ALLMED 6 (2025) 100075

Contents lists available at ScienceDirect

Allergy Medicine

journal homepage: www.sciencedirect.com/journal/allergy-medicine

Full Length Article

Association between multi-component traditional chinese medicine therapy and diet quality in patients with food allergies and eczema

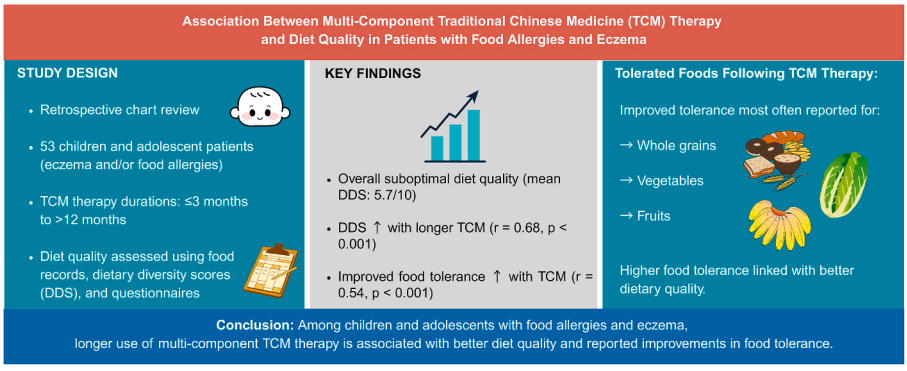
Qianhui Zhang [a,b,*], Ava Retsch [b,c,d], Shane Martin [b,e], Danna Chung [b], Paul Ehrlich [b,f,g], Xiu-Min Li [b,h,i]

[a] Department of Nutrition and Public Health, Hunter College, City University of New York, 2180 Third Avenue, New York, NY, 10035, USA
[b] Center for Integrative Health and Acupuncture P.C., 933 Mamaroneck Avenue, Mamaroneck, NY, 10543, USA
[c] Department of Emergency Medicine, Albany Medical Center, 43 New Scotland Avenue, Albany, NY, 12208, USA
[d] College of Health Sciences and Technology, Rochester Institute of Technology, 1 Lomb Memorial Dr, Rochester, NY, 14623, USA
[e] Rush Medical College, 600 S Paulina Street, Chicago, IL, 60612, USA
[f] Allergy and Asthma Associates of Murray Hill, 161 Madison Avenue, New York, NY, 10016, USA
[g] Department of Pediatrics, NYU-Langone School of Medicine, 1559 York Avenue, New York, NY, 10028, USA
[h] Department of Pathology, Microbiology and Immunology, New York Medical College, 100 Woods Road, Valhalla, NY, 10595, USA
[i] Department of Otolaryngology, New York Medical College, Westchester Medical Center, 100 Woods Road, Valhalla, NY, 10595, USA

HIGHLIGHTS

- This is the first study to investigate the diet quality among patients with food allergies and eczema using Traditional Chinese Medicine (TCM).
- TCM duration is positively associated with diet quality in patients with food allergies and eczema.
- Diet quality was greater after >12 months of TCM use.
- Reduced food restriction, particularly for whole grains, vegetables, and fruits, was reported post-TCM.

GRAPHICAL ABSTRACT



ARTICLE INFO

Keywords:
Traditional Chinese medicine
Food allergy
Eczema
Atopic dermatitis
Diet
Food tolerance

ABSTRACT

Background: Food allergies and eczema are often linked to food restrictions and limited diet quality. Traditional Chinese medicine (TCM) has been found to be a safe and effective therapy for food allergies and eczema. This study aims to explore the relationship between TCM therapy duration and diet quality among children and adolescents with food allergies and/or eczema.
Methods: A retrospective chart review was conducted as a practice-based exploratory study of 53 children and adolescents who used TCM to manage food allergies and/or eczema. TCM use, food tolerance, and diet quality were assessed through practice-based questionnaires, food records, and dietary diversity scores (DDS). Spearman correlation, Mann-Whitney U, and Kruskal-Wallis H tests were used for statistical analyses.

This article is part of a special issue entitled: Food Allergy published in Allergy Medicine.

