

## Original Research Article

# Aloe vera, wheat germ oil, tea tree extract and honey-based emollient cream in the management of atopic dermatitis: a post-hoc analysis

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**Received:** 06 August 2023

**Revised:** 04 September 2023

**Accepted:** 12 September 2023

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## ABSTRACT

**Background:** Atopic dermatitis is a chronic skin condition characterized by dry, itchy and inflamed skin. This study evaluated the complementary benefits efficacy and tolerability of emollient c containing Aloe vera, Wheat germ oil, tea tree extract, and honey in patients with dry skin conditions.

**Methods:** Cross-sectional analysis for clinical cases with dry skin receiving moisturizing cream formulation was undertaken at 156 centres. 286 case records of atopic dermatitis receiving standard of care as cleansers, Topical corticosteroids, moisturizers were further analysed for improvement in skin dryness and itchiness.

**Results:** Regular use of Emollient formulation containing aloe vera, wheat germ oil, tea tree extract, honey was further analysed along with safety assessment over 8 weeks of observation period. The mean age of the study participants was 36.58 years. There was significant change in VAS score for dryness (p-value< 0.01), itch (p-value <0.01) with Patient Global Assessed rating as good (64.23%) for effectiveness and ease of application. Mild stinging, mild burning and irritation was experienced by 5 (1.75%) patients.

**Conclusions:** The aloe vera, wheat germ oil, tea tree extract, honey enriched emollient formulation was efficacious and well tolerable in study participants in providing moisturizing, antimicrobial, and anti-inflammatory effects making it a preferred complementary therapy for managing atopic dermatitis following the short course therapy with TCS as a pertinent clinical strategy to avoid the atopic flares in such cases.

**Keywords:** Atopic dermatitis, Itching, Dry skin, Hydration, Emollient, Moisturizer

## INTRODUCTION

Atopic dermatitis is a common, chronic, intensely itchy, relapsing and inflammatory skin condition affecting about one-fifth of individuals at a certain point in their

lives, however, prevalence rates vary widely around the world. Young children are most frequently affected by atopic dermatitis.<sup>1</sup> This condition significantly lowers the quality of life (QoL) and causes severe morbidity.<sup>2,3</sup> Patients are impacted not just by social stigma associated

with visible skin ailment, but also by their condition's extreme itching, which frequently causes skin injuries and serious sleep difficulties.<sup>4</sup> Apart from physical symptoms, atopic dermatitis has substantial mental impact which may cause sleep issues, more frustration and anxiety, and decreased self-esteem.<sup>5</sup> Adequate skin hydration is also the most fundamental part of care for both preventing flares and treating atopic dermatitis.

Emollients are creams that are applied topically and are the current preferred standard of care for atopic dermatitis because they contain occlusive ingredients that reduce trans-epidermal water loss (TEWL), moisturizing ingredients that bind water and lipids that seal the epidermal barrier. For people suffering from atopic dermatitis, emollients offer an occlusive barrier to the skin, hold onto moisture, and shield it from allergens. Various emollient products have been marketed to treat atopic dermatitis with claim of therapeutic effect. The emollient cream contains aloe vera, wheat germ oil, tea tree extract and honey that are beneficial for atopic dermatitis. Aloe vera exhibits anti-inflammatory, anti-irritant, wound healing and moisturizing effects.<sup>6,7</sup>

Aloe vera and wheat germ oil moisturise dry skin and eradicate *Staphylococcus aureus* bacteria from colonised atopic dermatitis skin.<sup>8</sup> Tea tree oil has broad-spectrum antimicrobial activity with non-specific cell membrane destruction being a significant mode of action.<sup>9,10</sup> As per traditional medicine honey has been proven as more efficacious in treatment of range of skin disorders. Honey possesses antibacterial properties which helps in healing of skin by stimulating tissue repair.<sup>11,12</sup> This study was conducted in outpatient departments all over India with an objective to assess efficacy, usage trend and tolerability of emollient cream containing aloe vera, wheat germ oil, tea tree extract and honey for management of patients with atopic dermatitis.

