

Efficacy and Safety of a Standardized Herbal Topical Formulation Containing *Dorema ammoniacum* for Mild to Moderate Plaque Psoriasis: A Randomized Double-Blind Placebo-Controlled Trial

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Abstract

Background: Psoriasis is a chronic inflammatory skin disease for which topical corticosteroids remain the most commonly used treatment; however, their long-term use may be limited by adverse effects and tachyphylaxis. In Persian medicine, *Dorema ammoniacum* (Oshaq) has been used for inflammatory skin conditions, suggesting a potential complementary therapeutic approach.

Objective: This study aimed to evaluate the efficacy and safety of a standardized topical formulation containing *Dorema ammoniacum* resin, vinegar, and wheat germ oil in patients with mild-to-moderate plaque psoriasis.

Methods: As the first double-blind, placebo-controlled randomized trial of this formulation, the study sought to provide high-quality clinical evidence using the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI) as validated outcome measures.

Results: For the intervention group, mean PASI score decreased significantly ($P = 0.007$) from 6.03 to 4.18 by week 8. The placebo group showed no significant change. At week 4 ($P = 0.003$) and week 8 ($P < 0.001$), between-group differences were significant. The intervention group's DLQI score decreased significantly ($P \leq 0.001$) from 20.43 to 15.18 by week 8, and significant between-group differences were noted ($P \leq 0.001$) favoring the intervention. No serious adverse events were noted.

Conclusion: The Oshaq-based topical formulation is significantly better than placebo. It improves the severity of mild-to-moderate plaque psoriasis and the quality of life of affected patients. Larger studies with extended follow-up and active comparators are needed to assess its therapeutic role further.

Keywords: Psoriasis, Phytotherapy, Persian medicine, *Dorema ammoniacum*

1. Introduction

Psoriasis is a chronic inflammatory skin disease that is prone to flare-ups throughout life (1, 2). The prevalence of this condition varies across populations, generally ranging from 0.1% to 3% (3). This prevalent condition can greatly influence the quality of life of affected individuals (4), potentially resulting in depression and suicidal tendencies (5). Enhanced mental satisfaction, social engagement, and regular

activities are commonly experienced post-recovery (6).

In modern medicine, there is no definitive treatment for psoriasis. Numerous chemical drugs and non-pharmacological treatments have been used over the years to treat psoriasis, including topical treatments, systemic medications, and phototherapy or combination therapies. However, long-term management remains challenging due to

treatment-related adverse effects, tachyphylaxis, steroid phobia, poor adherence, and frequent disease relapse. Prolonged use of topical corticosteroids may result in skin atrophy, barrier dysfunction, and rebound exacerbation. At the same time, systemic therapies are often associated with cumulative toxicity and high costs. Consequently, a substantial proportion of patients seek safer, sustainable alternatives for long-term disease control, leading to increased interest in complementary and herbal therapies (7, 8).

Persian medicine has also addressed chronic skin diseases such as psoriasis with a holistic approach, including maintaining the balance of body fluids, detoxification, and controlling local inflammation (9). In this regard, a formulation of *Dorema ammoniacum* resin, along with other ingredients such as vinegar, has been traditionally recommended to treat psoriasis-like conditions by reducing inflammation, scaling, and itching in affected areas of the body. The formulation prepared in the present study is based on traditional knowledge. It has been further optimized in accordance with the principles of pharmaceuticals. The integration of traditional knowledge with traditional science aims to assess the potential of these herbal formulations through evidence-based research (10).

Many studies on herbal formulations for the treatment of psoriasis are available in the literature. However, small sample sizes, poor blinding, inconsistent formulations, and inconsistent outcome measures often characterize them. Furthermore, these formulations are often not standardized, which creates confusion about their actual efficacy (11).

