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Effect of Ayurvedic formulations, *Ayush* NT capsule and *Ayush* LK gel in the management of Psoriasis- An open-label, single-arm multicentre study

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Psoriasis, a complex chronic immune-mediated inflammatory skin disorder, is influenced by both genetic and environmental factors, leading to persistent cutaneous manifestations that significantly affect patient's quality of life. Existing systemic and local conventional therapies have limitations due to the chronic nature of the disease, creating a need for innovative interventions. Ayurveda, with its extensive repertoire, offers a promising avenue for exploration in addressing the challenges posed by psoriasis. An open label, single arm, multicentre study was conducted at two Ayurveda Research Institute in India to assess the therapeutic effect of Ayurveda formulations; *Ayush NT* (*Nimbatiktam*) capsule and Ayush LK (*Lajjalu Keram*) g l, in psoriasis. A total of 110 participants aged 18 to 60 years, diagnosed with psoriasis, were enrolled based on predefined selection criteria. All participants were administered *Ayush NT* capsule twice daily after meals with lukewarm water along with local application of *Ayush LK* gel on the affected areas twice daily for 24 weeks. Changes in psoriasis area and severity index (PASI) scores, dermatology life quality index (DLQI) questionnaires, and clinical signs and symptoms of the disease were compared before and after the treatment. Data of 108 participants were analysed which revealed significant improvement in PASI and DLQI scores. By day 168, PASI scores reduced from 16.86±8.217 to 6.83±4.449, persisting at 4.43±3.647 by day 196 during follow up also. DLQI showed a notable drop from 21.10±6.232 to 9.13±4.428. No Adverse events reported during trial period. Ayurveda interventions AYUSH NT capsule and AYUSH LK gel showcased good therapeutic potential in improving psoriasis severity and overall quality of life of psoriasis patients which is well tolerated.

Keywords: Ayurveda, Dermatology life quality index (DLQI), Lajjalu Keram, Nimbatiktam, Novel therapy, Psoriasis area severity index (PASI)

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Psoriasis is a chronic dermatological manifestation characterized by erythematous, indurated, scaly, pruritic lesions on the skin, marked by recurring cycles of remissions and relapses. The hallmark of psoriasis is persistent inflammation that leads to unregulated keratinocyte proliferation, with a pivotal role in both the initiation and maintenance of psoriasis Keratinocyte proliferation together with dysfunctional differentiation leads to inflammation, epidermal hyperplasia, and angiogenesis[1,2]. Many hypothesis posits that psoriasis is an immune-mediated inflammatory skin disorder that manifests in individuals carrying psoriasis susceptibility genes, with a genetic predisposition when exposed to specific environmental agents or triggers[3]. Psoriasis has a prevalence of approximately 1.99% in East Asia, 1.92% in Western Europe, and 1.10% in some Latin American countries[4]. An earlier study in 2010 had estimated the prevalence of psoriasis in India in the range of 0.44% to 2.80%[5]. Approximately 80% of patient cases of psoriasis comprise of the Plaque variety[6]. The cardinal features of plaque

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psoriasis include erythematous, scaly and well demarcated plaques.

The multifaceted etiological factors underpinning psoriasis as a systemic pathology can exert a profound impact on patients' quality of life and disease burden and the impairment inflicted by psoriasis on psychological well-being is akin to that observed in serious conditions such as cancer, and depression, underscoring the significant psychosocial ramifications of this dermatological disorder[7]. The disease severity is categorized as mild, moderate and severe psoriasis, based on a comprehensive assessment that includes psoriasis area and severity index (PASI), body surface area (BSA), and investigator's global assessment (IGA)[8]. Psoriasis is notably subject to the influence of various external factors, that encompass a broad spectrum, commencing with psychological stressors, minor localized skin traumas, diverse infectious agents, medications for comorbidities and lifestyle choices such as alcohol consumption and smoking alongside environmental variables[9].

Due to the chronic relapsing nature of psoriasis, long term therapy is often required. Devising an appropriate therapeutic approach involves assessment of disease severity, comorbidities, duration of diseases, site, age, systemic involvement, treatment history etc.[10]. While topical therapy is often employed for mild psoriasis, a multifaceted therapeutic approach may be warranted, encompassing topical agents, phototherapy, systemic non-biological therapy, and/or biologic interventions, tailored to the individual patient's clinical presentation and response to treatment[11,12]. Over the preceding decade, a notable increase in therapeutic modalities and strategic approaches has emerged, particularly catering to individuals afflicted with moderate-to-severe psoriasis. Despite the availability of a wide array of treatment options and emergence of novel treatment that address innovative pathways, the efficacy of psoriasis management is constrained by many factors such as the presence of co morbidities, inter-individual variability in treatment responses, adverse effects, treatment resistance as well as exacerbating factors such as stress, and economic burden[13]. Ayurveda categorizes dermatological disorders under the wide spectrum of '*Kushta*", where skin disorders are delineated according to their distinct characteristic attributes and clinical manifestations. Such a classification confers a notable advantage by affording the physician a degree of flexibility in selecting appropriate treatment modalities, contingent upon the on the *Dosha* predominance and other disease characteristics[14].