* Corresponding author. Department of Nutrition and Public Health, Hunter College, City University of New York, 2180 Third Avenue, New York, NY, 10035, USA.
E-mail address: jera.zhang@hunter.cuny.edu (Q. Zhang).

https://doi.org/10.1016/j.allmed.2025.100075
Received 6 August 2025; Received in revised form 7 October 2025; Accepted 9 October 2025
Available online 10 October 2025

Results: Participants had suboptimal diet quality (mean DDS 5.7 out of 10). Longer duration of TCM therapy was significantly associated with higher DDS ($r = 0.68$, 95% CI: 0.50–0.81, $p < 0.001$). DDS was significantly greater in those using TCM > 12 months compared to ≤ 3 months ($p < 0.001$). Patients' reports of improved food tolerance, particularly for whole grains, vegetables, and fruits, were also positively associated with longer TCM therapy ($r = 0.54$, 95% CIs 0.31 to 0.71, $p < 0.001$).
Conclusions: Among children and adolescents with food allergies and eczema, longer use of multi-component TCM therapy is associated with reported improvements in food tolerance and better diet quality.

Abbreviations:

TCM	Traditional Chinese medicine
FA	Food allergy
DDS	Dietary diversity scores

1. Introduction

Food allergy (FA) and eczema are prevalent and burdensome health conditions. FA affects approximately 10% of the global population and 8–11% of adults and children in the United States [1–4], with an estimated healthcare cost of $24.8 billion annually [5]. Eczema, also known as atopic dermatitis, affects 10–20% of children and 2–10% of adults worldwide [6,7], imposing significant physiological, psychological, and economic burdens from itchiness, sleep disturbance, and impaired quality of life [8]. FA and eczema are closely related, with food allergens commonly triggering eczema flares [9]. Current treatment options remain limited. FA management relies on strict avoidance of allergenic foods and emergency epinephrine, which carry psychological, economic, and social challenges [10,11]. Eczema is typically treated with moisturization and topical corticosteroids [12], though some patients may develop refractory disease or steroid withdrawal [13]. Traditional Chinese medicine (TCM) is one potential approach and has shown promising results in treating FA and eczema [14,15]. As part of mainstream medicine in countries such as China, Japan, and Korea, TCM has demonstrated safety and efficacy in improving disease severity and quality of life, as well as reducing steroid use and disease recurrence among patients with FA and/or eczema. For example, a retrospective study of medical records found that the multi-component TCM therapy showed good tolerance among patients with moderate to severe eczema and reduced the total serum IgE level in 70% of study participants [16].

For those with FA and/or eczema, continuous food avoidance may result in limited food choices and diet quality. Consuming various food groups is associated with more potentially immunomodulatory nutrients and a more favorable microbiome for better immune tolerance [17]. Over-restriction of the diet could lead to malnutrition, nutrient deficiencies, economic and psychological burden, and impaired quality of life [18–20]. These concerns are particularly important for children and adolescents, as a balanced diet with adequate nutrition and various food choices are essential for their growth and long-term health. One cross-sectional study of 76 children with FA found that over 70% of participants had a suboptimal diet quality [21]. In a multi-center study, children with FA (n = 91) had lower weight-to-length ratio and lower intake of calories, protein, calcium, zinc, and some polyunsaturated fatty acids when compared to healthy controls [22]. Other studies showed consistent findings that children and adolescents with eczema and/or FA had compromised diets with higher odds of vitamin D deficiency, low calcium, lower bone mineral density, higher risk for malnutrition and fracture, as well as a pro-inflammatory dietary pattern due to lower intake of vegetables, fruits, and nuts, but higher intake of meat/sausages and sweets/snacks [23,24]. The limited dietary diversity in this population indicated limited diet quality, making people susceptible to nutrient insufficiency and adverse health-related outcomes.

Research on how to improve diet quality for children and adolescents with FA and/or eczema is limited. As a novel therapy for people with FA and/or eczema, the multi-component TCM therapy has been found to be safe and effective in treating these conditions and inducing immune tolerance. We hypothesized that TCM therapy could help improve dietary outcomes with better food tolerance and less food restriction among children and adolescents with FA and/or eczema. This study aims to investigate how the multi-component TCM therapy might affect diet quality among children and adolescents with FA and/or eczema.

