Elimination Diet Guided by Food-Specific IgG Antibodies Measurements in Chronic Adult Acne in Thailand: A Prospective RCT Study

Mart Maiprasert^{1,*}, Pongsiri Khunngam¹, Sarawalai Rakchart², Napatra Tovanabutr³, Rungsima Wanitphakdeedecha⁴, Yutthana Srinoulprasert⁵ and Chatree Chai-Adisaksopha³

¹Department of Anti-Aging and Regenerative Medicine; ²Department of Aesthetic Medicine, Dhurakij Pundit University, Bangkok, Thailand

³Department of Internal Medicine, Chiang Mai University, Chiang Mai, Thailand

⁴Department of Dermatology; ⁵Department of Immunology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Abstract: *Background*: Adult female acne is increasingly prevalent and significantly affects quality of life. Current treatments, including antibiotics and hormonal therapies, often yield varied efficacy and risks. While adult acne shares similarities with adolescent acne, its pathogenesis involves genetic, hormonal, immune, and dietary factors. Emerging growing understanding, dietary influences remain poorly understood, overshadowed by persistent myths. Inflammation, preceding follicular plugging and hyperkeratinization, suggests a potential shift towards addressing gut inflammation and digestive issues. IgG-mediated food reactions, linked to conditions like IBS and migraines, are controversial in diagnosing acne but warrant investigation, especially in Thai patients.

Objective: Evaluate the efficacy of elimination diets guided by food-specific IgG antibodies measurement in chronic adult acne.

Patients and Methods: This randomized controlled trial and prospective cohort study enrolled 75 participants with chronic acne aged 19 to 45 years, meeting stringent inclusion criteria. Participants were randomized into three groups: one receiving elimination diets based on reversed IgG antibody measurements, another on common food-specific IgG antibodies, and a third on individual IgG antibody measurements. Elimination diets were informed by Genarrayt[™] 200+ Food IgG kit results, with compliance monitored through dietary checklists. Primary outcomes were assessed using the Global Acne Grading System (GAGS) Score, with secondary outcomes including the Thai version of the Dermatology Life Quality Index Questionnaire and a Multiorgan-Symptoms Checklist. Follow-ups were conducted at 2, 4, 8, and 12 weeks.

Results: The study cohort, predominantly female (74.7%), exhibited a mean age of 29.3 ± 5.3 years and an average GAGS Score indicating moderate acne severity. Significant differences in GAGS Scores were found among groups (P<0.001), indicating reduced acne severity in the elimination diet groups. Statistically significant reductions in weight and BMI were observed in one group (p-values = 0.048), but not in the other groups. Compliance with follow-up criteria was high.

Conclusion: Elimination diets guided by food-specific IgG antibodies measurement show promise in reducing chronic adult acne severity, as indicated by GAGS Scores. This study sheds light on the relationship between diet and adult acne pathophysiology, emphasizing the potential of personalized treatment approaches. Further research is warranted to validate these findings and elucidate underlying mechanisms.

Keywords: Adult acne, elimination diet, IgG-mediated food intolerance, chronic acne, dermatology.

INTRODUCTION

Acne, traditionally conceived as a rite of passage limited to adolescence, has increasingly become a persistent concern among adults, notably affecting females and exerting profound impacts on their psychological and emotional well-being [1-4]. The prevalence of adult female acne varies widely across studies, underlining its significant burden on public health and necessitating focused attention [5-6]. While adult acne shares some mechanistic similarities with its adolescent counterpart, it presents distinct clinical features and poses unique therapeutic challenges, often defying conventional treatment approaches and prompting a call for tailored interventions [1,7-14].

Recent investigations have underscored the intricate relationship between diet and acne, particularly implicating the Western dietary pattern in exacerbating the condition [15-16]. High-glycemic-load diets and milk consumption, for instance, have been associated with heightened levels of insulin and insulin-like growth factor 1 (IGF-1), perpetuating a cascade of hormonal

^{*}Address correspondence to this author at the Department of Anti-aging and Regenerative Medicine, Dhurakij Pundit University, Bangkok, Thailand; E-mail: mart.mai@dpu.ac.th

and metabolic changes that fuel acne pathogenesis [16-26]. Nevertheless, prevailing dermatological paradigms have historically relegated dietary influences to a secondary role, fostering misconceptions and impeding progress in acne management [27-29].