Following this traditional rationale, various pharmacological effects of *Dorema ammoniacum* (Oshaq) resin, including anti-

inflammatory, antioxidant, antibacterial, and cytotoxic activities, as well as clinical effects in melasma and other dermatological conditions such as pityriasis and scalp kerion, have been reported in previous studies (12-14). Vinegar, or acetic acid, is used as a chronic wound care agent with antiseptic activity, including anti-inflammatory, antimicrobial, and anti-allergic effects, in addition to its metabolic effects (15, 16). Wheat germ oil, with its high content of natural antioxidants, is also proposed as a potentially powerful alternative to vitamin E, with roles in tissue repair and protection against tissue damage, including skin. Wheat germ oil is also traditionally used to prevent psoriasis (17, 18). Therefore, according to these traditional concepts, a combination of Oshaq resin, vinegar, and wheat germ oil was used in this study to evaluate its potential efficacy in the management of psoriatic lesions (19).

2. Objectives

This study represents the first double-blind, placebo-controlled randomized trial to investigate a traditionally inspired yet standardized topical formulation composed of *Dorema ammoniacum* resin, vinegar, and wheat germ oil, using the Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) as validated endpoints. The present trial aimed to evaluate the efficacy and safety of this formulation in patients with mild-to-moderate plaque psoriasis and to provide high-quality clinical evidence for its potential as a complementary therapeutic option.

3. Methods

3.1. Study design and participants

The present study was a randomized, double-blind, placebo-controlled, parallel-arm clinical trial carried out at the outpatient dermatology clinic of Emam Reza Hospital in Mashhad, Iran. Recruitment of

study subjects commenced in January 2023 and ran until September 2023, with the study finishing in February 2024. The Research Ethics Committee of Mashhad University of Medical Sciences approved it (no. IR.MUMS.REC.1401.312), and all procedures were conducted in accordance with this registration approval. This research has also been registered in the Iranian Registry of Clinical Trials under the code IRCT20220616055195N1.

3.2. Eligibility criteria

The eligible participants in the study were male and female patients aged 12 years or older with clinical documentation of chronic plaque-type psoriasis and body surface area involvement of less than 10%, referred to the dermatology clinics' outpatient wards at Imam Reza Hospital, Mashhad, Iran.

The exclusion criteria were: (1) Topical anti-psoriatic use in the past 14 days and systemic anti-psoriatic agents within the last month of the study (2) Pregnancy, Lactation or plan to be pregnant during the study; (3) Allergic reactivity to herbal/Plant products; (4) abnormal baseline laboratory findings indicative of hepatic, renal, or systematic disorders; and (5) concomitant current use of any topical or systemic medication. All participants were required to provide written informed consent before enrollment.

3.3. Randomization, allocation concealment, and blinding

Participants were randomized 1:1 using computer-generated block randomization (block sizes 4, 6, or 8) via Sealed Envelope. Allocation codes were placed in sequentially numbered, opaque, sealed envelopes prepared by an independent statistician. Participant enrollment and baseline assessment were performed by the study dermatologist, who had no access to the randomization sequence. After eligibility

confirmation and consent, a research assistant who was not involved in the outcome evaluation opened the next sealed envelope in sequence to implement the group assignment. Participants, treating clinicians, outcome assessors, and data analysts were blinded. Study ointments and placebo were packaged in identical coded tubes (A/B) with indistinguishable appearance, color, odor, and viscosity.

3.4. Intervention formulation and manufacturing

The investigational ointment was prepared by combining 15% Dorema ammoniacum gum powder, 10% vinegar (acetic acid), and 20% wheat germ oil in an Eucerin® base (55%) as the emulsifying and carrier agent. All raw materials were purchased from a local medicinal herb supplier in Mashhad, Iran, and their botanical authenticity was confirmed and approved by the Herbarium Center of Ferdowsi University of Mashhad. The ointment and placebo were manufactured under pharmacist supervision according to a standardized compounding procedure. The placebo consisted of the Eucerin base supplemented with an inert, food-grade coloring agent to match the appearance of the active ointment. As the Eucerin base naturally sequestered the volatile compounds of the active ingredients, no masking agents or fragrances were required to ensure the odor was indistinguishable between the two preparations. Both preparations were packed in identical opaque plastic containers, labeled with blinded codes (A/B), and stored at room temperature (15–25 °C) away from direct light until use. The final pH of the formulation was 6.0, ensuring compatibility with the skin's physiological pH. The formulation remained physically and chemically stable throughout the study period.