2. Methods

2.1. Study design and subjects

This was a practice-based evidence study conducted as a retrospective observational chart review of 53 patients who received TCM for the management of FA and/or eczema. The electronic medical records were obtained from a New York-based TCM practice between November 12, 2021 to July 25, 2024. This pilot study with a focus on diet quality was part of the chart review study: Practice-based traditional Chinese therapy effect on laboratory safety and clinical and immunological outcomes, approved by the Institutional Review Boards at New York Medical College (Protocol #12798). This study was conducted according to the guidelines laid down in the Declaration of Helsinki.

Inclusion criteria for the electronic medical record analysis required that patients had a chief complaint of FA and/or eczema, age < 18 years, started the multi-component TCM therapy for at least one week, and had dietary assessment data available. After reviewing the 88 electronic medical records with dietary data available in the practice database between November 12, 2021 to July 25, 2024, we excluded the records for other diseases (n = 8), following TCM less than a week (n = 18), age more than 18 (n = 7), and being exclusive breastfeeding or formula feeding (n = 2). A total of 53 electronic medical records were included in the analysis.

2.2. Multi-component TCM therapy

The multi-component TCM therapy for FA and/or eczema patients comprised of different remedies as previously described [15,16,25,26], including dietary supplements of Mei Huang Tea [*Pruni Mume formula* (**Remedy A**, a dried aqueous extract of *Prunus mume*, *Zanthoxylum schinifolium, Angelica sinensis*, *Zingiber officinalis*, *Cinnamomum cassia*, *Phellodendron chinensis*, *Panax ginseng*, and *Ganoderma lucidum), and* Shi Zhen tea I (a dried aqueous extract of *Sclerotium Poriae Cocos*, *Cortex Moutan*, *Fructus Kochiae*, *Flos Lonicerae*, *Radix Arnebiae*, *Fructus Forsythiae*, *Indigo Naturalis*)], 1–3 g in the form of capsules; external herbal Bath Additives (*Phellodendron chinensis* formula, **Remedy B**, a dried aqueous extract of *Cortex Phellodendri*, *Radix Rhizoma Rhei*, *Radix Sophorae Flavescentis, Cortex Dictamni*, *Dayscarpi Radicis*, *Fructus Tribuli Terrestris*, and *Rhizoma Smilacis Glabrae*), in granule form (15g/pack per bath, once daily), and cream (Fructus Tribuli topical herbal cream, **Remedy C** composing of oil extract of *Fructus Tribuli*, *Radicis Angelicae Sinensis*, *Flos Lonicerae*, *Radix Arnebiae*, and *Sophora flavescens,* and *Indigo*), to apply to the skin 2-3 times. The dietary supplements were produced by Brion Herbs Corporation (Irvine, CA), and external

remedies were provided by US Time Technology Inc (Elmsford, NY) following good manufacturing practice. The tests for heavy metal, pesticide residual, and microbial content met required standards. The remedy A-C are the main treatment protocol for the patients. Dosage adjustments and remedy modifications were made as necessary over the course of treatment. Patients were seen at Center for Integrative Health and Acupuncture, in the Otolaryngology Department at Westchester Medical Center, New York.

2.3. Data collection and measures

Demographic and health characteristics collected from the electronic medical records were age, gender, months of multi-component TCM therapy, and recent compliance rate to TCM protocol.

Dietary data were obtained through practice-based questionnaires and food intake forms in electronic medical records. Diet quality was indicated by dietary diversity scores (DDS). The DDS demonstrated whether patients had a high diversity of food groups in their daily diet, which is related to nutritional adequacy and has been a longstanding recommendation from the dietary guidelines in different countries [27]. We also measured change of food tolerance, which demonstrated whether patients were able to tolerate more food groups after the initiation of TCM therapy. A registered dietitian on the research team performed the dietary analyses.