In light of evolving understandings, inflammation has emerged as a pivotal precursor to acne development, potentially superseding follicular plugging hyperkeratinization [30-31]. Within this context, IgGmediated food intolerances, characterized by delayed hypersensitivity responses, have surfaced as plausible triggers for acne via immune-mediated inflammatory pathways [31-34]. Despite promising prospects, the utility and clinical relevance of elimination diets guided by IgG antibodies remain contested, urging further scrutiny [35-36].

This study endeavors to scrutinize the outcomes of elimination diets informed by IgG-mediated food intolerance in Thai acne patients, aiming to illuminate its therapeutic efficacy and broaden our comprehension of acne pathogenesis. By dissecting the intricate interplay between dietary factors, immune responses, and acne manifestation, this research aspires to refine therapeutic paradigms and enhance patient-centric care approaches, ultimately alleviating the burden of acne and ameliorating patient outcomes.

OBJECTIVES

This study aimed to assess the impact of an elimination diet guided by food-specific IgG antibodies measurement on clinical outcomes evaluated by the Global Acne Grading System (GAGS). The primary objective was to investigate the effectiveness of this dietary intervention in reducing acne severity among participants. Secondary objectives included evaluating the psychosocial and emotional impact on affected adults through the use of the Thai version of the Dermatology Life Quality Index Questionnaire (DLQI). Additionally, a Multi-organ Symptoms Checklist (MSC) employed to assess systemic symptoms was potentially associated with the elimination diet guided by specific IgG antibodies. Furthermore, changes in Body Mass Index (BMI), weight, and percent body fat from baseline to the end of the trial were analyzed as secondary outcomes.

Study Population

Participants aged between 19 to 45 years with chronic acne persisting for over 12 months, regardless of prior treatment outcomes, and presenting a Global Acne Grading Scale score within the moderate to severe range (GAGS Score = 18-38) were eligible for inclusion in this study. Additionally, a BMI greater than 17.5 was required for participation. Exclusion criteria included current or planned use of oral contraceptive pills within 3 months, pregnancy, no restriction on diet, recent use of oral antibiotics or systemic steroids within 3 months, and absence of specified medical conditions such as congenital adrenal hyperplasia, syndromes includina seborrhea-acne-hirsutism-androgenetic alopecia, polycystic ovarian syndrome, hyperandrogenism-insulin resistance-acanthosis nigricans, synovitis-acne-pustulosis-hyperostosis-osteitis, pyogenic arthritis-pyoderma gangrenosum-acne, or Apert syndrome [6]. The study delineated participants' acne history based on three characteristics: persistent acne, intermittent acne, and irregular acne.

Interventions

The implementation of an Elimination Diet is guided by the analysis of food-specific IgG antibodies, as determined by the findings of Food-specific Serum IgG Antibodies Assay reports.

Food-specific Serum IgG Antibodies Assay Report

Serum samples were analyzed using the Genarrayt[™] 200+ Food IgG kit to quantify IgG antibodies to 222 foods. Antibody levels determined whether foods were to be eliminated, with thresholds set as follows: <24 U/ml (green), 24-30 U/ml (yellow), >30 U/ml (red). Compliance with the elimination diet was monitored via dietary checklists at each visit. The control group received recommendations opposite to those based on IgG levels, as detailed in Appendix 1.

Randomization

The study population was divided into three groups using Block Randomization with block sizes of three and six:

- Control group: Participants received an Elimination diet based on their individual report of IgG Antibodies measurements in reverse.
- Common-food report group: Participants received an Elimination diet based on the report of the most common types of food among Thai patients with chronic adult acne [37].
- Actual test group: Participants received an "Elimination diet" based on their individual report of IgG Antibodies measurements.