3.5. Intervention and control procedures

Patients in the intervention group

applied a thin layer of the Oshaq-based ointment from head to toe twice a day (morning and evening) for 8 weeks to all psoriatic plaques after bathing with gentle soap, ensuring each PP was fully covered. The placebo group applied a preparation with an identical appearance and texture, consisting of the Eucerin base with inert, food-grade coloring, but without any active agent. To minimize potential confounding factors, participants were instructed to avoid any topical or systemic anti-psoriatic treatment throughout the study and to maintain their skin care and hygiene habits unchanged; emollients were permitted, except for 2 h before using the tested ointment. The two groups received similar dietary recommendations according to the clinic protocol. Adherence was assessed by patient self-report at each visit, and patients who were nonadherent (<70%) were managed according to predefined analytical procedures. Participants who experienced severe irritation, an allergic reaction, or met any of the withdrawal criteria defined in the protocol were withdrawn from the intervention while remaining under observation for safety assessment.

3.6. Outcomes and assessments

The outcome of interest was the change in PASI between baseline and week 8. Other outcome measures included changes in DLQI from baseline to week 8 and interim results from week 4 to week 8. PASI and DLQI were measured over time at baseline (week 0), week 4, and week 8 using standardized methods and evaluated by a blinded dermatologist.

3.7. Treatment adherence, associated therapies, and safety Measurements

Participants were monitored for local and systemic adverse effects throughout the study. At each visit, they were assessed for any signs of irritation, redness, burning,

itching, or an allergic reaction in the area of application. Any signs of adverse response, as seen or noted, were properly documented by the study dermatologist.

3.8. Sample size

Based on a 2.5-unit difference between the two groups in PASI, with a standard deviation of 3.0, $\alpha = 0.05$, and a desired power of 90%, the sample size calculation yielded 32 patients per group. However, to prevent dropout, we recruited 70 study patients and assigned them to the two study groups.

3.9. Statistical analyses

Statistical analyses were conducted with Stata version 18 (StataCorp, College Station, TX, USA). The Shapiro–Wilk test was used to assess normality of the continuous variable. Continuous variable data were presented as mean $\pm$ standard deviation (SD) or median (interquartile range [IQR]), where appropriate; for categorical data, presentation was as frequency and percentage. All analyses were conducted using a per-protocol method, involving only participants who completed the study. Using multivariate analysis of variance and covariance (MANOVA/ANCOVA), time-based and group-based differences were quantified for group, time, and the group-by-time interaction. Adjustments were made based on disease duration and baseline values. Pairwise comparisons were made based on 95% confidence intervals. A statistically significant difference was noted with two-sided p-values < 0.05.

4. Results

A total of 97 subjects were screened for eligibility, and 70 were assigned to the intervention (n=35) or control group (n=35). One participant was lost to follow-up, and two dropped out due to AEs (itching, redness) in the intervention group. In the control group, 3 patients were lost to follow-

up due to failure to attend scheduled visits. The final analysis included 32 patients per group. (Figure 1).

The mean and SD of age were $35.28 \pm$

11.03 years. Overall, the study participants were 45% female and 55% male. The mean duration of psoriasis was 6.88 ± 4.38 months (Table 1).

Table 1: Baseline characteristics of study participants.