The DDS was calculated as the count of different food groups recorded in the practice-based food intake form. The practice-based food intake form was a dietary intake recall form for patients to record their food and beverage intake on the day prior to their clinic visit and to note how this reflected their typical diet. Based on this dietary recall, the DDS was calculated as the number of different food groups consumed by the patient, resulting in a score from 0 to 10. The scoring method was based on Food and Agriculture Organization (FAO)'s DDS guidelines (2022) and adapted to reflect the common food groups consumed locally in this study population. The following ten food groups were reviewed by a local dietitian and included in the analysis: whole grains, vegetables, fruits, beans/peas/lentils, nuts/seeds, meat, poultry, seafood, eggs, and dairy. To calculate the scores, a score of 1 was assigned if a food from a specific group was consumed at least once, regardless of the amount. A score of 0 was assigned to any food group that was not consumed. The individual score for each patient was calculated by summing the combined total food group scores. A higher score indicated better dietary quality [28,29]. The change of food tolerance was reported in the practice-based dietary questionnaire. The practice-based dietary questionnaire included patients' self-reported change of tolerance or consumption for 10 common food groups. According to the Dietary Guidelines for Americans (2022), the food groups included fruits, vegetables, whole grains, beans/peas/lentils, nuts/seeds, fish/shellfish, meat, poultry, egg, and dairy. For the question "How has your intake of the following foods and beverages changed after starting TCM treatment?", participants selected "increased", "about the same", or "decreased" based on their perceived tolerance to the quantity and/or variety of these food groups. The report of "increased" indicated improved tolerance to the food group; the report of "about the same" indicated no change of tolerance; the report of "decreased" indicated decreased tolerance. For each record, higher total count of "increased" was considered as higher score indicating more improvements of food tolerance following the TCM therapy.

The length of using the multi-component TCM therapy was recorded in months, which was also categorized into four groups: equal or less than three months, three to six months, six to twelve months, and more than 12 months. This categorization was based on the observed improvement pattern in the TCM practice and approved by the practitioner. The compliance with TCM therapy was reported by patients on a scale from 0 to 100. A hundred indicated full compliance with the TCM protocol; a higher number indicated higher compliance.

2.4. Statistical analysis

Descriptive statistics including mean, standard deviation (SD), percentage, minimum, and maximum were calculated for each variable as appropriate. The Kolmogorov-Smirnov test was used to test normality of the data with the significance value > 0.05 indicating normal distribution. For data that were not normally distributed, the Mann-Whitney U test was used to determine if there are statistically significant differences between two groups; the Kruskal-Wallis H test was used to determine if there are statistically significant differences between two or more groups; Spearman correlation coefficient was used to assess correlations between different variables. Statistical analyses were performed using SPSS software ver. 29.0 (IBM, Armonk, NY, USA). A p-value < 0.05 was considered statistically significant.

3. Results

3.1. Characteristics of study sample

The electronic medical record review was conducted for 53 children and adolescents with FA and/or eczema who were using the multi-component TCM therapy to manage their conditions. As shown in Table 1, 53 patients (41.5% female; age mean 5.3 years) were included in the analysis. Fifty-one patients reported having certain food restriction prior to starting the TCM therapy. By the time of review, the length of time using the TCM to manage their conditions varied from 0.5 to 102 months. The reported compliance with TCM protocol ranged from 55 to 100 with the mean self-reported compliance score of 94 (SD 10) out of 100; higher score indicates higher compliance.

3.2. Dietary quality

The average DDS for our subjects was 5.7 (SD 1.4, range 3–9) out of 10, indicating that the patient population had a moderate dietary quality level with five to six different food groups included in their daily diet. Nuts, seeds, eggs, and dairy products were the top ones absent from their diet. No significant difference in DDS was found for gender ($p = 0.397$) or type of chief complaint ($p = 0.068$).

Longer TCM treatment was associated with higher DDS ($r = 0.68$, 95% CIs 0.50 to 0.81, $p < 0.001$). Specifically, the mean DDS was 4.3 for TCM $\leq$ 3 months, 5.2 for TCM between 3 and 6 months, 5.5 for TCM between 6 and 12 months, and 6.8 for TCM more than 12 months, as shown in Table 2. There was a statistically significant difference in DDS between different lengths of TCM treatment, $\chi^2(3) = 25.760, p < 0.001$.

Table 1
Characteristics of study sample.

