A Clinical Trial to Evaluate the Effects of the Calming Seborrheic Serum on Scalp Health

Clinical Trial

Author: Citruslabs Research Team

Sponsor: Dermazen

Citruslabs, 1639 11th Street, Santa Monica, USA

Created 12 December 2024

Abstract

This single-group study evaluated the efficacy of the Dermazen Calming Seborrheic Serum on scalp health parameters over four weeks. Thirty-five participants aged 18 and older with concerns such as dandruff, itchiness, and scalp flakiness were recruited, with 27 completing the study. Participants applied the serum daily and completed weekly questionnaires, while dermatologist evaluations of scalp photos were conducted at Baseline and Week 4. By Week 1, significant improvements were observed in seven of 11 self-reported scalp health parameters, including dandruff, redness, and scalp buildup. By Week 2, additional parameters, such as overall scalp health and flakiness, showed significant improvement, sustained through Week 4. Dermatologist evaluations showed visual improvements in overall scalp health in 77.78% of participants, with flakiness and redness improving in 66.67% and 51.85% of participants, respectively. Positive perceptions of the serum increased throughout the study, with over 90% of participants reporting improvements in dandruff, flakiness, and a soothed scalp by Week 4. The findings suggest that Dermazen Calming Seborrheic Serum effectively improves scalp health and alleviates symptoms of seborrheic dermatitis, warranting further investigations in larger, controlled trials.

1. Introduction

The skin, the body's largest organ, performs numerous essential functions. It is a protective barrier against pathogens and friction and is vital to the immune system[1,2]. The skin's sensitivity to touch and pressure aids in sensation and proprioception, and it helps regulate body temperature and hydration[3,4]. Furthermore, it is crucial for Vitamin D metabolism[5].

The skin has three primary layers: the epidermis, dermis, and hypodermis[6]. The outermost layer, the epidermis, consists of several sub-layers, each with distinct roles: the stratum basale (involved in cell division), stratum spinosum (keratin and lipid production), stratum granulosum (waterproofing), stratum lucidum (additional protection), and stratum corneum (the primary barrier against external factors)[7].

Malassezia yeast, which thrives in oily environments due to its lipophilic properties, is a natural component of the skin's microbiome[8]. It is most commonly found in areas with high sebaceous gland activity, such as the scalp, face, and upper body[9]. While typically harmless, Malassezia is associated with various skin

 © *Citruslabs, All rights reserved.*

issues, including dandruff, seborrheic dermatitis (characterized by redness and scaly skin), and flaky or itchy patches[10]. These conditions are often managed with antifungal creams or shampoos designed to minimize the effects of the yeast. Another Malassezia-related condition, pityriasis versicolor, manifests as scaly white or depigmented spots on the skin.

Suffering from these skin issues can cause itching and discomfort and negatively impact confidence and overall quality of life.

This study aimed to examine the efficacy of the Dermazen Calming Seborrheic System on scalp health.

2. Methods

2.1. Participants

A total of 35 male and female participants aged 18 or over, living in the United States, were recruited for this study. By Week 4, eight participants had withdrawn due to inactivity. Statistical analysis was performed on all available data on an intention-to-treat (ITT) basis. All participants satisfied the following inclusion and exclusion criteria.

Inclusion Criteria:

- Male or female.
- Eighteen years of age or over.
- Anyone with complaints regarding scalp health, including any two of the following:
    - Scalp flakiness.
    - Scalp itch.
    - Scalp buildup.
    - Dandruff.
    - Redness or Discoloration.
- Is not currently, and has not in the past month, been treated for Malassezia yeast-associated conditions.
- Not planning to introduce any new oral or topical treatments, including medications or supplements, over the study duration.
- Does not currently take and is not planning to introduce new oral or topical treatments, including medications and supplements, over the study duration targeted at scalp or skin health and appearance.
- Must be willing to rinse their hair every morning (washing with shampoo is not required daily).
- Must be willing and safely able to discontinue all oil-containing haircare products for the duration of the study (besides conditioner - any conditioner can be used as long as it is applied without touching the scalp).
- Must be willing to limit touching their scalp for the duration of the study.
- Must be living with someone who can take study photos of the scalp at Baseline and Endline (Week 4).