The Ayurvedic system of medicine offers a promising avenue for the management of psoriasis, leveraging its tailored treatment options that integrate purificatory and palliative therapeutic procedures alongside non-therapeutic interventions, taking into account variables such as disease severity, patient characteristics, body constitution, and metabolic function. Ayurveda presents a promising avenue for addressing chronic dermatological conditions such as psoriasis with its holistic and individualized approach to treatment. The Central Council for Research in Ayurvedic Sciences has formulated two novel therapeutic formulations for use in skin diseases, inspired by classical Ayurvedic texts, *viz.*, *Ayush NT (Nimbatiktam)* capsule, in which *Azadiracta indica* A. Juss is the principal ingredient and stem, bark, seeds, leaf and root used for preparation of capsule, and the Ayush LK (*Lajjalu Keram*) gel, a coconut oil-based topical preparation where *Mimosa Pudika* L. is the active drug.

The objective of this clinical study was to assess the therapeutic effect of *Ayush NT* capsul*e* and *Ayush LK* gel in psoriasis.

Methodology

Study setting and design

This was an open label, single arm, multicentre study conducted at two peripheral institutes of Central Council for Research in Ayurvedic Sciences (CCRAS) *viz.*, Regional Ayurveda Research Institutes (RARI) at Ahmedabad and Regional Ayurveda Research Institutes (RARI), Vijayawada during 2020.

Ethical approval and trial registration

The Institutional Ethics Committees of each participating centre has approved this study. The study was conducted in compliance with applicable ethical guidelines. The study was initiated after approval of the study protocol, participant information sheet, and informed consent form from the Institutional Ethics Committee of each participating centre. The study was registered with the Clinical Trial Registry CTRI/2020/02/023638 [Registered on 28/02/2020].

Participants

Inclusion and Exclusion Criteria:

The inclusion criteria comprised individuals of both sexes aged between 18 and 60 years, with

psoriasis diagnosed with dermatological consultation, without psoriatic arthropathy, and exhibiting the classical psoriatic triad: bright pink or red lesions with well-defined borders, covered by silvery white scales that could be easily detached from the lesion; pinkish moist tender skin beneath the scales; and the presence of tiny blood droplets upon scraping the moist skin (Auspitz's sign). Additionally, individuals were included only when disease duration was between 3 months to 5 years, with less than 50% of the body surface involvement, and a positive histopathological finding (Skin-biopsy) and V.D.R.L/HIV/Hepatitis negative status were considered for inclusion in the study. Willingness to participate in the study was also a prerequisite for enrolment in the trial.

Individuals were excluded if they presented with generalized skin lesions or with conditions such as Herpes simplex, Herpes zoster, Scabies, Acne, Urticaria, and immunologically mediated skin diseases including Pemphigus vulgaris, Dermatitis herpetiformis, Guttate, Pustular, Lupus erythematosus, and Psoriatic arthropathy. Individuals with poorly controlled hypertension (blood pressure exceeding 160/100 mm Hg), pregnant or lactating women, and those with uncontrolled diabetes mellitus (fasting blood sugar levels exceeding 250 mg/dL) were not considered eligible for inclusion. Patients suffering from major systemic illnesses requiring long-term drug therapy, such as rheumatoid arthritis, tuberculosis, psycho-neuro-endocrinal disorders, etc., were also excluded. Moreover, individuals receiving corticosteroids, phototherapy, biologics, antidepressants, or any other medications potentially influencing the study outcomes were ineligible.

Furthermore, patients with concurrent serious hepatic dysfunction (defined as AST and/or ALT levels exceeding three times the upper normal limit), renal dysfunction (defined as serum creatinine levels exceeding 1.4 mg/dL), uncontrolled pulmonary dysfunction (asthmatic and COPD patients), AIDS, STDs, or other severe concurrent diseases were excluded. Alcoholics and/or drug abusers, individuals with a history of hypersensitivity to the trial drug or any of its components, and those who had participated in any other clinical trial within the past six months were also not considered for enrolment. Finally, any other condition deemed by the investigator to potentially jeopardize the study was grounds for exclusion.