Characteristics	Participants (n = 53)
Age in years (mean, minimum-maximum)	5.3 (0.6–16.7)
Gender n (%)	
Female	22 (41)
Male	31 (59)
Chief Complaints n (%)	
Food allergies & Eczema	47 (89)
Food allergies only	4 (7)
Eczema only	2 (4)
Had Diet Restriction before TCM n (%)	51 (96)
Months on TCM (mean, minimum-maximum)	20.2 (0.5–102)
Months on TCM n (%)	
TCM $\leq$ 3 months	10 (19)
TCM $>$ 3, $\leq$ 6 months	12 (23)
TCM $>$ 6, $\leq$ 12 months	10 (19)
TCM $>$ 12 months	21 (40)
Self-reported TCM Compliance[a] (mean, minimum-maximum)	94.3 (55–100)[b]

[a] Self-reported TCM compliance was reported on a scale from 0 to 100, with 100 being the 100 % adherence of the TCM protocol.
[b] Data not available from two patients.

Table 2
Dietary diversity scores and food tolerance by sample characteristics.

	Dietary diversity scores	Number of food groups with improved tolerance
	Mean (SD, Range)	Mean (SD, Range)
Overall	5.7 (1.4, 3.0–9.0)[a]	2.1 (2.4, 0.0–8.0)[b]
Months on TCM		
TCM ≤ 3 months	4.3 (0.9, 3.0–6.0)	0.5 (0.9, 3.0–6.0)
TCM > 3, ≤ 6 months	5.2 (0.9, 4.0–7.0)	1.4 (0.9, 4.0–7.0)
TCM > 6, ≤ 12 months	5.5 (1.1, 4.0–7.0)	1.3 (1.1, 4.0–7.0)
TCM > 12 months	6.8 (1.2, 5.0–9.0)	3.6 (1.2, 5.0–9.0)
Gender		
Female	5.9 (1.3, 4.0–9.0)	2.4 (2.6, 0.0–8.0)
Male	5.6 (1.5, 3.0–9.0)	1.7 (2.1, 0.0–8.0)
Chief Complaint		
Food allergies & Eczema	5.6 (1.4, 3.0–9.0)	2.2 (2.5, 0.0–8.0)
Food allergies only	6.8 (1.0, 6.0–8.0)	2.3 (1.3, 1.0–4.0)
Eczema only	7.5 (2.1, 6.0–9.0)	0

[a] The maximum dietary diversity score (DDS) was 10; the higher the score the higher dietary quality.
[b] Higher numbers of improvement indicated more food groups that were tolerated after the initiation of TCM therapy.

After Bonferroni adjustment, as shown in Fig. 1, the significant difference in DDS was found between the TCM therapy > 12 months and ≤ 3 months (Z = 4.721, *adjusted* $p < 0.001$), as well as between the TCM therapy > 12 months and 3–6 months (Z = 3.321, *adjusted* $p = 0.005$), suggesting the most change of diet quality happened after one year of TCM therapy among children and adolescents with FA and/or eczema.

3.3. Improved food tolerance

Among the patients who had prior food restrictions (n = 51), more than half (n = 31, 61%) reported having some improved tolerance to food after the initiation of their TCM therapy for FA and/or eczema. The improved tolerance was reported for whole grains (39% of patients who had prior food restrictions), vegetables (31%), fruits (31%), eggs (27%), beans and lentils (25%), nuts and seeds (18%), dairy (18%), seafood (14%), poultry (10%) and red meat (8%). No decreased tolerance was reported. No significant difference in improvement was found for gender ($p = 0.333$) or type of chief complaint ($p = 0.260$).

Longer TCM treatment was associated with more reports of improved tolerance ($r = 0.54$, 95% CIs 0.31 to 0.71, $p < 0.001$). Specifically, the average number of reports was 0.5 for TCM ≤ 3 months, 1.4 for TCM between 3 and 6 months, 1.3 for TCM between 6 and 12 months, and 3.6 for TCM more than 12 months, as shown in Table 2, suggesting that those who were on TCM more than one year had improved tolerance to three to four different food groups. Among those who used TCM for more than 12 months and had prior food restrictions (n = 20), 95% of them (n = 19) reported improved tolerance to certain food groups, in particular vegetables and whole grains. There was a statistically significant difference in the number of improvement reports between different lengths of TCM treatment, $\chi^2(3) = 16.505$, $p < 0.001$. After Bonferroni adjustment, as shown in Fig. 1, the significant difference in improvement was found between the TCM therapy > 12 months and ≤ 3 months (Z = 3.658, *adjusted* $p = 0.002$), as well as between the TCM therapy > 12 months and 3–6 months (Z = 2.648, *adjusted* $p = 0.048$), which was consistent with the finding for DDS.