Exclusion Criteria:

- Anyone not in good health.
- Anyone who has any chronic health conditions, such as oncological or psychiatric disorders.
- Anyone who has any known serious allergic reactions that require the use of an Epi-Pen.
- Anyone pregnant, breastfeeding, or trying to conceive over the next four weeks.
- Anyone who cannot or will not commit to the study protocol.
- Anyone with a history of substance abuse.
- Anyone who has undergone an invasive medical procedure in the six weeks prior to the study or has a procedure planned during the study duration.
- Anyone with psoriasis, any infectious skin diseases, ichthyosis, or autoimmune skin

 © Citruslabs, All rights reserved.

diseases like lupus erythematosus or dermatomyositis.

- Anyone with any severe dermatological condition.
- Anyone with any severe dermatological condition.
- Anyone with any allergies to the product ingredients.
- Anyone who has used any of the product ingredients (such as sea salt, tea tree oil, etc.) and has experienced discomfort.
- Anyone taking medications, oral supplements, or herbal remedies for skin health and appearance.

2.2. Study Design and Intervention Procedure

This virtual open-label, single-group study required participants to complete questionnaires at home and provide photographs of their scalps. Consent forms describing the study process, instructions, evaluation methods, and bill of rights were provided to participants before study onboarding. Participants completed the Baseline questionnaire and provided a Baseline photo of their scalp for expert scalp skin grading.

All participants used the test product, the Dermazen Calming Seborrheic Serum. They were required to apply the product to the entire scalp about 30 minutes before bed once daily. They were also instructed to limit the amount of time they spent touching their scalp for the duration of the study. In the morning, they rinsed the product out of their hair with water or shampoo provided by Dermazen.

Questionnaires were completed in Week 1, Week 2, Week 3, and Week 4. Photos were taken for dermatologist scalp skin grading at Baseline and Week 4.

2.3. Data Analysis and Statistics

Expert scalp skin grading data were presented as the number and percent of participants the dermatologist classified as having improved in each analyzed parameter. This was not statistically analyzed (Table 2).

Data from the questionnaires were collected using a textual 5-point Likert scale for each question. The textual Likert data was transformed into numerical values from 1 to 5, whereby a score of ‘1’ represents the worst answer and a score of ‘5’ the best. Statistical analysis compared participant outcomes at each check-in to their Baseline response. First, numerical questionnaire data were checked for normality using the Pearson test. Normally distributed data were analyzed using a mixed-effects analysis with Dunnett’s multiple comparisons test. Statistical analyses were performed in GraphPad Prism 10, and the significance level was set at 0.05.

For product-specific questions evaluated only at Week 1, Week 2, Week 3, and Week 4, results were presented as the percentage of subjects reporting each answer.

3. Results

3.1. Impact of the Dermazen Calming Seborrheic Serum on Scalp Health Parameters Evaluated by Questionnaires

The effect of the product on 11 scalp health parameters was evaluated through questionnaires completed by participants at Baseline, Week 1, Week 2, Week 3, and Week 4.

By Week 1, seven of 11 parameters were significantly improved from the Baseline: dandruff, scalp buildup, redness or skin discoloration, itchiness, emotional discomfort, agitation associated with scalp health, and how soothed and calmed the scalp felt. (Table 1 and

 © *Citruslabs, All rights reserved.*

Figure 1). This indicates that the product can exert its effect quickly and improve a variety of scalp health parameters.

By Week 2, three additional parameters were significantly improved compared to the Baseline alongside the seven sustained from Week 1. These improvements were seen in overall scalp health, flakiness, and physical scalp discomfort (Table 1 and Figure 1). This was maintained through Weeks 3 and 4. In Week 4, the most improved parameter was how soothed and calmed the scalp felt, which showed an impressive 120.11% increase in score.

One parameter, overall well-being, showed no significant change throughout the study (Table 1 and Figure 1).

This demonstrates that the Dermazen Calming Seborrheic System can rapidly improve and maintain positive effects on scalp health parameters, ultimately leading to a positive overall improvement.