Trial drug

In the clinical study, 200 mg Ayush NT capsules were administered orally twice daily after meals with lukewarm water for 24 weeks. Conversely, *Ayush LK* gel was applied locally on the affected areas twice daily throughout the 24-week duration of the study. It absorb into the skin, so there is no need to remove the gel afterward. The key ingredient of Ayush NT (*Nimbatiktam*, *Nimba* (*Azadirachta indica* A. Juss.), is known in Ayurveda for its multifaceted pharmacological properties, particularly in the context of skin diseases[15]. Pre-clinical studies on *Nimbatiktam* established its safety profile, with acute toxicity assessments in albino rats and mice demonstrating no toxicity at oral doses up to 2000 mg/kg and intraperitoneal doses up to 1000 mg/kg. Additionally, sub-acute toxicity investigations in albino rats at doses of up to 100 mg/kg daily for 6 weeks, and in dogs at oral doses of 10 and 20 mg/kg for 4 weeks, revealed no evidence of systemic toxicity[16]. *Ayush LK* (*Lajjalu Keram*) gel is an oleo-gel prepared using *Mimosa pudica* L. in coconut oil base, owing to its emollient properties, and the ability to moisturize the skin. The formulation was meticulously optimized to achieve the desired viscosity, texture, and stability necessary for effective topical application. The finalized gel formulation also underwent testing to assess its stability, and skin compatibility prior to use in the study.

The interventions employed in the trial were manufactured at GMP certified pharmacy, following strict adherence to relevant guidelines. Lajjalu Keram gel was applied to the affected area twice daily. As it was absorbed in the skin so no need to remove the gel afterwards.

Outcome measures

Changes in PASI score, from baseline to consecutive assessments on Day 28^{th}, 56^{th}, 84^{th}, 112^{th}, 140^{th}, and 168^{th} day of the intervention period and at Day 196 (follow-up without intervention) was the primary outcome measure. PASI is a structured tool used for the quantitative evaluation of the clinical severity of plaque psoriasis, which systematically evaluates the extent of psoriatic involvement across four anatomical regions (head, trunk, upper extremities, lower extremities) by assessing the degree of erythema, induration, and desquamation, as well as the percentage of affected body surface area[17].

The secondary outcome measures of the study included changes observed in the clinical signs and

symptoms of psoriasis, and change in the DLQI Questionnaire score assessed during each consecutive follow-up visits. The DLQI is a patient-reported, questionnaire-based tool designed to evaluate the impact of skin diseases, on various aspects of patients' quality of life[18].

Sample size

On the basis of an anticipated change of 10 points in PASI score pre- and post-treatment and a standard deviation of 25 mm based on prior research, the sample size was calculated as approximately 98 with 95% Confidence Level ($\alpha=0.05$) and 80% power. Considering a dropout rate of 20%, the adjusted sample size per group was re-calculated to be approximately 123, rounded off as 120, with 60%.

Study procedures

After obtaining the signed informed consent, individuals meeting the predetermined eligibility criteria were enrolled in the open-label study. Participants were provided comprehensive instructions regarding the utilization of the trial intervention and were instructed to diligently maintain a treatment adherence form to document their compliance. Baseline assessments encompassing demographic, clinical, and disease-specific evaluations were meticulously conducted and documented in both the Case Report Form (CRF) and the electronic CRF (e-CRF). The prescribed study interventions, for a duration of 28 days, were dispensed during the initial visit (baseline). Subsequent evaluations were scheduled on the 28th, 56th, 84th, 112th, 140th, and 168th days, during which changes in PASI, DLQI, and clinical symptoms were meticulously recorded. Throughout each visit until the 168th day, participants continued to receive trial interventions, and the completed, signed treatment adherence forms were collected in the subsequent visits respectively to monitor the adherence. Participants were encouraged to promptly notify the Principal Investigator of any observed adverse events or with any inquiries they might have during the course of the study. The final visit occurred on day 196, during which outcome assessments were documented to ascertain the sustained impact of the study interventions on psoriasis activity. Laboratory investigations, including routine blood and urine examinations, fasting blood sugar assessment, HbA1c analysis, liver function tests (LFT), kidney function tests (KFT), serum IgE levels, and electrocardiogram (ECG) evaluations, were conducted both during the initial screening phase and on the 168th day of the study. Additionally, skin biopsy procedures were exclusively performed during the screening phase for the purpose of diagnosing psoriasis.

Statistical analysis

The data collected via the CRF were meticulously entered into Microsoft Excel for validation and subsequent analysis. Following validation, statistical analysis was performed utilizing STATA 16.0 software. Dichotomous and categorical variables were expressed as frequencies and percentages, while quantitative variables were presented as mean±standard deviation (SD). Comparative analyses of quantitative parameters were conducted utilizing ANOVA or Friedman test, with a significance level set at 5%. A modified intention-to-treat analysis (mITT) was employed, wherein only data from participants who completed at least one follow-up were included to report the outcome measures. Descriptive statistics detailing baseline demographics and other relevant characteristics were analysed for 108 participants. In addition, laboratory investigations for safety analysis were carried out at baseline, 84th, and 168th days.