		Placebo (Comparison Group) N= 32 (50.0)	Oshaq (Treatment Group) N= 32 (50.0)
Age (Years), Mean (SD)		34.91 (12.55)	35.66 (9.45)
Duration of disease (Month), Mean (SD)		5.78 (3.65)	7.97 (4.81)
Sex	Male	17 (53.1%)	18 (56.2%)
	Female	15 (46.9%)	14 (43.8%)

Data are frequencies (%) unless specified differently.

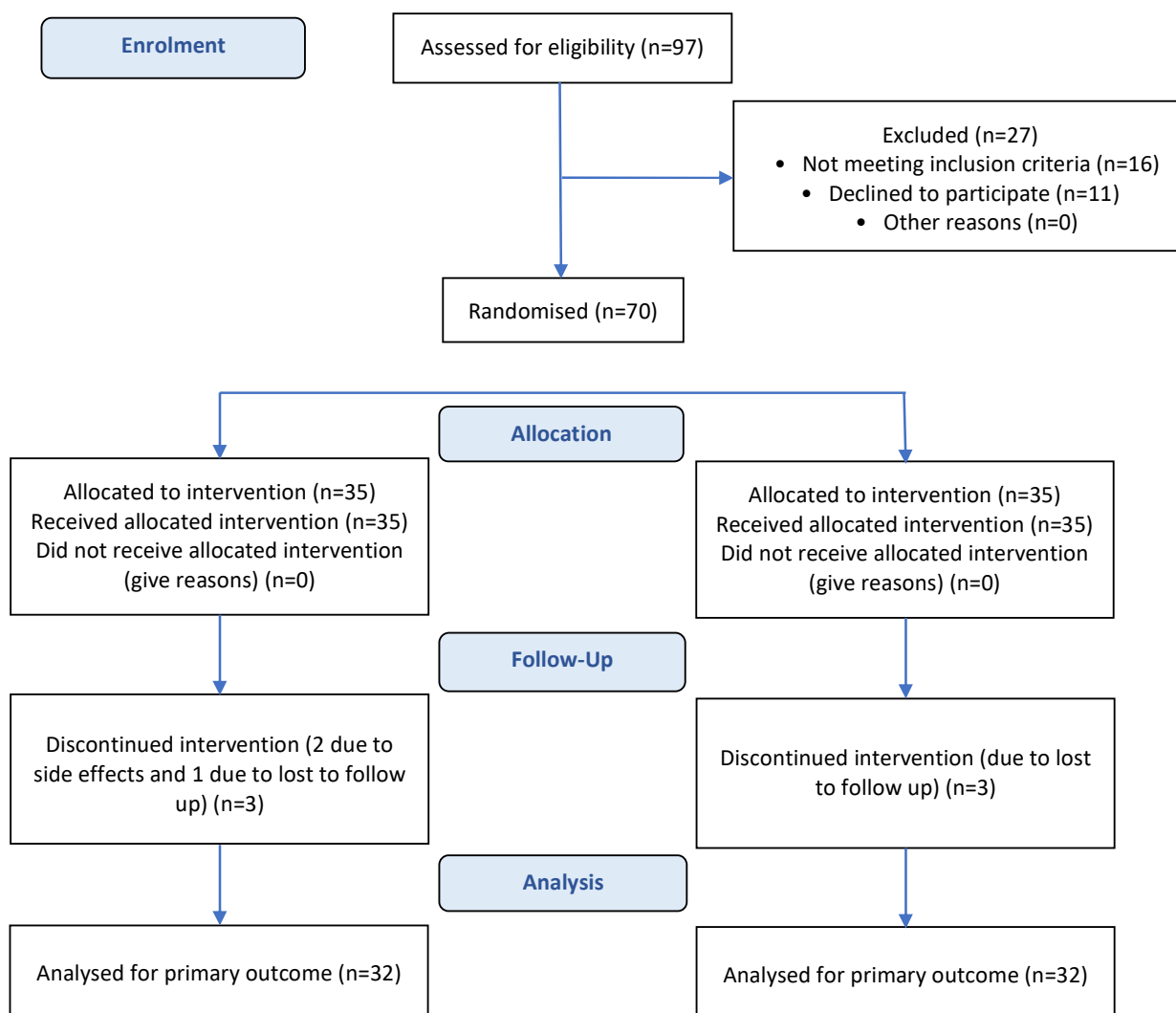


Figure 1 :CONSORT Flow Diagram of the study

As indicated in Table 2, the average PASI index significantly decreased over time (within-group) only in the treatment group ($P=0.007$) (**Error! Reference source not found.**). However, the average of this index in between-group comparisons differed significantly at 1 month ($P=0.003$) and 2 months ($P<0.001$) after the study. The results

from multivariate analysis showed that the interaction effect of time and group was statistically significant ($P=0.049$) (**Error! Reference source not found.**). Clinical improvement was observed in the patients, as illustrated in the representative case shown in Figure 2.

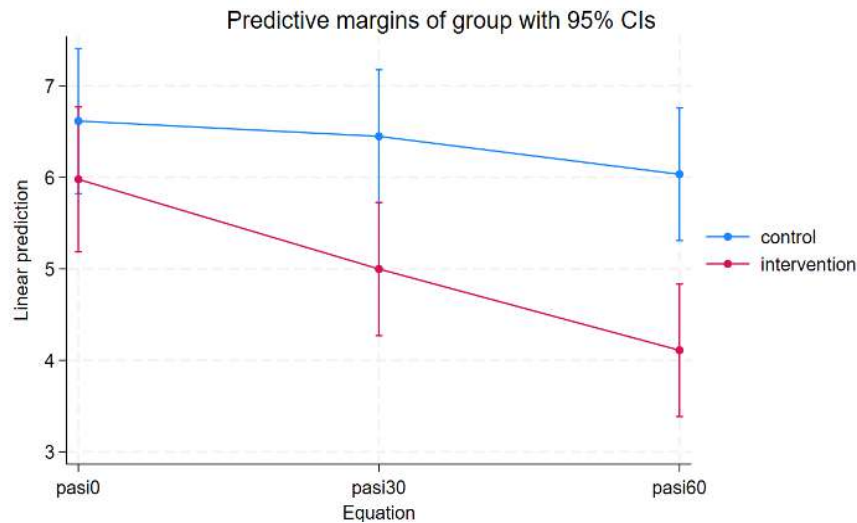


Figure 1: Trend of PASI score at baseline, week 4, and week 8 in the intervention and control groups.

Table 2: Comparison outcomes at different time points (month)

Outcome	Group	Mean (SD)			P-value
