent with prior studies on Ayurvedic herbal oils, which have demonstrated low rates of adverse reactions due to their biocompatible and nourishing properties.

From an Ayurvedic perspective, the efficacy of Scurf Herbal Oil can be understood through its action on vitiated Vata and Kapha doshas (in dandruff, or Darunaka) and Pitta dosha (in hair fall, or Khalitya). The cooling and emollient properties of coconut oil, combined with the Kapha-Pitta shamaka effects of *Wrightia tinctoria* and the antimicrobial action of *Datura metel*, address the dryness, flaking, and inflammation associated with these conditions. This holistic approach, which targets both symptoms and underlying imbalances, may explain the oil's dual efficacy in reducing dandruff and hair fall, as well as its ability to promote overall scalp health.

The high participant satisfaction and intent to continue use suggest that Scurf Herbal Oil meets the growing consumer demand for natural, user-friendly alternatives to synthetic treatments. Its sensory attributes, such as texture and scent, likely contribute to its acceptability, making it a practical option for daily scalp care. These findings have implications for both clinical practice and the herbal product market, particularly in regions like India, where dandruff and hair fall are prevalent and Ayurvedic remedies are culturally accepted. By offering a safe and effective alternative, Scurf Herbal Oil has the potential to reduce reliance on chemical-based treatments and improve quality of life for individuals affected by these common scalp conditions.

In conclusion, this Phase II trial provides robust evidence for the efficacy and safety of Scurf Herbal Oil in managing mild to moderate dandruff and hair fall. The significant reductions in symptom severity, coupled with high participant satisfaction and an excellent safety profile, position this herbal formulation as a promising natural therapeutic option.

6. CONCLUSION

This Phase II trial demonstrates that Scurf Herbal Oil is a safe, effective, and user-friendly solution for mild to moderate dandruff and hair fall. The significant clinical improvements observed—backed by participant satisfaction—make it a promising addition to natural dermatological care. This study presents the results of a prospective, open-label, single-arm Phase II clinical trial aimed at evaluating the efficacy and safety of Scurf Herbal Oil, a topical herbal formulation, for managing dandruff and hair fall. Conducted over a 6-week period, the study enrolled 120 adult participants suffering from mild to moderate dandruff and self-reported hair fall. The results revealed a statistically significant reduction in dandruff severity and hair fall rates, with a strong safety and tolerability profile. These findings suggest that Scurf Herbal Oil holds promise as a natural therapeutic intervention for common scalp conditions.

Overall, Scurf Herbal Oil represents a natural, well-tolerated alternative to synthetic scalp treatments, potentially improving not just scalp health but also user confidence and quality of life.

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