## METHODS

### *Study design and patient population*

The study was a post-approval, cross-sectional, observational, single-arm clinical study aiming to evaluate the efficacy and tolerability of an emollient cream containing aloe vera, wheat germ oil, tea tree extract, and honey for daily use in the treatment of dry skin conditions and atopic dermatitis. The study was conducted between June 2023 and July 2023 at 156 clinical centres across India. Main centre for recruitment was Shreeji Skincare Clinic, Ahmedabad, Gujarat.

The study enrolled 984 participants aged 18 to 65 years suffering from dermatitis with dry skin type, requiring complimentary add on or maintenance therapy with emollients. Out of these participants, 286 individuals with atopic dermatitis were taken as intent-to-treat (ITT) population. Of these, 140 (48.95%) were male and 146

(51.05%) were female. Patients with allergic skin disease other than cases of dry skin were excluded from study.

### *Procedure*

The study focused on participants who completed the 8-week therapy of emollient cream. Among 984 patients, 389 participants were lost to follow up. Patient global assessment (PGA) scale was utilized in this study to assess the treatment effectiveness, and overall outcome. A post-hoc analysis was conducted on subjects with the diagnosis of atopic dermatitis to explore specific aspects and variables of interest. The study consisted of three visits. At visit 1 (screening visit), all the participants were prescribed with emollient cream. Visit 1 evaluated inclusion/exclusion criteria, demographics, and physical examinations, including age, height, weight, body mass index, medical history, current treatment history, and concomitant medications for existing medical conditions like allergy, asthma, depression or hypertension (Table 1). During visit 2 (post 2 weeks), the assessment focused on evaluating the improvement in dryness and itchiness for a duration of 2 weeks in patients with atopic dermatitis. Similarly, at visit 3 (post 8 weeks), assessment of dryness and itchiness was done. PGA was also conducted to evaluate the outcome improvement at visit 3. As this study was conducted in a real-life setting, the studied intervention emollient cream was prescribed by the attending dermatologists, and patients obtained it from the pharmacy stores. Assessment of compliance was done using case record form. Throughout the entire study duration, close monitoring and complete documentation of adverse events (AEs) and treatment-emergent adverse events (TEAEs) was done.

The present study was conducted in accordance with the declaration of Helsinki (Brazil, October 2013), good clinical practices for clinical research in India 2005, new drugs and clinical trials rules 2019, ICH GCP E6 (R2) guidance on good clinical practice, and with ICMR's National ethical guidelines for biomedical and health research involving human participants, 2017. Approval from independent ethics committee was also obtained before the initiation of the study for each centre. The study had been registered with the clinical trials registry of India (CTRI) with CTRI number CTRI/2023/06/053853.

### *Emollient cream*

The emollient cream was applied three to four times daily or as directed by the treating physician throughout the study period (Table 2).

### *Statistical methods*

Patient demographic details, including modifiable and non-modifiable risk factors and comorbidities, analyzed using descriptive statistics. For qualitative variables, frequencies and percentages reported. Quantitative

variables summarized using means, medians, standard deviations, minimum and maximum values, and 95% CI. To assess significance of continuous and categorical variables, Student's paired T test was utilized, with a  $p > \text{value}$  less than 0.05 considered clinically significant.

Two-tailed test employed for these analyses. Continuous variables presented as mean  $\pm$  standard deviation, while categorical variables were presented as numbers and proportions of patients. All statistical analyses were performed using SPSS software version 29.0.1.0 (171).

**Table 1: Baseline details of patients of atopic dermatitis.**

Variables	Parameters	N	Percentage (%)
Occupation	Business	45	15.73
	House wife	73	25.52
	Retired	9	3.15
	Self employed	38	13.29
	Service	87	30.42
	Student	34	11.89
Type of diet	Vegetarian	97	33.92
	Non-Vegetarian	172	60.14
	Eggetarian	15	5.24
	Vegetarian, non-vegetarian	2	0.70
No. of comorbidities	1	56	19.58
	2	24	8.39
	>3	24	8.39
	None	182	63.64
Existing medical conditions	Allergies	32	11.2
	GI problems	18	6.3
	Asthma	12	4.2
	Hormonal issues	8	2.8
	Anxiety	8	2.8
	Hypertension	6	2.1
	Allergies, GI problems	5	1.7
	COPD	5	1.7
	Other Conditions	45	15.7
	None	147	51.4