		Baseline	Week 4	Week 8	
PASI	Control	6.55 (2.78)	6.36 (2.52)	5.95 (2.44)	0.639
	Intervention	6.03 (2.54)	5.07 (2.29)	4.18 (2.09)	0.007
DLQI	Control	18.21 (4.91)	17.50 (4.37)	17.40 (4.83)	0.753
	Intervention	20.43 (3.62)	17.56 (3.72)	15.18 (3.84)	0.000

Table 3: The effect of Intervention, time, and their interaction on the PASI outcome (adjusted for disease duration)

variable	Pairwise comparison	Mean difference (95%CI)	P value (Pairwise)	P value* (MANOVA)
Group	intervention vs control	-1.72 (-1.90 to -0.77)	≤0.001	≤0.001
Time	Week 4 vs baseline	-0.57 (-1.21 to 0.06)	0.079	0.002
	Week 8 vs baseline	-1.22 (-1.86 to -0.58)	≤0.001	
	Week 8 vs week 4	-0.65 (-1.29 to -0.01)	0.046	
Intervention* Time	Week 4 vs baseline in control	-0.18 (-1.09 to 0.71)	0.683	0.049
	Week 8 vs baseline in control	-0.60 (-1.50 to 0.30)	0.192	
	Week 8 vs week 4 in control	-0.41 (-1.31 to 0.49)	0.369	
	Week 4 vs baseline in intervention	-0.95 (-1.86 to -0.05)	0.038	
	Week 8 vs baseline in intervention	-1.85 (-2.75 to -0.94)	0.000	
	Week 8 vs week 4 in intervention	-0.89 (-1.79 to 0.01)	0.054	
	intervention vs control at baseline	-0.66 (-1.59 to 0.26)	0.161	
	intervention vs control at week 4	-1.43 (-2.36 to -0.50)	0.003	
	intervention vs control at week 8	-1.91 (-2.84 to -0.98)	0.000	