3.2. Impact of the Dermazen Calming Seborrheic Serum on Scalp Skin Health Parameters Graded by Dermatologists

A dermatologist analyzed photos of participants' scalps at Baseline and Week 4 (Table 2). These photos were graded on improvement from the Baseline on the following four parameters:

- Overall scalp health
- Scalp flakiness
- Scalp redness/discoloration
- Scalp buildup

When comparing scalp photos from Baseline to Week 4, the dermatologist observed improvements in overall scalp health in 77.78% of participants, which correlates with the questionnaire and participant perception parameters. Furthermore, the dermatologist observed improvements in scalp flakiness in 66.67% of participants and scalp redness and discoloration in 51.85% of participants. The parameter that improved in the lowest percentage of participants was scalp buildup (40.74%).

Overall, these results show visual improvements that are consistent with the improvements observed by participants in the questionnaires.

3.3. Participants' Perceptions of the Dermazen Calming Seborrheic System on Scalp Health

Participants were asked to respond to questions at the end of Week 1, Week 2, Week 3, and Week 4, which provided insight into their perceptions of the test product. Participants responded to product evaluation questions on a "strongly agree" to "strongly disagree" scale. The "strongly agree" and "agree" responses were combined into a single "combined agree" result to evaluate the overall participant perception.

At Week 1, participants responded to 13 questions surrounding their perception of the product. ≥70% of participants responded favorably to two of the 13 questions (Table 3): 70% agreed that their scalp flakiness had improved, and 76.7% agreed that their skin felt more soothed and calmed.

At Week 2, ≥70% of participants agreed with 10 of the 13 questions (Table 3). Notably, 86.7% agreed that their scalp health had improved, 83.3% agreed that their dandruff had improved and their scalp felt more calmed and soothed, and 80% agreed that their scalp buildup and flakiness had improved and their scalp felt healthier.

At Week 3, ≥70% of participants agreed with ten of the 13 questions, with the most notable being 81.2% of participants agreeing that their itchiness had improved and that their scalp felt healthier, 85.2% agreeing that their scalp health, dandruff, and flakiness had improved, and 88.9% agreeing that their

 © *Citruslabs, All rights reserved.*

scalp buildup had improved and that their scalp felt more soothed and calmed (Table 3).

At Week 4, ≥70% of participants agreed with 11 of 13 questions. The most notable responses were 92.3% of participants agreeing that their dandruff, scalp buildup, and flakiness had improved and that their scalp felt more soothed and calmed (Table 3).

Three additional questions were asked in Week 4, which indicated participant satisfaction. 84.6% of participants agreed that they would recommend the product to a friend or family member and that they would continue using it. Furthermore, 88.5% of participants enjoyed the experience of using the product (Table 3).

Discussion

This study aimed to evaluate the impact of the Dermazen Calming Seborrheic Serum on various scalp health parameters over four weeks. The results demonstrated significant improvements in participant-reported outcomes for various health concerns, including dandruff, redness, itchiness, and flakiness, indicating the product's efficacy in addressing symptoms commonly associated with seborrheic dermatitis and related conditions.

Notably, the findings highlight rapid improvements, with seven of 11 parameters showing significant enhancement by Week 1, including dandruff, redness, and scalp buildup. By Week 2, additional parameters such as overall scalp health and flakiness demonstrated significant improvements, which were sustained through Weeks 3 and 4. Among all parameters, the most pronounced improvement was observed in the participants' perception of a soothed and calmed scalp, with a remarkable 120.11% increase by Week 4. These results suggest that the Dermazen serum provides rapid and sustained relief for various scalp issues.

Dermatologist assessments further supported these findings, with 77.78% of participants showing improvement in overall scalp health, 66.67% in flakiness, and 51.85% in redness and discoloration based on photo evaluations. However, improvement in scalp buildup was observed in only 40.74% of participants, indicating that this parameter may be slower to respond and may require longer treatment durations.

Participant feedback throughout the study was overwhelmingly positive, with ≥70% of participants agreeing on improvements in key parameters by Week 2. By Week 4, this favorable perception extended to 11 parameters, with over 90% of participants reporting improvements in dandruff, scalp buildup, flakiness, and a soothed and calmed scalp. Additionally, 84.6% of participants stated they would recommend the product to others, and 88.5% reported enjoying the product experience.