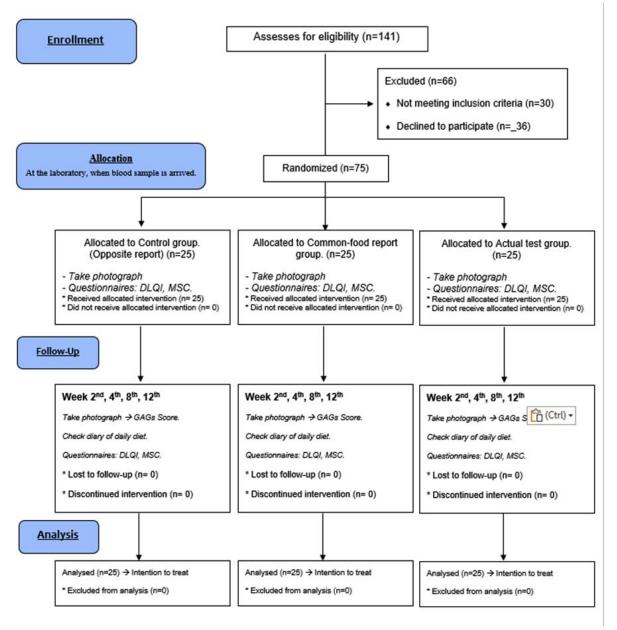


Figure 1: Flow chart diagram.

Allocation Concealment

Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) were used, and they were opened by a laboratory technician at N Health Laboratory as soon as the test report of each blood sample was completed.

Implementation

Blinding was maintained by enforcing food restriction across all groups to mitigate bias or loss to follow-up. Allocation occurred at the laboratory conducting IgG antibodies measurements. Control group results were reversed. Investigators and statisticians were blinded to treatment allocation. Outcome assessment was performed independently by three blinded dermatologists.

OUTCOMES

Primary Outcome

The Global Acne Grading System Score (GAGS Score) was employed to assess acne severity comprehensively, considering eruptions not only on the face but also on the chest and back [38].

Secondary Outcomes

Secondary outcome measures included the Thai version of the Dermatology Life Quality Index

Questionnaire (DLQI), aimed at capturing the impact of acne on patients' quality of life. Additionally, the Thai version of the Multi-organ Symptoms Checklist (MSC), tailored for this study, evaluated inflammatory symptoms across various systems. These outcomes were assessed at baseline and at 2, 4, 8, and 12 weeks. Body Mass Index (BMI), weight, and percent body fat were also recorded at the beginning and end of the trial.

Sample Size

Given the absence of prior research on the relationship between acne severity and elimination diets guided by food-specific lgG antibodies measurement, sample size determination relied on the control group's mean GAGS Score (25 ± 10) representing moderate acne severity and the treatment group's mean GAGS Score (15 ± 10) indicating mild acne severity. Using a significance level (alpha error) of 0.05 and a power (beta error) of 0.9 for a two-sided test, an estimated total sample size of 69 patients (23 per arm) was calculated. Accounting for a 10% dropout rate, the total sample size was adjusted to 75 patients, with each arm consisting of 25 patients.

Statistical Analysis

Statistical analyses were conducted using the Statistical Package for STATA Program version 17. Data normality was assessed using the Shapiro-Wilk test. Continuous variables were presented as mean and standard deviation, while categorical variables were expressed as frequency and percentage. Descriptive analysis included the calculation of percentages, means, and standard deviations for quantitative data. Paired t-tests were employed to compare before and after parameters within each group (BMI, weight, percent body fat). Repeated measure ANOVA was utilized for comparing the three groups. Generalized Linear Regression was applied to evaluate repeated measurements of GAGS Score, DLQI, and MSC within each group. Differences were considered significant if the P value was <0.05 and highly significant if the P value was <0.01.

RESULTS

A cohort of 75 participants with chronic adult acne participated in the study, with 74.7% being female. The mean age of the patients was 29.3 ± 5.3 years, and the onset of acne occurred at an average age of 17.7 ± 5.5 years. The participants had an average BMI of $23.2 \pm$

4.9 and a percent body fat of 28.7 ± 8.7 . The average severity of acne, as measured by the Global Acne Grading System Score (GAGS Score), was 22.8 ± 3.4 .