**Table 2: Study drug.**

Parameters	Treatment
Product name	<b>Dewsoft emollient cream</b>
	<b>Ingredients list:</b> Aloe vera, honey, wheat germ oil, tea tree extract, purified water, caprylic/capric triglyceride, olivem 1000, oliwax, light liquid paraffin, propylene glycol, octyldodecanol, cetostearyl alcohol, stearic acid, glyceryl mono stearate, triethanolamine, oxynex st, hyaluronic acid, lanolin anhydrous, sodium lauryl sulphate, methyl paraben, propyl paraben, fragrance
Dosage form	Cream
Dosage	Apply three to four times daily or as prescribe by physician
Route of administration	Topical
Manufacturer	Torrent pharmaceuticals Ltd

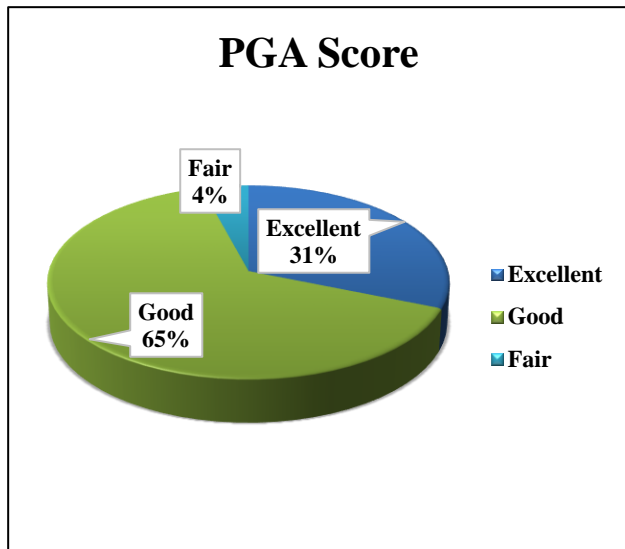
## RESULTS

Out of the total 984 participants enrolled in the study; the study specifically focused on data of the 286 patients (29.06%) who had atopic dermatitis. Among these patients, 140 (48.95%) were male and the 146 (51.05%) were female.

The mean age, weight, and height of study participants were  $36.58 \pm 11.11$  years and  $67.59 \pm 11.53$  kg, as well as the  $160.39 \pm 12.96$  cm (Table 3).

Based on statistical analysis, it was observed that emollient cream had a significant impact in attenuating dry skin conditions in patients with atopic dermatitis. The cream showed a significant reduction ( $p < 0.01$ ) in skin dryness with delta ( $\Delta$ ) change from 3.29 to -1.16 (-31.52%) at  $2 \pm 1$  week and of -2.50 (-69.04%) at  $8 \pm 1$  week. Furthermore, it effectively reduced itchiness ( $p < 0.01$ ) with a delta ( $\Delta$ ) change from 2.99 to -1.13 (-34.70%) at  $2 \pm 1$  week and -2.34 (-70.68%) at  $8 \pm 1$  week in patients with atopic dermatitis and dry skin condition (Table 4). PGA score after using emollient creams

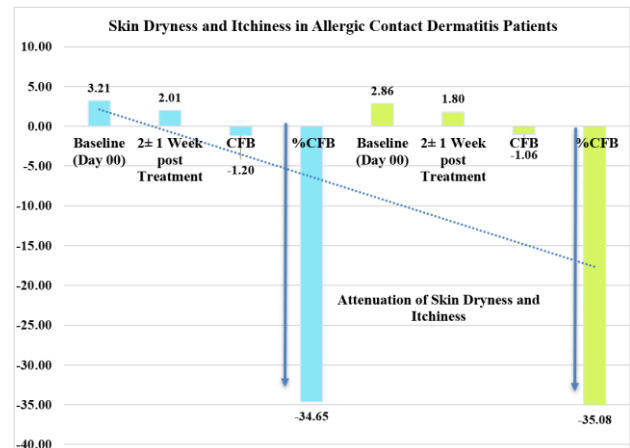
demonstrated that 89 participants (31.38%) showed excellent results, followed by 185 participants (64.23%) showing good results (Figure 1). For patients with allergic contact dermatitis a significant reduction in skin dryness was seen by 34.65% after 2±1 weeks and by 73.67% after 8±1 weeks. Furthermore, emollient cream also effectively reduced itchiness in patients with allergic contact dermatitis by 35.08% after 2±1 weeks and by 74.11% after 8±1 weeks (Figure 2).