Adjusted for duration of disease and baseline PASI



Figure 2: Clinical progression in a representative patient with plaque psoriasis on the left knee. (a) Baseline. (b) After 8 weeks of Persian medicine treatment, demonstrating significant resolution of erythematous plaques and scaling.

Comparison of the secondary outcome: The DLQI scores in the intervention group decreased significantly over time ($p \leq 0.001$), from 20.43 at baseline to 15.18 at week 8, a difference of 5.25 points (Figure 4). The difference in change in DLQI between groups was also significant for the intervention

compared with the control ($p \leq 0.001$) (Table 2). In multivariate analyses, the time $\times$ group interaction was significant ($p = 0.004$), indicating greater improvement in quality of life in the intervention group than in the placebo group (Table 4).

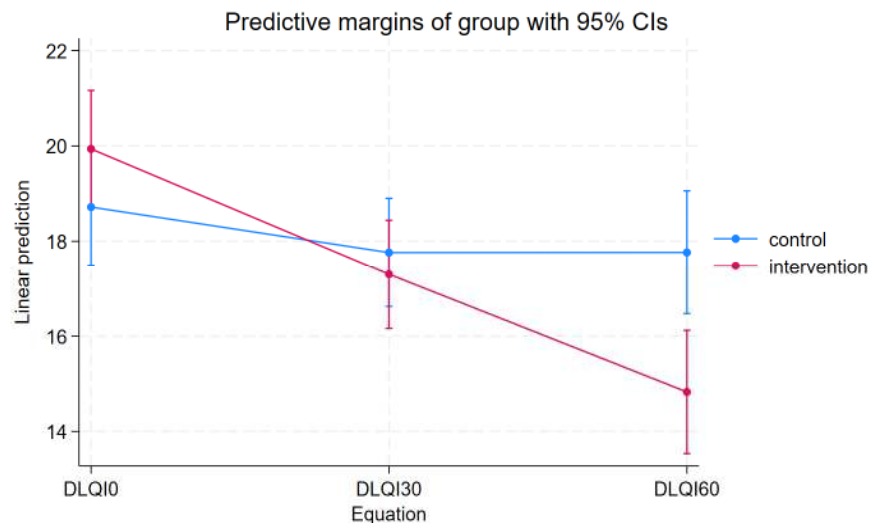


Figure 3: Trend of DLQI score at baseline, week 4, and week 8 in the intervention and control groups.

4.1. Adverse Events

No serious adverse events were recorded during the study. The local adverse reactions

were mild and self-limiting, such as itching and erythema, recorded in two volunteers receiving the active formulation, prompting discontinuation of the treatment. In contrast,

no clinically significant adverse reactions were recorded in the placebo group.

Table 4: The effect of Intervention, time, and their interaction on the DLQI outcome (adjusted for disease duration)