These results provide strong evidence of the Dermazen Calming Seborrheic Serum's efficacy in improving scalp health and managing symptoms associated with seborrheic dermatitis. Future studies could further validate these findings in a randomized controlled trial and explore the product's long-term benefits.

Conclusion

The results of this study demonstrate significant and rapid improvements in participants' perceptions of scalp health after using the Dermazen Calming Seborrheic Serum. Improvements in key scalp health parameters, including dandruff, flakiness, redness, and itchiness, were observed as early as Week 1 and sustained throughout the study duration, highlighting the serum's effectiveness in addressing common symptoms associated with seborrheic dermatitis and related conditions. Furthermore, dermatologist evaluations corroborated participant-reported

 © *Citruslabs, All rights reserved.*

outcomes, providing additional evidence of the serum's efficacy in enhancing scalp health.

These findings provide a strong foundation for future research. Larger, randomized controlled trials could further elucidate the serum's benefits and explore its long-term effects on scalp health. Overall, the study suggests that the Dermazen Calming Seborrheic Serum is a promising intervention for improving scalp health and managing symptoms of seborrheic dermatitis.

References

1. D'Souza B, Kasar AK, Jones J, et al. A Brief Review on Factors Affecting the Tribological Interaction between Human Skin and Different Textile Materials. *Materials (Basel)*. 2022;15(6):2184. doi:10.3390/ma15062184
2. Tienda-Vazquez MA, Hanel JM, Marquex-Arteaga EM, et al. Exosomes: A Promising Strategy for Repair, Regeneration and Treatment of Skin Disorders. Accessed November 26, 2024. https://pmc.ncbi.nlm.nih.gov/articles/PMC10296902/
3. Gidado IM, Qassem M, Triantis IF, Kyriacou PA. Review of Advances in the Measurement of Skin Hydration Based on Sensing of Optical and Electrical Tissue Properties. *Sensors (Basel)*. 2022;22(19):7151. doi:10.3390/s22197151
4. Romanovsky AA. Skin temperature: its role in thermoregulation. *Acta Physiol (Oxf)*. 2014;210(3):498-507. doi:10.1111/apha.12231
5. Saponaro F, Saba A, Zucchi R. An Update on Vitamin D Metabolism. *Int J Mol Sci*. 2020;21(18):6573. doi:10.3390/ijms21186573
6. Yousef H, Alhajj M, Sharma S. Anatomy, Skin (Integument), Epidermis. In: *StatPearls*. StatPearls Publishing; 2024. Accessed March 19, 2024. http://www.ncbi.nlm.nih.gov/books/NBK470464/
7. NIH SEER Training Modules. Layers of the Skin | SEER Training. National Cancer Institute SEER Training Modules. Accessed November 26, 2024. https://training.seer.cancer.gov/melanoma/anatomy/layers.html
8. Naik B, Sasikumar J, B V, Das SP. Fungal coexistence in the skin mycobiome: a study involving Malassezia, Candida, and Rhodotorula. *AMB Express*. 2024;14:26. doi:10.1186/s13568-024-01674-8
9. Saunte DML, Gaitanis G, Hay RJ. Malassezia-Associated Skin Diseases, the Use of Diagnostics and Treatment. *Front Cell Infect Microbiol*. 2020;10:112. doi:10.3389/fcimb.2020.00112
10. Gupta AK, Batra R, Bluhm R, Boekhout T, Dawson TL. Skin diseases associated with Malassezia species. *J Am Acad Dermatol*. 2004;51(5):785-798. doi:10.1016/j.jaad.2003.12.034

 © *Citruslabs, All rights reserved.*

Table 1. Statistical Outcomes of Changes in Scalp Health Parameters According to Questionnaire Data. % Change indicates a change in mean values from the Baseline. An increase in score indicates an improvement. Green cells highlight statistically significant outcomes (P≤0.05). This table provides the numerical data presented in Figure 1.