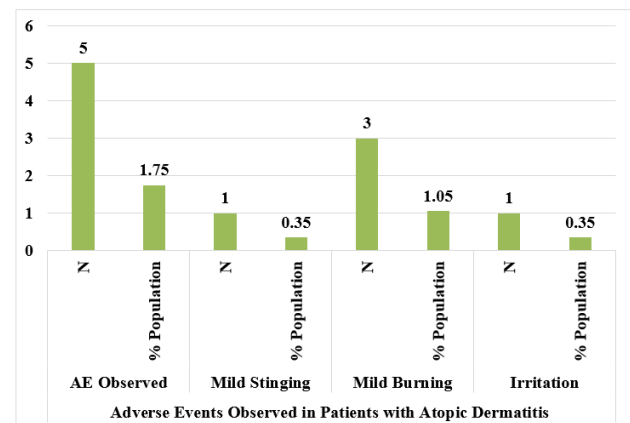
**Figure 1: PGA score in patients of atopic dermatitis.**

For patients who used emollient cream as a sole treatment, skin dryness was attenuated by 28.18% ( $p<0.01$ ) and 63.20% ( $p<0.01$ ) at 2±1 and 8±1 weeks respectively. Similarly, itchiness was attenuated by 30.45% ( $p<0.01$ ) and 62.87% ( $p<0.01$ ) at 2±1 and 8±1 week respectively (Table 5). For patients who used emollient cream in combination with other treatments (i.e., cleansers, steroids) experienced significant attenuation in skin dryness by 35.30% ( $p<0.01$ ) at 2±1 weeks and by 77.77% ( $p<0.01$ ) at 8±1 weeks. Furthermore, reduction was seen in itchiness by 41.57% ( $p<0.01$ ) at 2±1 week and by the 84.08% ( $p<0.01$ ) at the 8±1 week for the patients with atopic dermatitis (Table 6).

Upon analysing the adverse events, it was found that out of 286 participants only 5 subjects (1.75%) experienced adverse events. These events included mild stinging, mild burning, and irritation, which were observed in 1, 3, and 1 patient, respectively (Figure 3). The occurrence of these adverse events suggests a low incidence rate. Based on these findings, it can be concluded that the emollient cream was well tolerable for use in studied population.



**Figure 2: Patient assessed outcomes for skin dryness and itchiness for allergic contact dermatitis.**



**Figure 3: Adverse events observed in patients with atopic dermatitis.**

**Table 3: Demographic parameters of patients having atopic dermatitis.**

Variables	Demographics		
	Male (n=140), (48.95%)	Female (n=146), (51.05%)	Overall (n=286), (100%)
	Mean (SD)	Mean (SD)	Mean (SD)
Age (in years)	38.59 (11.22)	34.64 (10.72)	36.58 (11.11)
Height (cm)	163.90 (14.37)	156.93 (10.49)	160.39 (12.96)
Weight (kg)	71.96 (10.67)	63.59 (10.79)	67.59 (11.53)

**Table 4: Descriptive statistics for skin dryness and itchiness in patients of atopic dermatitis.**

Parameters	Dryness						Itchiness							
	Baseline (Day 0)	2±1 week post treatment	CFB	% CFB	8±1-week post treatment	CFB	% CFB	Baseline (Day 00)	2±1 week post treatment	Change from baseline (CFB)	%CFB	8±1-week post treatment	CFB	% CFB
<b>N</b>	286	286	286	286	280	280	280	285	285	285	285	279	279	279
<b>Mean</b>	3.29	2.13	-1.16	-31.52	0.79	-2.50	-69.04	2.99	1.86	-1.13	-34.70	0.65	-2.34	-70.68
<b>SD</b>	0.94	0.77	0.95	37.08	0.92	1.43	50.84	0.97	0.89	0.96	37.59	1.01	1.49	55.27
<b>SEM</b>	0.05	0.05	0.06	2.21	0.05	0.08	3.03	0.06	0.05	0.06	2.24	0.06	0.09	3.30
<b>Median</b>	4	2	-1	-33.33	1.00	-3.00	-75.00	3	2	-1	-33.33	0.00	-3.00	-100
<b>Minimum</b>	0	0	-4	-100	0.00	-4.00	-100.00	0	0	-4	-100	0.00	-4.00	-100
<b>Maximum</b>	4	4	2	200	4.00	3.00	300.00	4	4	2	200	4.00	3.00	300
<b>P value</b>	<0.01				<0.01				<0.01				<0.01	