In terms of acne patterns, the majority of participants had intermittent acne (62.7%), followed by persistent acne (26.7%) and irregular acne (10.7%). Current acne characteristics included 48.0% presenting with large papules and nodules, 29.3% with small papules and nodules, and 22.7% with an allergic-like rash alongside acne. Additionally, 72.0% of participants had truncal acne, while 20.0% had never experienced back acne, and 8.0% had previously had back acne.

Regarding the severity of teenage acne, 38.7% of participants had a moderate degree, 28.0% had a mild degree, 20.0% had a severe degree, and 13.3% had never experienced acne during their teenage years.

Before entering the research program, 26.7% of participants had not received any acne treatment in the six months leading up to the study. Among those who had received treatment, 60.0% had received only topical treatment, 9.3% had received only facial treatment (e.g., comedone extraction, IPL), and 4.0% had received oral treatment. The duration of acne treatment before entering the research varied, with 46.7% of participants treated for 6-12 months and 26.7% treated for more than one year.

Statistically significant differences were found among the three groups when comparing GAGS Scores (P<0.001). Both the Common-food report group and the Actual test group differed significantly from the control group (P<0.001). Regarding Dermatology Life Quality Index Questionnaire (DLQI) values, the common-foods report group differed from the control groups (P=0.003), but no difference was detected between the control group and the actual test group (P=0.480). Additionally, Multi-organ Symptoms Checklist (MSC) values showed no variation among the three groups (P=0.955).

There was no statistically significant difference between the three groups in BMI, weight, and percent body fat. Of interest, the Common-Food Report group had a statistically significant decrease in weight and BMI (p = 0.048), but no change in body fat percentage. The GAGS score box plot showed that the Actual Test group had the lowest median acne severity, and less dispersion, which indicates that an IgG-based elimination diet may be effective in decreasing acne severity. The DLQI scores, reflecting the quality of life,

Table 1: Demographic	data.	Baseline	Characteristics
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Factors	Total	Group 0 Control Group	Group 1 Common-food Report Group	Group 2 Actual Report Group	
Total N	75	25	25	25	
Female, n (%)	56 (74.7%)	17 (68.0%)	20 (80.0%)	19 (76.0%)	
Age (years), mean±SD	29.3±5.3	29.2±6.2	28.2±4.4	29.8±5.6	
Weight (kgs), mean±SD	62.8±16.2	62.0±18.2	62.0±18.0	63.8±11.8	
Height (cms), mean±SD	164.0±8.2	164.4±10.0	163.4±6.3	164.2±8.3	
B.M.I., mean±SD	23.2±4.9	22.8±5.0	23.0±5.2	23.7±4.5	
GAGS Score, mean±SD	22.8±3.4	22.9±3.6	22.9±4.0	22.1±2.6	
Percent body fat (%), mean±SD	28.7±8.7	27.1±7.7	29.1±8.6	30.0±9.8	
Age when acne start (yrs.), mean±SD	17.7±5.5	17.0±4.2	17.8±5.3	18.8±6.2	
Pattern of acne, n (%) - Persistent acne	20 (26.7%)	8 (32.0%)	7 (28.0%)	5 (20.0%)	
- Intermittent acne - Irregular acne	47 (62.7%) 8 (10.7%)	17 (68.0%) 0 (0.0%)	14 (56.0%) 4 (16.0%)	16 (64.0%) 4 (16.0%)	
Teenage acne, n (%) - No - Mild - Moderate - Severe	10 (13.3%) 21 (28.0%) 29 (38.7%) 15 (20.0%)	2 (8.0%) 10 (40.0%) 9 (36.0%) 4 (16.0%)	2 (8.0%) 6 (24.0%) 10 (40.0%) 7 (28.0%)	6 (24.0%) 5 (20.0%) 10 (40.0%) 4 (16.0%)	
Current acne, n (%) - Small - Large - Allergic-like	22 (29.3%) 36 (48.0%) 17 (22.7%)	6 (24.0%) 14 (56.0%) 5 (20.0%)	10 (10.0%) 8 (32.0%) 7 (28.0%)	6 (24.0%) 14 (56.0%) 5 (20.0%)	
Body acne, n (%) - Yes - Never - Previous	54 (72.0%) 15 (20.0%) 6 (8.0%)	18 (72.0%) 5 (20.0%) 2 (8.0%)	20 (80.0%) 4 (16.0%) 1 (4.0%)	16 (64.0%) 6 (24.0%) 3 (12.0%)	
Current Rx, n (%) - No - Topical Rx - Oral Rx	20 (26.7%) 45 (60.0%) 3 (4.0%)	9 (36.0%) 15 (60.0%) 1 (4.0%)	4 (16.0%) 15 (60.0%) 1 (4.0%)	7 (28.0%) 15 (60.0%) 1 (4.0%)	
- Facial treatment Duration of Rx, n (%) - No	7 (9.3%)	2 (8.0%) 9 (36.0%)	5 (20.0%) 4 (16.0%)	0 (0.0%) 7 (28.0%)	
- 6 - 12 months - more than 1 years	35 (46.7%) 20 (26.7%)	11 (44.0%) 5 (20.0%)	13 (52.0%) 8 (32.0%)	11 (44.0%) 7 (28.0%)	