Results

A total of 124 participants were screened from both study sites and from which 110 participants were enrolled; 60 from RARI, Vijayawada and 50 from RARI, Ahmedabad. Despite aiming to enroll 120 participants, the study could only recruit a total of 110 individuals due to the emergence of the COVID-19 pandemic. Additionally, the decision to halt enrolment was justified as the dropout rate was lower than anticipated, with only 10% observed, instead of the anticipated 20% during sample size calculation.

A total of 101 participants completed the study, with nine drop outs. To address missing data from participants who completed at least one follow-up but subsequently dropped out, the Last Observation Carry Forward (LOCF) method was employed for imputation and the data from the seven participants were incorporated into the analysis, resulting in a total dataset of 108 individuals for statistical evaluation. Data of two participants who failed to attend any follow-up visits were excluded from the analysis. A schematic representation illustrating the participant flow throughout the study is provided in (Fig. 1).

The mean age of the enrolled participants was 40.57±10.337 reflects a distribution indicative of a cohort positioned within the middle-aged demographic spectrum. Similarly, the mean Body Mass Index (BMI) observed among participants was 25.57±3.824. Analysis of demographic characteristics revealed that 64.8% of the enrolled individuals were male, underscoring a slight male predominance within the study population. Moreover, a notable proportion of participants, comprising 87 individuals (80.6%), hailed from socioeconomic backgrounds above the poverty line, while the majority of participants (85.2%), were residents of urban areas, reflecting an urban-centric demographic profile. The onset of disease was reported as insidious in 74 participants (68.5%), indicating a chronic progression of symptoms over time. A considerable proportion of participants (63.0%), reported specific triggering factors associated with their condition, with dietary triggers being the most commonly cited, reported by 57 individuals (52.8%), followed by climactic triggers, reported by 10 individuals (9.3%). Majority of participants were either *Vata-Kaphaja* or *Vata-Pittaja Prakriti*. The demographic and baseline characteristics of study participants are provided in the Table 1. Table 2 presents a comprehensive overview of the characteristics of the skin lesions observed in the participants at baseline.

The Ayurveda interventions demonstrated a substantial effect on the PASI score throughout the study duration. At baseline, the mean PASI score stood at 16.86±8.217, indicative of significant disease severity among the participants. Following the

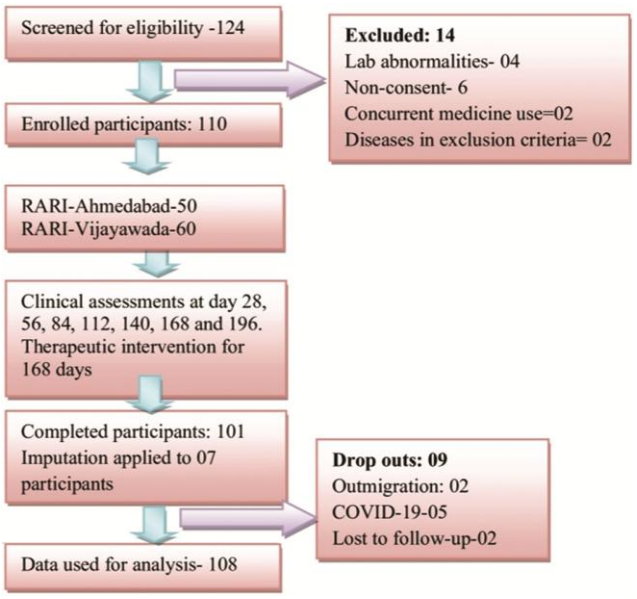

Fig. 1 — Participant flow in the study

Table 1 — Description of demographic and other baseline characteristics of the study participants