**Table 5: Descriptive statistics of patients with atopic dermatitis using emollient cream as the sole treatment.**

Parameters	Dryness				Itchiness			
	Baseline (Day 00)	2±1 week post treatment	CFB	% CFB	Baseline (Day 00)	2±1 week post treatment	Change from baseline (CFB)	% CFB
<b>N</b>	147	147	147	147	147	147	147	147
<b>Mean</b>	3.16	2.12	-1.04	-28.18	2.84	1.87	-0.97	-30.45
<b>SD</b>	1.03	0.79	1.01	45.01	1.03	0.79	1.01	45.01
<b>Median</b>	3	2	-1	-33.33	3	2	-1	-33.33
<b>Minimum</b>	0	0	-4	-100	0	0	-4	-100
<b>Maximum</b>	4	4	2	200	4	4	2	200
<b>P value</b>	<0.01				<0.01			

**Table 6: Exploring descriptive statistics for atopic dermatitis patients: emollient cream combinations with cleansers and steroids.**

Parameters	Dryness				Itchiness			
	Baseline (Day 00)	2±1 week post treatment	CFB	% CFB	Baseline (Day 00)	2±1 week post treatment	Change from baseline (CFB)	% CFB
<b>N</b>	95	95	95	93	95	94	94	92
<b>Mean</b>	3.45	2.14	-1.3	<b>-35.30</b>	3.15	1.79	-1.35	-41.57
<b>SD</b>	0.87	0.79	0.87	26.78	0.77	0.79	0.9	24.63
<b>SEM</b>	0.08	0.08	0.08	2.77	0.07	0.08	0.09	2.56
<b>Minimum</b>	0	0	-4	-100	0	0	-4	-100
<b>Maximum</b>	4	4	1	100	4	4	1	33.33
<b>P value</b>	<0.01				<0.01			



## DISCUSSION

The present study evaluated the safety and efficacy of emollient cream in the treatment of dry skin conditions in atopic dermatitis. Atopic dermatitis often leads to intense itching, discomfort, and visible changes in the skin, which greatly impacts an individual's QoL. The results of our study suggests that use of emollient cream containing aloe vera, wheat germ oil, tea tree extract and honey showed significant reduction ( $p < 0.01$ ) in skin dryness by 31.52% after  $2 \pm 1$  week and by 69.04% after  $8 \pm 1$  week and itchiness by 34.70% after  $2 \pm 1$  week and by 70.68% after  $8 \pm 1$  week of treatment in patients with atopic dermatitis and dry skin condition. Furthermore, the PGA demonstrated the positive impact of emollient cream in atopic dermatitis patients.

While primary prevention strategies for atopic dermatitis are currently lacking, recent studies have highlighted the effectiveness of emollients in improving skin hydration in management of atopic dermatitis.<sup>13</sup> Skin humectants, containing emollients have shown superior moisturizing properties, ultimately alleviating skin dryness and disease severity in individuals with atopic dermatitis.<sup>14</sup>

Aloe vera possesses anti-inflammatory and anti-infectious properties which helps in healing skin lesions.<sup>15,16</sup> In a double-blind study conducted by Vardy et al which involved 44 subjects aged 22 to 80 years, therapy with aloe vera was found to be significantly superior to placebo in the reduction of pruritus to 5.3%, scaliness to 17.6% and erythema to 20.3% in patients with dermatitis and was associated with better global improvement ratings as assessed by both participants and physicians.<sup>16</sup> The results of this study are in line with our present study in improving the symptoms associated with dermatitis.