showed a slightly better trend in the Common-Food Report group, although ANOVA revealed no statistically significant difference between the groups. Likewise, MSC scores did not differ between groups, indicating that dietary modifications did not affect overall symptoms.

Patient compliance was documented through questionnaires at each follow-up visit, with the majority adhering well to the criteria of 75-100%. Subgroup analysis was not conducted.

DISCUSSION

In the control group, GAGS Score values decreased during the first two weeks, similar to the other two groups, but no statistically significant difference was found over the 12-week follow-up period. This lack of significance may be attributed to two factors: Firstly, the natural fluctuation in acne severity over time, and secondly, the imposition of food restrictions in the control group, albeit not specifically tailored to individual reports. This broader dietary restriction might inadvertently eliminate allergenic foods, affecting outcomes.

Both the Actual test group and the Common-foods report group showed a noticeable decrease in GAGS Score at the 12-week mark, with the Actual test group demonstrating a more pronounced reduction. This finding suggests that eliminating diet guided by foodspecific IgG antibodies may indeed alleviate acne inflammation. While following the Common-foods report also yielded positive outcomes, it may not entirely address individual allergenic triggers, explaining the lesser reduction in GAGS Score compared to the Actual test group.

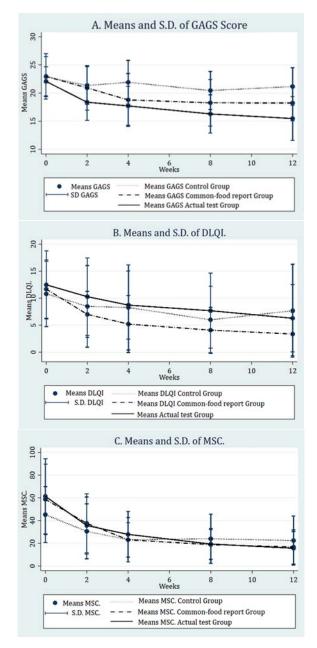
This study aligns with a narrative review on adverse food reactions, highlighting the association between non-IgE mediated food allergy and functional gastrointestinal disorders (FGIDs) [39]. Food reactions can involve various pathophysiological mechanisms, impacting multiple organ systems [40]. Dietary interventions targeting both immune- and non-immunemediated food-induced diseases could improve patient quality of life and reduce management costs [41].

In the Actual test group, although the GAGS Score decreased significantly in the initial two weeks, the rate of reduction slowed in the last two months. This suggests that resolving gut dysfunction involves more than just eliminating diet guided by food-specific IgG antibodies. Factors like leaky gut syndrome and dysbiosis, associated with IgG food allergy, require attention [42-45]. Probiotics, prebiotics, synbiotics, and postbiotics have emerged as potential therapies for preventing and treating food allergy and associated conditions [46-48].

No statistically significant differences were found in the DLQI and MSC results among the groups, likely due to the subjective nature of the questionnaire and participant blinding. However, DLQI values decreased notably in the Common-foods report group, differing significantly from the other groups.