4. Discussion

To our knowledge, this exploratory cross-sectional practice-based evidence study was the first to examine the potential effect of multi-component TCM therapy on diet quality among people with FA and/or eczema. Results suggested that TCM was associated with improved diet quality. Particularly, longer TCM treatment was associated with increased food tolerance and better diet quality among children and adolescents with FA and/or eczema.

Participants in this study had a moderate level of diet quality with

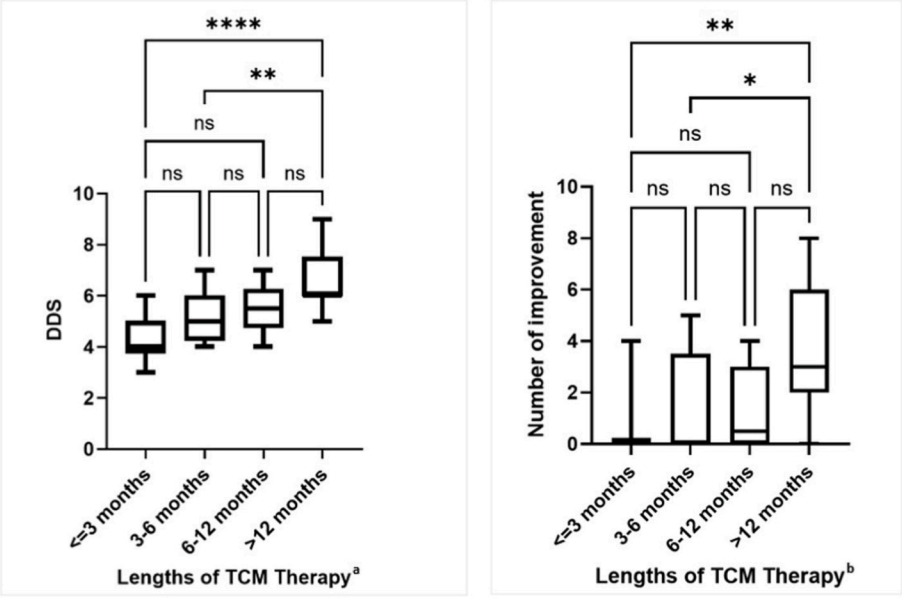


Fig. 1. Dietary diversity scores and reports of improved food tolerance by TCM therapy length. The Kruskal-Wallis H test was used to compare dietary diversity scores (DDS) and the number of reported improvements between different lengths of TCM therapy. Bonferroni adjustment was used in multiple comparisons with adjusted p values. ns suggested adjusted $p > 0.05$, ** suggested adjusted $p < 0.01$, **** suggested adjusted $p < 0.0001$.
a. Higher DDS indicated higher dietary quality. Each box represented the mean, standard deviation, minimum and maximum of DDS for the respective length of TCM therapy.
b. Higher numbers of improvement indicated more food groups that were tolerated since TCM therapy. Each box represented the mean, standard deviation, minimum and maximum of improvements for the respective length of TCM therapy.

DDS being 5.7 out of 10, suggesting their consumption of only five to six food groups on average. The Dietary Guidelines for Americans (2022) recommended to have a variety of foods from all recommended food groups, which correspond to all the food groups in our analysis. Our results suggested the need to improve diet quality among patients with FA and/or eczema. On the other hand, TCM treatment showed promising results in improving diet. The patients in general had good compliance with TCM protocol. We observed a statistically meaningful relationship between the length of TCM therapy and diet quality. The children and adolescents who were on TCM for more than 12 months had a significantly higher mean DDS and more reports of improved food tolerance than those who used TCM for less than six months, indicating the promising role of TCM to help improve the overall dietary outcomes for individuals with FA and/or eczema in the long term. Specifically, patients reported eating more whole grains, vegetables, fruits, eggs, beans and lentils which are all key components of a healthful diet.