Wheat germ oil is rich in various essential vitamins and minerals like in vitamins E, B6, B12, magnesium, calcium and zinc. Studies further state that wheat germ oil possess anti-inflammatory and soothing properties which helps in the management of atopic dermatitis.<sup>18,17</sup> Wheat germ oil has also been reported to exhibit antioxidant property which benefits the immune system and wound improvement process.<sup>18</sup> Honey has numerous medicinal properties. Many *in vivo* and *in vitro* studies have proved the broad spectrum antimicrobial properties of honey and also its ability to promote the process of wound healing.<sup>19-23,22</sup> A study was conducted to study the effects on honey on atopic dermatitis patients. The results yielded that the lesions were significantly improved post treatment with honey as compared to control lesions.<sup>23</sup> Another ingredient of emollient cream Tea Tree extract has anti-microbial and anti-inflammatory effects on skin.<sup>24</sup> A study by Wallengren concluded that tea tree oil proved to be more effective anti-eczematic agent than other agents compared in the study like zinc oxide and clobetasol butyrate.<sup>25</sup>

Results of all the discussed studies aligns with our study and further strengthens our results. There are certain limitations to this study that should be acknowledged. One major challenge encountered by treating physician was the assessment of the patient adherence to the study product. Additionally, due to observational and non-comparative study design the findings of our study are not supported by histological evaluation or objective/quantitative assessments. However, this study provided vital information to treating physicians regarding the benefits of the above discussed ingredients in the management of atopic dermatitis.

It is important to note that the significant reduction in dryness and itchiness observed in our study indicates an improvement in physical discomfort and an enhancement in the QoL of patients with dry skin conditions.

## CONCLUSION

This study significantly contributes to the growing research on emollient cream enriched with aloe vera, wheat germ oil, tea tree extract, and honey. It demonstrated significant efficacy in alleviating skin dryness and itchiness among patients with atopic dermatitis when used with standard of care. Furthermore, it improved the overall QoL of these patients when used daily. The rich moisturizing formula makes it an ideal adjunct for dry skin conditions.

## ACKNOWLEDGEMENTS

Authors would like to thanks to Dr. Nayan Patel (MBBS) and Ms. Maheshvari Patel (PhD Scholar, Pharmacology) for their valuable support in the preparation of this manuscript. Additionally, we sincerely thank WHEARA study Investigator(s) panel for participation in the study as clinical researcher and all the patients who participated in this study for their contribution. \*WHEARA study Investigator(s) Panel: Pandya N. (Surendranagar), Choksi S. (Surat), Shah A. (Vadodara), Patel R. (Raigarh), Matte P. (Nagpur), Agarwal B. (Jabalpur), Narkhede G. (Jalgaon), Mali R. (Chinchwad), Pethe S. (Pune), J. R. (Mysore), Rai V. (Mangalore), Naveen K., (Dharwad), Sitaram L. M. (Shivamogga), Aarthi B. K. (Chennai), Vasudevan P., (Chennai), Zacharia U., (Kottayam), Roshindas T M (Thrissur), K Muhammed (Vatakara), Sachinkumar MU (Kalpetta), Peter S. (Ernakulam), Mathew C. (Aluva), Fathima S. (Kannur), Menon S. (Thiruvananthapuram), Mir M. (Hyderabad), Rai P. (Pratapgarh), Srivastava K. (Lucknow), Maheswari N. (Lucknow), Panigrahy R. (Bhubaneswar), Sahu P. (Cuttack), Purva (Ranchi), Panigrahi P. (Balasore), Kumar S. (Kishanganj), Kumar N. (Gaya), Kanaujia M. (Dhanbad), Raizada A. (Angul), Das A. (Barasat), Lohia A. (Guwahati), Das K. (Cooch Behar), Prodaan A. (Burdwan), Gurung D. (Siliguri), Verma B. (Bolpur), Mittal N. (Jaipur), Som K. (Thane), Vyas B. (Mumbai), Singh P. (Roorkee), Sree Devi K. (Rajahmundry), Verma

K. (Jhansi), Reddy B. (Medchol), Rama Krishna T. (Mahabubnagar) and Baig M. (Nagpur).

*Funding: Funding sources by Torrent Pharmaceuticals Ltd, Ahmedabad, India.*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee CTRI Registration: Yes, CTRI/2023/06/053853*

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**Cite this article as:** Ganjoo A, Shah S, Godse KV, Porwal S, Caplash P, Pereira R et al. Aloe vera, wheat germ oil, tea tree extract and honey-based emollient cream in the management of atopic dermatitis: a post-hoc analysis. *Int J Res Dermatol* 2023;9:362-8.