Question	Baseline (n=34)		Week 1 (n=30)			Week 2 (n=30)			Week 3 (n=27)			Week 4 (n=26)			% Change
	Mean	SD	Mean	SD	P-value	Mean	SD	P-value	Mean	SD	P-value	Mean	SD	P-value	
How would you rate your overall scalp health?	2.74	0.45	3.00	0.69	0.0576	3.27	0.83	0.0062	3.81	0.62	<0.0001	3.85	0.78	<0.0001	40.82
How would you rate your overall well-being?	3.91	0.51	3.80	0.48	0.8359	3.80	0.48	0.8359	3.85	0.53	>0.9999	3.81	0.57	>0.9999	-2.48
How would you rate your dandruff	2.85	0.89	3.13	0.78	0.0395	3.37	0.85	0.0161	3.81	0.88	0.0002	3.85	0.78	0.0001	35.01
How would you rate your scalp buildup?	2.68	0.68	3.07	0.87	0.0180	3.50	0.82	<0.0001	3.81	0.92	0.0001	3.92	0.89	<0.0001	46.46
How would you rate any redness or skin discoloration	3.26	0.79	3.67	0.96	0.0163	3.93	0.83	<0.0001	4.19	0.79	<0.0001	4.12	0.77	<0.0001	26.20
How would you rate any flakiness from your scalp?	2.62	0.92	2.97	0.89	0.0685	3.47	0.90	0.0003	3.74	0.86	<0.0001	3.81	0.85	0.0002	45.55
How would you rate any itch?	2.56	0.79	3.10	0.99	0.0073	3.50	0.82	<0.0001	3.74	0.90	<0.0001	3.81	0.85	<0.0001	48.90
How would you rate any physical discomfort associated with your scalp health?	2.91	0.93	3.30	1.06	0.1644	3.73	0.83	0.0002	3.93	0.83	0.0003	4.08	0.69	<0.0001	40.12
How would you rate any emotional discomfort associated with your scalp health?	2.53	1.02	3.23	1.14	0.0008	3.70	0.92	<0.0001	3.93	0.73	<0.0001	4.12	0.82	<0.0001	62.88
How would you rate any agitation associated with your scalp health?	2.62	0.85	3.40	1.04	0.0002	3.73	0.94	<0.0001	3.81	0.88	<0.0001	3.96	0.72	<0.0001	51.28
How soothed and calmed does your scalp feel?	1.68	0.64	2.93	0.69	<0.0001	3.10	0.99	<0.0001	3.63	0.79	<0.0001	3.69	0.97	<0.0001	120.11

 © Citruslabs, All rights reserved.

Table 2. Changes in Scalp Health Parameters According to Dermatologist Grading. Data are presented as the number (N) and proportion (%) of participants the dermatologist classified as having improved in each parameter from Baseline to Week 4. N=27.

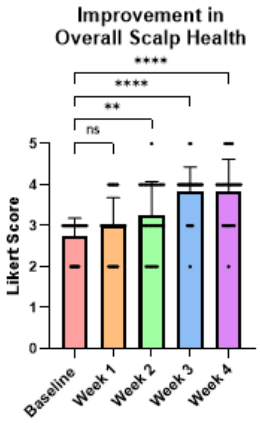
	Improvement Baseline-Week 4	
	N	%
Overall Scalp Health	21	77.78%
Scalp Flakiness	18	66.67%
Scalp Redness/Discoloration	14	48.15%
Scalp Buildup	11	40.74%

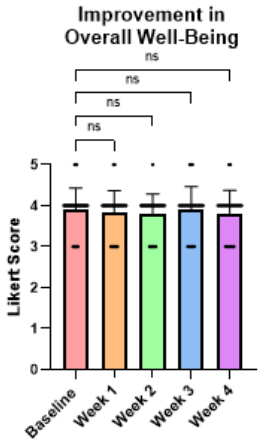
Table 3. Participant Perceptions of the Impact of the Product on Scalp Health. Green cells highlight a combined positive response of ≥70%.