Regarding BMI, weight, and body fat percentage, a statistically significant reduction in weight and BMI was observed in the common-food report group. A similar trend was noted in the actual test group, although not statistically significant, possibly due to sample size limitations or the study duration. No significant changes were observed in these parameters in the control group, despite some studies suggesting a link between IgG-mediated food allergy, inflammation, and obesity [49-50]. Studies on elimination diets guided by food-

specific IgG antibodies and weight loss have produced inconsistent results, necessitating further investigation [51-53].



A. Means GAGS Score + S.D.

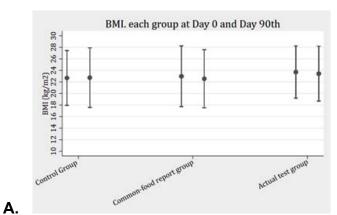
- B. Means DLQI. + S.D.
- C. Means MSC. (Multi-organ Symptoms Checklists) + S.D.

Control group = Elimination diet with opposite result of true report of food-specific IgG antibodies.

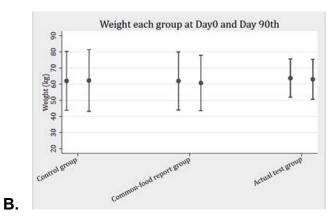
Common-food report group = Elimination diet with most common types of food-specific IgG antibodies.

Actual test group = Intervention group (Elimination diet with true report of food-specific IgG antibodies.

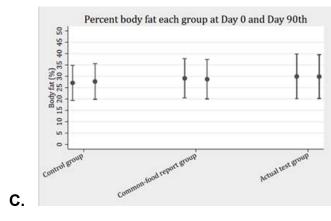
Picture 2: Outcome parameters in each group at 0, 2nd, 4th, 8th, and 12th week.



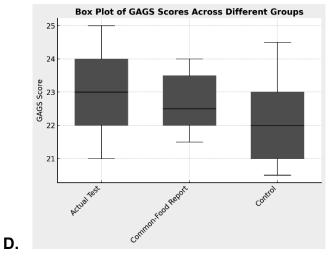
	BMI Day0	BMI Day 90	P-value
Control Group	22.7 <u>+</u> 4.7	22.7 <u>+</u> 5.2	0.766
Common-food report Group	22.9 <u>+</u> 5.3	22.5 <u>+</u> 5.0	0.048
Actual test Group	23.7 <u>+</u> 4.5	23.4 <u>+</u> 4.8	0.162
P-value	0.746	0.804	



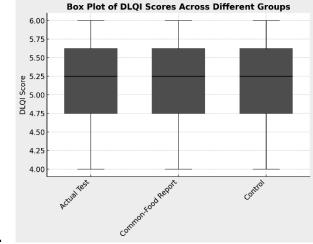
	Weight Day0	Weight Day 90	P-value
Control Group	62.0 <u>+</u> 17.9	62.3 <u>+</u> 18.8	0.598
Common-food report Group	62.0 <u>+</u> 17.7	60.8 <u>+</u> 16.8	0.048
Actual test Group	63.7 <u>+</u> 11.7	63.0 <u>+</u> 12.2	0.139
P-value	0.606	0.532	



	% Body Fat D0	% Body Fat D90	P-value
Control Group	27.1 <u>+</u> 7.7	27.7 <u>+</u> 7.8	0.162
Common-food report Group	29.1 <u>+</u> 8.6	28.7 <u>+</u> 8.7	0.465
Actual test Group	30.0 <u>+</u> 9.8	29.8 <u>+</u> 9.6	0.881
P-value	0.506	0.687	

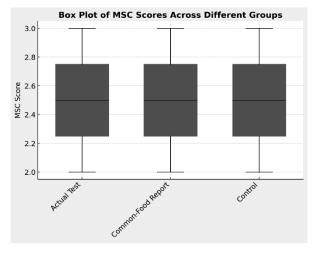


Column	Metric	Group	GAGS Score Median	GAGS Score IQR	GAGS Score Min	GAGS Score Max
0	GAGS Score	Actual Test	23	2	21	25
1	GAGS Score	Common- Food Report	22.5	1.5	21.5	24
2	GAGS Score	Control	22.3	1.8	20.5	24.5



Column	Metric	Group	DLQI Score Median	DLQI Score IQR	DLQI Score Min	DLQI Score Max
0	DLQI Score	Actual Test	5	1.5	4	6
1	DLQI Score	Common- Food Report	5	1.5	4	6
2	DLQI Score	Control	5	1.5	4	6

Ε.