Baseline Characteristics (n = 108)		n (%)
Age: Mean ± SD		40.57±10.337
Gender	Male	70 (64.8%)
	Female	38 (35.2%)
Marital status	Married	94 (87.0%)
	Unmarried	14 (13.0%)
Educational status	Illiterate	4 (3.7%)
	Read & Write	104 (96.3%)
Past occupation	Desk Work	40 (37.0%)
	Field work with physical labour	18 (16.7%)
	Field work	17 (15.7%)
	House wife	29 (26.9%)
	Student	4 (3.7%)
Present occupation	Desk work	42 (38.9%)
	Field work with physical labor	16 (14.8%)
	Field work	17 (15.7%)
	House wife	31 (28.7%)
	Student	2 (1.9%)
Socio-economic status	Above Poverty Line	87 (80.6%)
	Below Poverty Line	21 (19.4%)
Religion	Hindu	100 (92.6%)
	Muslim	4 (3.7%)
	Christian	4 (3.7%)
Habitat	Urban	92 (85.2%)
	Semi-urban	3 (2.8%)
	Rural	13 (12.0%)
Onset of disease	Acute	34 (31.5%)
	Insidious	74 (68.5%)
Previous episodes	Yes	53 (49.1%)
	No	55 (50.9%)
Any aggravating factor	Yes	68 (63.0%)
	No	40 (37.0%)
If Yes	Dietary	57 (52.8%)
	Climatic triggers	10 (9.3%)
Any relieving factor	Yes	19 (17.6%)
	No	87 (80.6%)
Dietary history	Vegetarian	40 (37.0)
	Non-Vegetarian	68 (63.0)
Physical exercise	Heavy Labor	5 (4.6)
	Moderate Labor	51 (47.2)
	Office Job	9 (8.3)
	Sedentary	43 (39.8)
Allergy to some material	Yes	20 (18.5)
	No	88 (81.5)
Emotional stress	Mild	25 (23.1)
	Moderate	57 (52.8)
	Too much	26 (24.1)
Built	Average	49 (45.4%)
	Emaciated	8 (7.4%)
	Well Built	51 (47.2%)
Nutrition	Nourished	103 (95.4%)
	Malnourished	5 (4.6%)

… *Contd.*

Table 1 — Description of demographic and other baseline characteristics of the study participants (Contd.)

Baseline Characteristics (n = 108)		n (%)
Prakriti	*Vataja*	3 (2.8%)
	Pittaja	3 (2.8%)
	Kaphaja	3 (2.8%)
	Vata-Pittaja	26 (24.1%)
	Vata-Kaphaja	53 (49.1%)
	Pitta-Kaphaja	11 (10.2%)
	Sannipataja	9 (8.3%)
Body Mass Index (B.M.I)	25.57±3.824	

*Values are reported as n (%) for categorical variables, indicating the number and percentage of participants exhibiting specific characteristics. Continuous variables are presented as Mean ± SD, representing the mean value and standard deviation of quantitative parameters measured at baseline.

Table 2 — The characteristics of skin lesions at baseline

Characteristics of the lesion (n = 108)			n (%)
Inspection of the lesion	Distribution	Symmetrical	37 (34.3%)
		Asymmetrical	71 (65.7%)
	Surfaces	Flexor	60 (55.6%)
		Extensor	48 (44.4%)
	Number	Single	17 (15.7%)
		Multiple	91 (84.3%)
	Morphology	Macular	45 (41.7%)
		Papular	45 (41.7%)
		Vesicular	6 (5.5%)
		Crusty	12 (11.1%)
	Surface of the lesion	Regular	28 (25.9%)
		Irregular	80 (74.1%)
	Involved area of the lesion		
	Area of friction or pressure	Yes	53 (49.1%)
		No	55 (50.9%)
	Sweaty regions	Yes	58 (53.7%)
		No	50 (46.3%)
	Exposed regions	Yes	86 (79.6%)
		No	22 (20.4%)
	Genital and Surrounding area	Yes	11 (10.2%)
		No	97 (89.8%)

*Values are reported as n (%) for categorical variables.

initiation of the trial interventions, a progressive and statistically significant reduction in PASI score was observed over time. By day 28, the mean PASI score had decreased to 14.95±7.224, further reducing to 6.83±4.449 at day 168, and 4.43±3.647 at day 196. The difference in PASI score at Day 168 was statistically significant with $p<0.001$ when compared with the baseline value. At baseline, the mean DLQI score was 21.10±6.232, indicating a considerable impairment in the quality of life among participants. By day 28, there was a discernible decrease in the mean DLQI score to 19.29±5.640, suggesting a slight improvement in quality of life following the initiation of interventions. Notably, by day 168, a substantial reduction in DLQI score was observed, with the mean score decreasing to 9.13±4.428. This significant reduction signifies a marked improvement in the quality of life among participants over the course of the study. Even after the cessation of intervention, the positive trend persisted, as evidenced by the further decline in DLQI score to 6.50±4.669 at day 196. The progressive reduction in DLQI scores throughout the study period reflects a tangible enhancement in the quality of life experienced by participants. The detailed descriptions of change in the PASI and DLQI score are provided in Table 3.

At baseline, the majority of participants reported experiencing itching (105 participants, 97.2%), dryness of the skin (101 participants, 93.5%), roughness (100 participants, 92.6%), circular erythema (78 participants, 72.2%), exfoliation (87 participants, 80.5%), and hyperpigmentation (84 participants, 77.8%). However, by Day 168, there was a noticeable reduction in the prevalence of these symptoms, with itching reported by 71 participants (65.7%), dryness of the skin by 67 participants (62.0%), roughness by 34 participants (31.5%), circular erythema by 25 participants (23.1%), exfoliation by 41 participants (38.0%), and hyperpigmentation by 57 participants (52.8%). Notably, these improvements persisted even after the cessation of intervention, as evident from the follow-up assessment at Day 196. All findings were statistically significant with $p<0.001$. Table 4 depicts the gradual change observed in the characteristic clinical symptoms observed among participants from baseline visits to subsequent visits and to the final follow-up assessment at Day 196.