variable	Pairwise comparison	Mean difference (95%CI)	P value (Pairwise)	P value* (MANOVA)
Group	intervention vs control	-2.82 (-3.63 to - 2.01)	≤0.001	≤0.001
Time	Week 4 vs baseline	-2.85 (-5.15 to -0.59)	0.008	0.002
	Week 8 vs baseline	-5.25 (-7.52 to - 2.97)	0.006	
	Week 8 vs week 4	-2.37 (-4.65 to 0.09)	0.038	
Intervention* Time	Week 4 vs baseline in control	-0.71 (-2.24 to 0.80)	0.354	0.004
	Week 8 vs baseline in control	-0.81 (-2.33 to 0.71)	0.295	
	Week 8 vs week 4 in control	-0.09 (-1.64 to 1.43)	0.904	
	Week 4 vs baseline in intervention	-2.87 (-4.40 to -1.34)	≤0.001	
	Week 8 vs baseline in intervention	-5.25 (-6.77 to -3.72)	≤0.001	
	Week 8 vs week 4 in intervention	-2.37 (-3.90 to -0.84)	0.002	
	intervention vs control at baseline	1.47 (-0.09 to 3.04)	0.066	
	intervention vs control at week 4	-0.68 (-2.25 to 0.88)	0.390	
	intervention vs control at week 8	-2.96 (-4.53 to -1.39)	≤0.001	
Adjusted for duration of disease and baseline DLQI				

5. Discussion

Sixty-four patients with mild to moderate plaque psoriasis were included in the study and evaluated in a double-blind, randomised clinical trial. The topical mixture of Dorema ammoniacum gum-resin with vinegar and wheat germ oil was significantly more effective than the placebo in improving the primary outcome (after 8 weeks) and secondary outcomes. The average PASI score in the intervention group decreased from 6.03 (at baseline) to 4.18 (at week 8), a decrease of 1.85 points, whereas the placebo group showed no decline. Persistent decreases were also observed in the DLQI score (average reduction of 5.25 points in the intervention group). From a clinical perspective, these improvements are meaningful. The mean reduction in the DLQI score (5.25 points in the intervention group) exceeded the commonly accepted MCID threshold of 4 points, indicating a clinically relevant improvement in patients' quality of life. Although the absolute decrease in the PASI score was more modest, the change was statistically significant and consistent with a

beneficial treatment effect. Taken together, the concurrent improvements in PASI and DLQI suggest that the formulation has detectable, clinically meaningful efficacy in mild-to-moderate plaque psoriasis.

This study's findings are consistent with the literature on herbal treatment for plaque psoriasis, which shows slight but steady decreases in the inflammation, scaling, and patient-reported symptoms (7, 20). However, compared with most previously published herbal trials, the present study benefits from rigorous double-blinding, standardized formulation, and the use of validated clinical outcome measures, which may partly explain the clearer and more consistent treatment effect observed in our trial. While direct comparisons with prior studies are complicated by variations in study design and outcome definitions, the methodological rigor of the current trial strengthens the reliability and clinical relevance of the observed findings. The methodological rigor of the current trial strengthens the reliability and clinical relevance of the observed findings.

Clinical investigations involving *Dorema ammoniacum* (Oshaq) have previously documented symptom alleviation in dermatologic conditions such as melasma and dermatophytosis (12, 21). Despite differences in methodology and control conditions, these studies consistently noted clinical benefits following topical application of Oshaq-based products. Possible explanations for the increased differentiation between the intervention and placebo groups include the use of validated metrics such as PASI and DLQI, the specific combination of Oshaq, vinegar, and wheat germ oil, and the use of the combination product throughout the study. The differences in the amounts of active ingredients, treatment duration, and comparator type in prior studies likely explain the variation in treatment efficacy. However, the evidence as a whole supports the efficacy of the improvements observed in this study. The changes in PASI and DLQI scores are likely due to the known pharmacological activities of the ingredients in the topical formulation. At the molecular level, psoriasis is characterized by dysregulation of the IL-23/Th17 axis, overproduction of inflammatory cytokines IL-17, IL-22, and TNF- α , and activation of the NF- κ B pathways. Modulation of these pathways is considered central to effective disease control. *Dorema ammoniacum*'s antimicrobial, antioxidant, and anti-inflammatory attributes are supported by both experimental and clinical studies (12, 22). According to research, some bioactive substances present in *Dorema* species may inhibit NF- κ B activation and the Th17 inflammatory response, which are critical to keratinocyte hyperproliferation and subsequent epidermal inflammation. Another component, vinegar (acetic acid), has antimicrobial, anti-inflammatory, and antiseptic properties, especially in the management of chronic wounds; thus, it may help reduce local inflammation and microbes