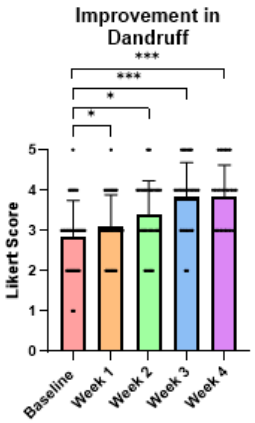
Question	Combined Agree			
	Week 1	Week 2	Week 3	Week 4
Since using the product, my scalp health has improved	63.30%	86.70%	85.20%	88.50%
Since using the product, my overall well-being has improved.	46.70%	53.30%	63.00%	69.20%
Since using the product, my dandruff has improved.	66.70%	83.30%	85.20%	92.30%
Since using the product my scalp buildup has improved.	66.70%	80.00%	88.90%	92.30%
Since using the product, any redness or skin discoloration has improved.	56.70%	70.00%	74.10%	88.50%
Since using the product, any flakiness from my scalp has improved.	70.00%	80.00%	85.20%	92.30%
Since using the product, any itch has improved.	53.30%	76.70%	81.50%	80.80%
Since using the product, any physical discomfort associated with my scalp health has improved.	60.00%	66.70%	77.80%	84.60%
Since using the product, any agitation associated with my scalp health has improved.	56.70%	76.70%	70.40%	80.80%
Since using the product my scalp feels more soothed and calmed.	76.70%	83.30%	88.90%	92.30%
Since using the product I have more confidence in my appearance.	46.70%	60.00%	63.00%	65.40%
Since using the product, my scalp feels healthier.	66.70%	80.00%	81.50%	84.60%
Since using the product, I am less self-conscious about my scalp.	50.00%	70.00%	63.00%	76.90%
I would continue using this product.				84.60%
I would recommend this product to a friend or family member				84.60%
I enjoyed the experience of using this product.				88.50%

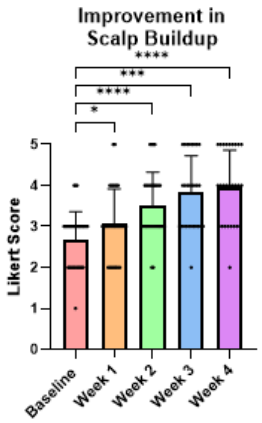
 © *Citruslabs, All rights reserved.*

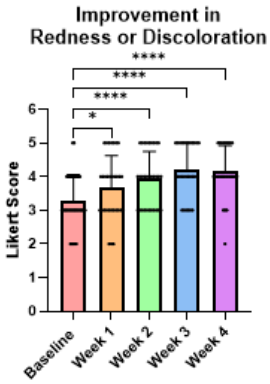
Figure 1. Visual Representation of Questionnaire Data. Data are graphed as group means, and standard deviation and individual data points are shown. An increase in score indicates an improvement. ns = P>0.05, * = P≤0.05, ** = P≤0.01, *** = P≤0.001, **** = P≤0.0001.