Clinical safety laboratory assessments, encompassing Complete Blood Count, Liver Function Panel, and Kidney Function Tests, were conducted at Day 84 and Day 168 to meticulously monitor alterations from baseline values. A statistically significant difference was reported in erythrocyte sedimentation rate and Absolute Eosinophil Count at Day 168 compared with baseline. Decreases in ESR signify reduced levels of systemic inflammation, while reductions in Absolute Eosinophil Count further corroborate the attenuation of immune-mediated responses, both pivotal in psoriasis pathology.

No adverse drug reactions (ADRs) or adverse events (AEs) were reported during the treatment duration. Comprehensive summary statistics detailing

Table 3 — Table portraying the change in outcome measures from baseline to subsequent follow-ups

Outcome measures (n = 108)	Baseline	28th day	56th day	84th day	112th day	140th day	168th day	196th day	p-value#
PASI SCORE	16.86 ±8.217	14.95 ±7.224	14.17 ±7.658	12.09 ±6.289	10.46 ±6.354	9.06 ±5.322	6.83 ±4.449	4.43 ±3.647	<0.001
DLQI Questionnaire									
Symptoms and feelings	5.01 ±1.148	4.69 ±1.451	4.38 ±1.074	4.03 ±1.115	3.56 ±1.105	3.19 ±1.006	2.59 ±1.050	1.99 ±1.063	<0.001
Daily Activities	4.65 ±1.342	4.26 ±1.278	4.01 ±1.172	3.56 ±1.178	3.15 ±1.167	2.66 ±1.087	2.22 ±1.044	1.63 ±1.181	<0.001
Leisure	3.89 ±1.654	3.50 ±1.501	3.23 ±1.392	2.85 ±1.237	2.50 ±1.249	2.04 ±1.085	1.55 ±1.054	1.17 ±1.098	<0.001
Work & School	1.91 ±0.704	1.77 ±0.664	1.66 ±0.658	1.50 ±0.663	1.28 ±0.681	1.05 ±0.632	0.79 ±0.670	0.50 ±0.649	<0.001
Personal Relationships	4.02 ±1.612	3.63 ±1.457	3.43 ±1.320	3.05 ±1.187	2.69 ±1.106	2.38 ±0.983	1.69 ±1.020	1.10 ±1.004	<0.001
Treatment	1.62 ±1.108	1.56 ±0.835	1.45 ±0.766	1.16 ±0.726	0.81 ±0.676	0.63 ±0.635	0.30 ±0.600	0.19 ±0.571	<0.001
DLQI Questionnaire Total	21.10 ±6.232	19.29 ±5.640	17.94 ±5.404	16.12 ±4.820	13.99 ±4.733	11.85 ±4.442	9.13 ±4.428	6.50 ±4.669	<0.001

Values are reported as Mean ± SD
p-value computed using Repeated Measure ANOVA using Bonferoni correction, comparing baseline with Day 168
p-value of <0.05 has been considered as significant

Table 4 — Change in clinical symptoms from baseline to subsequent follow-ups

Presence of Chief Complaints (n = 108)	Baseline	28th day	56th day	84th day	112th day	140th day	168th day	196th day	p-value
Itching	105 (97.2%)	104 (96.3%)	105 (97.2%)	102 (94.4%)	93 (86.1%)	62 (57.4%)	71 (65.7%)	60 (55.6%)	<0.001(*)
Dryness of the skin	101 (93.5%)	102 (94.4%)	97 (89.8%)	89 (82.4%)	79 (73.1%)	63 (58.3%)	67 (62.0%)	58 (53.7%)	<0.001(*)
Roughness	100 (92.6%)	95 (88.0%)	91 (84.3%)	74 (68.5%)	57 (52.8%)	47 (43.5%)	34 (31.5%)	22 (20.4%)	<0.001(*)
Circular erythema	78 (72.2%)	76 (70.4%)	71 (65.7%)	65 (60.2%)	49 (45.4%)	25 (23.1%)	25 (23.1%)	17 (15.7%)	<0.001(*)
Exfoliation	87 (80.5%)	84 (77.8%)	81 (75.0%)	77 (71.3%)	63 (58.3%)	35 (32.4%)	41 (38.0%)	26 (24.1%)	<0.001(*)
Hyper pigmentation	84 (77.8%)	86 (79.6%)	83 (76.9%)	83 (76.9%)	79 (73.1%)	71 (65.7%)	57 (52.8%)	47 (43.5%)	<0.001(*)

Values are reported as n (%)
p-value compared using Cochrane-Q test
(*) A p-value of <0.05 has been considered as significant

both the actual values and changes from baseline, stratified by scheduled visit for each haematological and biochemical assessment, are meticulously presented in Table 5. Notably, examination of the data elucidates that the laboratory parameters remained within the reference range consistently throughout the study duration, affirming the safety profile of the intervention.