within psoriatic lesions (15, 16). In addition, the acidic environment may help shape the local immune response, facilitate the absorption of active compounds, and enhance the immune response. Wheat germ oil has been shown to provide protective benefits against tissue injury, enhance healing, and improve barrier function, thanks to its vitamin E and natural antioxidant constituents (18, 23). Restoration of epidermal barrier integrity may further diminish inflammatory triggers and improve therapeutic responsiveness. The three agents in the formulation, each with its own unique anti-inflammatory, immunomodulatory, antimicrobial, and emollient properties, are expected to enhance the treatment of plaque psoriasis by further aiding lesion resolution and maintaining clinical improvement.

From a clinical perspective, these improvements are meaningful. They could be quite beneficial for patients with mild to moderate plaque psoriasis, given the known shortcomings of conventional topical corticosteroids, such as tachyphylaxis, skin atrophy, and local toxicity (7). The smooth decrease in PASI over the 2 months, associated with a substantial improvement in DLQI, demonstrates that this combination, when used successfully, provides some symptom relief and permits a good quality of life, which is often altered in psoriasis patients (4). Of note, these results corroborate the possibility of standardized multi-herbal formulations as steroid-sparing in long-term disease management. The placebo-controlled methodology enhances the credibility of the findings. This formulation may thus be a useful adjunctive treatment for patients who refuse or cannot remain on long-term systemic corticosteroid therapy. With the trend toward increased use of herbal and complementary interventions (24), this preparation also has potential in such an alternative setting, especially for outpatients seeking safer life-long therapies.

There are a few limitations to this study that warrant mention. The main limitation of the study was the small sample size, which included only patients with mild to moderate plaque psoriasis. Second, the follow-up duration was relatively short, precluding an assessment of the long-term course. Third, bias may have been present in this study due to the subjective nature of self-reported adherence and the lack of objective inflammation biomarkers. Finally, this was a single-center study with a placebo arm, and comparisons with other standard topical agents are not possible. Other trials are needed to determine the exact position of this formulation in the therapy of psoriasis.

6. Conclusion

In conclusion, the present double-blind, placebo-controlled study showed that topical Dorema ammoniacum resin, vinegar, and wheat germ oil enhanced not only PASI but also DLQI scores compared to placebo after 8 weeks. These results indicate that the formulation may be used as an alternative agent with fewer side effects than standard topical corticosteroids in patients with mild to moderate plaque psoriasis. Nevertheless, further studies with longer follow-up and active comparators are necessary to delineate its clinical role and long-term efficacy better.

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Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflict of interest: The authors declare that they have no conflicts of interest.

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study.

Consent for publication: Written informed consent to publication (including images, personal and clinical details of the participant) was obtained from the patient.

Ethics approval and consent to participate: This study was conducted following the principles of the Declaration of Helsinki. The study protocol was reviewed and approved by the Research Ethics Committee of Mashhad University of Medical Sciences (approval number: IRMUMS.REC.1401.312). Written informed consent was obtained from all participants. This research has also been registered in the Iranian Registry of Clinical Trials under the code IRCT20220616055195N1.

Author contributions: Z.N.-P. and A.D. conceived and designed the study. M.J.Y. performed patient recruitment and dermatologic assessments. R.S. contributed to formulation development and pharmacologic supervision. H.H.M. designed and conducted the statistical analyses. All authors interpreted the data, revised the manuscript critically for important intellectual content, and approved the final version.

Generative AI Statement: Language editing assistance was provided using artificial intelligence-based tools for grammar and stylistic refinement only. All aspects of study design, data collection, statistical analysis, interpretation, and manuscript content were performed exclusively by the authors.

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