Column	Metric	Group	MSC Score Median	MSC Score IQR	MSC Score Min	MSC Score Max
0	MSC Score	Actual Test	2.5	1	2	3
1	MSC Score	Common- Food Report	2.5	1	2	3
2	MSC Score	Control	2.5	1	2	3

F.

- A. Means BMI. + S.D.
- B. Means Weight + S.D.
- C. Means Body fat percentage + S.D.
- D. Distribution of GAGS Scores Among Actual Tests, Common-Food Reports, and Control Groups.
- E. Comparison of Dermatology Life Quality Index (DLQI) Scores Across Study Groups.
- F. Assessment of Multi-organ Symptoms Checklist (MSC) Scores by Intervention Type.

Control group = Elimination diet with opposite result of true report of food-specific IgG antibodies.

Common-food report group = Elimination diet with most common types of food-specific IgG antibodies.

Actual test group = Intervention group (Elimination diet with true report of food-specific IgG antibodies.

Picture 3: Outcome parameters in each group at day 0 and day 90th.

Generalizability

Studies are likely to confirm that IgG-mediated food allergy contributes to the pathophysiology of acne, and implementing an elimination diet guided by foodspecific IgG antibodies can effectively reduce acne severity. This finding adds complexity to understanding the relationship between food and acne, challenging various theories proposed over the past decade. Notably, even if patients cannot undergo testing for IgG-mediated food allergy, utilizing the Common-foods report as a guideline can still lead to a reduction in acne severity. If desired outcomes are not achieved, further testing may be warranted. The results of the Common-foods report, although conducted with Thai participants, were highly consistent with those from a study conducted in Saudi Arabia [54].



This 39-years male patient who was in actual test group. His GAGS Score was 27 at the beginning of study and turn to 18 at the end of study (Day 90th).

Picture 4: Example of a patient in the "Actual test group" at day 0 and day 90th.

Limitations

Following the 3-month follow-up period outlined in the protocol, it is anticipated that study results will improve. Extending follow-up to an additional 6 months to 1 year would be beneficial, but challenges arose due to the COVID outbreak, affecting participant recruitment and follow-up. After completing the study, the Control group received actual blood test results and recom-

mendations for diet elimination based on the report. It was noted that 90% of participants experienced a noticeable decrease in GAGS Score within 2-4 weeks.

Suggestions for Future Studies

In the Control group, it is recommended to limit the list of foods for elimination to 20-25 types, excluding

those related to the actual allergic food report. This approach prevents inadvertently eliminating foods to which participants are genuinely allergic.

Identifying common types of IgG-mediated foods in each country would be insightful to understand regional variations.

Investigating a holistic approach for treating gut dysfunction problems, such as Leaky gut syndrome, Dysbiosis, and IgG Food allergy, could enhance acne severity reduction. This approach may provide a clearer understanding of the relationship between nutritional issues and acne.

Future studies will need to consider a much more multidimensional assessment method, tapping multiple indices per patient within each group to provide a more robust view of health outcomes in the influenced areas. However, although GAGS is a reliable gold standard for assessing the severity of acne, additional indices would have provided a complete overview (skin-related quality of life or psychological [Dermatology Life Quality Index], and physiological changes). Using Multivariate Analysis of Variance (MANOVA) would allow these indices to be assessed together, providing information on the differential effects of interventions across multiple health outcomes.

CONCLUSION

This study highlights that an elimination diet guided by food-specific IgG antibodies measurements effectively reduces the severity of chronic adult acne, as indicated by the GAGS Score. These findings contribute to elucidating the relationship between food and adult acne pathophysiology. In this study, no significant differences were observed in the DLQI and Multi-organ Symptoms Checklist (MSC) among groups, as well as in BMI, weight, and body fat percentage.

Appendix 1: Report of IgG-mediated food antibodies measurement





A. = The actual results were reported individually in the "Actual test group"

- B. = The opposite results were reported individually in the "Control group"
- C. = The common-food report, derived from previous research39, was utilized for all participants in the "Common-food report group."

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