Discussion

This study depicts the outcomes of a multicentre, single-arm, phase III study evaluating the safety and therapeutic efficacy of Ayurveda interventions, namely *Ayush NT* (*Nimbatiktakam*) capsule and *Ayush LK* (*Lajjalu keram*) Gel, in plaque psoriasis. Statistically significant and clinically meaningful improvements were observed, in the primary and secondary endpoints, underscoring the therapeutic benefit conferred by these Ayurvedic interventions. The most important finding in the study was the sustained remittive effect observed post-treatment cessation, wherein the therapeutic gains persisted for up to 4 weeks. The interventions were found to be well-tolerated, even with long-term usage extending up to 168 days.

The findings pertaining to demographic parameters in this study may not be readily generalized due to the nature of study site, which primarily focused on participants from urban areas and did not account for occupational, nutritional, occupational or religious diversity. *Azadiracta indica* has been recognized for its wide array of beneficial properties in Ayurveda and is commonly used in the management of many diseases, especially dermatological disorders. Rich in a complex array of constituents such as nimbin, nimbidin, nimbolide, and limonoids; *A. indica* exerts its medicinal effects through modulation of various genetic pathways and biological activities[19]. Findings from a double blind clinical drug trial study on uncomplicated psoriasis had revealed that use of *A. indica* as adjunct to coal tar demonstrated better response in comparison to placebo group[20]. Neem

Table 5 — Laboratory assessments in the study participants

Lab Investigations (n = 108)	Baseline	84th day	168th day	p-value
Hemoglobin	13.40±1.792	13.32±2.006	13.42±1.917	0.768
Total RBC Count	4.74±0.529	4.78±0.605	4.82±0.615	0.236
T.L.C	7635.93±2035.486	7394.26±2181.011	7446.17±2480.338	0.467
N%	60.36±7.981	59.94±7.566	58.76±7.433	0.168
E%	3.74±2.628	3.17±1.872	3.54±2.261	0.126
B%	1.19±0.618	1.11±0.777	1.15±0.759	0.595
L%	30.13±7.360	30.80±6.948	31.02±7.472	0.547
M%	4.60±2.230	4.74±2.424	5.41±5.044	0.134
E.S.R mm at the end of 1st hour	35.94±22.730	30.94±17.482	28.53±16.273	0.008 (*)
Absolute Eosinophil Count	281.61±231.146	233.24±155.091	166.62±124.750	<0.001 (*)
Blood Sugar Fasting	100.94±23.687	101.64±22.872	100.91±18.414	0.947
Serum Total Cholesterol	182.52±33.245	179.17±32.056	176.21±30.100	0.264
Serum Triglycerides	148.76±63.112	147.42±56.236	148.93±61.584	0.964
HDL	40.70±8.090	38.89±6.734	39.93±14.324	0.348
LDL	110.97±31.506	111.18±28.778	107.20±26.260	0.376
VLDL	30.87±17.598	29.69±12.139	30.51±15.904	0.761
Cholesterol HDL ratio	4.68±1.432	4.75±1.129	5.04±3.429	0.381
Blood Urea	30.90±59.026	25.56±8.829	24.98±8.148	0.319
Serum Uric Acid	5.22±1.119	4.93±1.086	4.75±1.113	<0.001 (*)
Serum Ceratinine	0.84±0.226	0.86±0.221	0.87±0.241	0.137
S.G.O.T (A.S.T)	23.70±7.287	24.11±7.945	24.83±6.585	0.350
S.G.P.T (A.L.T)	25.92±11.106	25.31±9.386	25.19±10.019	0.744
Total Protein	13.64±67.051	7.16±0.372	7.03±0.345	0.312
S. Albumin	4.18±0.489	4.12±0.520	4.10±0.489	0.070
S. Globulin	3.01±0.536	3.03±0.486	3.08±1.647	0.663
A/G Ratio	1.49±0.471	1.43±0.432	1.49±0.483	0.023 (*)
Serum Total Bilirubin	0.53±0.247	0.56±0.261	0.65±0.848	0.197
Conjugated Bilirubin	0.26±0.174	0.27±0.193	0.28±0.176	0.247
Unconjugated Bilirubin	0.26±0.112	0.28±0.107	0.29±0.100	0.049 (*)
Serum Alkaline Phosphatase	97.49±23.198	98.39±23.413	98.17±23.546	0.838

Values are reported as Mean ± SD
p-value computed using Repeated Measure ANOVA using Bonferoni correction
(*)p-value of <0.05 has been considered as significant

extracts are valued for their potent anti-inflammatory properties, owing to the presence of limonoids, which exhibit inhibitory effects on the production of inflammatory mediators, making them valuable therapeutic agents for managing inflammatory conditions, such as psoriasis[21].