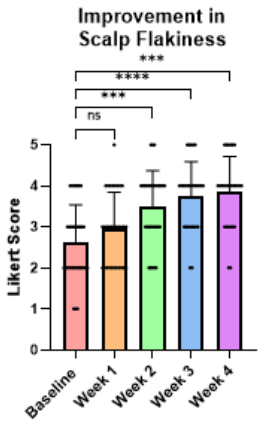




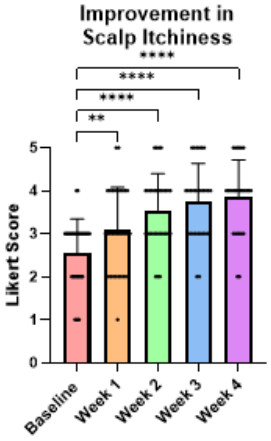


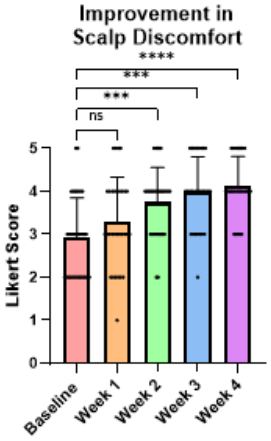


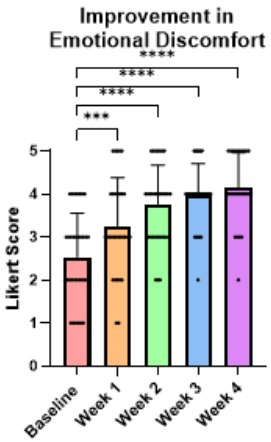


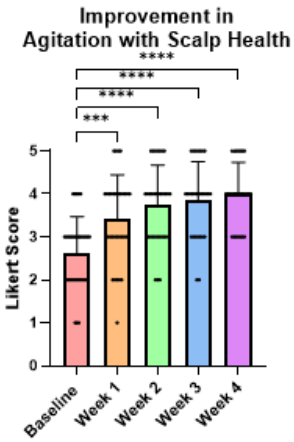


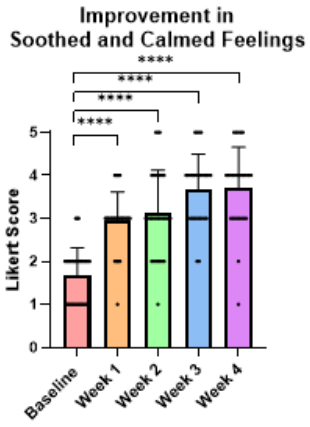
 © *Citruslabs, All rights reserved.*











 © Citruslabs, All rights reserved.

Appendix A: Data Interpretation

(Please consult an attorney before using any claims – these are just example claims from the data that could be used)

*The following information is provided for educational and informational purposes only. Claim examples by Citruslabs are not intended as legal advice or guidance. Citruslabs does not endorse any specific claims made by its clients and cannot guarantee the accuracy, reliability, or completeness of the information provided. The information contained herein is not a substitute for professional legal advice. Anyone seeking to make marketing claims based on the results of a clinical study should consult a qualified attorney to discuss the legal and regulatory requirements governing such claims. Citruslabs shall not be liable for any damages or losses arising from using this information or any reliance on the accuracy or completeness thereof.

- At Week 1, there was a statistically significant improvement in:
    - Dandruff level
    - Scalp buildup
    - Redness and skin discoloration
    - Scalp itchiness
    - Emotional discomfort associated with scalp health
    - Agitation associated with scalp health
    - How soothed and calmed the scalp felt
- At Week 1:
    - 70% of participants agreed that since using the product, any scalp flakiness had improved.
    - 76.7% of participants agreed that their scalp felt more soothed and calmed since using the product.

- At Week 2, there was a statistically significant improvement in:
    - Overall scalp health
    - Dandruff level
    - Scalp buildup
    - Redness and skin discoloration
    - Scalp flakiness
    - Scalp itchiness
    - Agitation associated with scalp health
    - How soothed and calmed the scalp felt
- At Week 2:
    - 86.7% of participants agreed that their scalp health had improved since using the product.
    - 83.3% of participants agreed that their dandruff had improved and that their scalp felt more soothed and calmed since using the product.

- At Week 3, there was a statistically significant improvement in:

 © *Citruslabs, All rights reserved.*

- Overall scalp health
- Dandruff level
- Scalp buildup
- Redness and skin discoloration
- Scalp flakiness
- Scalp itchiness
- Agitation associated with scalp health
- How soothed and calmed the scalp felt

- At Week 3:
  - 88.9% of participants agreed that their scalp buildup had improved and that their scalp felt more soothed and calmed since using the product.
  - 85.2% of participants agreed that their scalp health, dandruff, and scalp flakiness had improved since using the product.

- At Week 4, there was a statistically significant improvement in:
  - Emotional discomfort associated with scalp health, with a 62.88% improvement
  - Agitation associated with scalp health, with a 51.28% improvement
  - Scalp itchiness, with a 48.9% improvement
  - How soothed and calmed the scalp felt with a 120.11% improvement
- At Week 4:
  - 92.3% of participants agreed that their dandruff, scalp buildup, and flakiness had improved and that their scalp felt more soothed and calmed since using the product.
  - 88.5% of participants agreed that their overall scalp health and redness or skin discoloration had improved since using the product.
  - 84.6% of participants agreed they would continue using the product and recommend it to a friend or family member.
  - 88.5% of participants agreed that they enjoyed the experience of using the product
- At Week 4, a dermatologist observed that:
  - 77.78% of participants showed improvement in overall scalp health
  - 66.67% of participants showed improvement in scalp flakiness

 © *Citruslabs, All rights reserved.*