Mimosa pudica L. is described in Ayurveda as having *Kashaya*, *Tikta Rasa* and *Laghu, Ruksha, Sita Virya* and *Kapha-Pittahara* properties[22]. Phytochemical investigations conducted on *M. pudica* have identified various compounds, including alkaloids, non-protein amino acid (mimosine), fatty acids. C-glycosides, sterols, terpenoids, and tannins[23]. Wound healing studies on *Mimosa pudica* roots suggest that the high tannin content may contribute to its wound healing activity, potentially attributable to the astringent properties of tannins[24]. Coconut oil has potential beneficial role in skin disorders owing to its moisturizing, soothing, and emollient effects[25]. The findings from the present study indicate that the anti-inflammatory properties of *Mimosa pudica*, combined with the moisturizing and emollient qualities of coconut oil, has the potential to offer relief from symptoms associated with psoriasis. In the present study, the identified *Doshas* are *Pitta, Kapha*, and *Rakta*, while the *Dushyas* involved include *Rasadhatu, Raktadhatu*, and *Mamsadhatu*. The pathological progression, known as *Dosha-Dushya samurcchana*, has occurred due to the circulation of vitiated *Doshas* and their *Sthanasamshraya*-specific sites of pathological changes-primarily affecting the *Tvaka* (skin). This condition is clinically manifested as *Vyadhilakshnanas*, which are the signs and symptoms of psoriasis.

In the management of psoriasis, achieving satisfactory disease control remains a challenge for many patients despite the extensive therapeutic options currently available. While various topical agents and targeted oral therapies exist, their efficacy is often limited, necessitating the exploration of other

safe and effective treatment modalities. Traditional medicines such as Ayurveda offer promising avenues for integration into the therapeutic algorithm for psoriasis. Although topical therapies predominantly rely on corticosteroids and vitamin D derivatives, their long-term use is hampered by potential adverse effects[26]. Furthermore, biologic therapies may be ineffective for some patients or in individuals with mild disease, or lose efficacy over time. Thus, the inclusion of Ayurvedic treatments, renowned for their safety and efficacy, presents a valuable addition to the armamentarium against psoriasis, addressing the unmet needs of patients across the disease spectrum.

Psoriasis exerts a profound impact on the quality of life of affected individuals, extending beyond the physical manifestations of the disease to encompass its psycho-somatic and social ramifications. The chronic nature of psoriasis and its unpredictable flare-ups can disrupt daily activities, impairing social interactions and hindering participation in work, school, and recreational pursuits. As such, a comprehensive and promising therapeutic approach for psoriasis should not only target the clinical manifestations of the disease but also prioritize the enhancement of quality of life as a pivotal aspect of patient care. The findings from the study indicate that the Ayurveda interventions were much effective in improving the quality of life in the participants which is indeed promising.

Limitations

The lack of a control arm precludes direct comparison with alternative treatment modalities or placebo, limiting the ability to assess the relative efficacy of the intervention. The findings may not be fully generalized to all forms or severities of psoriasis, as the study population may not fully represent the broader psoriasis patient population.

Conclusion

The combination therapy of *Ayush NT* capsule and *Ayush LK* gel has demonstrated significant effect in improving disease-specific clinical symptoms, reducing disease severity, and enhancing quality of life among individuals with psoriasis. The beneficial effects of these interventions were sustained for up to 4 weeks following the cessation of treatment, indicating a lasting therapeutic impact. The interventions were well-tolerated, underscoring their safety and effectiveness in the management of psoriasis.

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Conflict of Interest

All the authors declare that they have no conflict of interest. However, the authors are employees at the funding agency which is a Government organization.

Author Contributions

SK conceptualised the study, SK,TM & RC designed the protocol, BS & BCR did fund acquisition and execution of study, RKR, NS & DM supervised the study execution, SD and SJ drafted and edited the manuscript, KMC,SP & JR reviewed and finalised the manuscript. All authors have contributed in the study inception, designing, execution, analysis and/or writing of manuscript. All the authors have reviewed and approved the manuscript prior to submission.

Ethical Approval

After obtaining the approval for institutional ethics committee of both the study institutes and after obtaining consent from the patients, the study was conducted.

Data Availability

Study data will be available upon request by the corresponding author.

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