Studies on dietary quality among people with FA and/or eczema are limited. Most previous studies focused on the association between diet quality and prevention of FA and/or eczema [30–32]. With existing FA and/or eczema, a restrictive diet to avoid multiple food triggers was associated with nutritional inadequacy and suboptimal health outcomes [22]. Nutrition status is a major determinant of immune competence, with deficiencies in vitamins (A, B, C, D, E), minerals (zinc, selenium, iron), fatty acids, or polyphenols each impairing barrier integrity, regulatory T-cell induction, and modulation of pro-inflammatory cytokines. For example, reduced intake of fruits, vegetables, and antioxidant nutrients (vitamin C and E, selenium) may reduce epithelial defenses and increase susceptibility to oxidative stress and inflammation, leading to higher prevalence of eczema [32]. A diverse and nutrient-rich diet, such as those abundant in fruits, vegetables, and whole grains, have been associated with reduced systemic inflammation and improved immune tolerance [33]. Diet diversity, as one indicator of diet quality, also shapes the gut microbiota, which plays a critical role in producing metabolites such as short-chain fatty acids that promote regulatory T-cell induction and suppress Th2-driven inflammation [24]. Therefore, supporting patients with a diverse diet may help optimize immune regulation for those with FA and eczema. Our findings captured the importance of diet and highlighted the role of TCM in improving dietary outcomes beyond treating FA and eczema. With the added benefits associated with diet quality, TCM can be a beneficial complementary therapy for people with FA and eczema.

This exploratory study had limitations. First, the sample size was small and limited to one clinic at one time point as the result of the exploratory nature. The retrospective design without control group also limits causal inference. A larger-scale longitudinal study or randomized study with adjustment for potential confounders is needed to validate the associations and confirm the finding [34]. Future studies may collect more data on ethnicity, education level, or socio-economic status, which may be potential confounders that also affect diet quality. Second, we only used DDS accompanied by reports in food tolerance as the proxy for diet quality in this study. Other aspects of diet quality, like proportionality and moderation, were not assessed due to limited dietary data in the electronic medical records and were not included in the analysis. Third, our compliance and dietary data on intake and change of food tolerance were self-reported, which are subject to potential reporting bias. Future studies can include objective measures and multiple days of dietary data for more comprehensive analysis. Lastly, we are aware of the limitation of this retrospective study in documenting the adverse effect. Based on previous retrospective and prospective studies, these well-defined regimens have high safety and tolerability including pediatric population [15,16,25,26,35]. In this current study, based on electronic medical record of subjective and objective records, there were no obvious adverse effects. However, the retrospective study may carry recall bias and selection bias. An IRB approved prospective study of "Practice-based study of TCM effect on biomarkers of multiple food allergy and eczema" is underway to validate our retrospective results.

5. Conclusion

Diet quality is important for growth and long-term health among children and adolescents with FA and/or eczema. Along with being a safe and effective therapy for FA and/or eczema, multi-component TCM therapy has a promising role in improving patients' diet quality and diet-related health outcomes.

CRediT authorship contribution statement

Qianhui Zhang: Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Conceptualization. **Ava Retsch:** Writing – review & editing, Investigation, Data curation. **Shane Martin:** Writing – review & editing, Resources. **Danna Chung:** Writing – review & editing, Resources. **Paul Ehrlich:** Writing – review & editing, Resources. **Xiu-Min Li:** Writing – review & editing, Supervision, Resources, Methodology, Conceptualization.

Ethical Standards disclosure

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving research study participants were approved by the Institutional Review Boards at New York Medical College (Protocol #12798) as part of the chart review study: Practice-based traditional Chinese therapy effect on laboratory safety and clinical and immunological outcomes. Informed consent was waived for this chart review study.

Data availability statement

The data presented in this study are available on request from the corresponding author due to privacy reasons.

Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: QZ, AR, DC, PE and SM declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. XML received research support to her institution from the National Institutes of Health (NIH)/ National Center for Complementary and Integrative Health (NCCAM) # 1P01 AT002644725-01 "Center for Chinese Herbal Therapy (CHT) for Asthma", and grant #1R01AT001495-01A1 and 2R01 AT001495- 05A2, NIH/NIAID R43AI148039, NIH/NIAID 1R21AI176061-01, NIH/NIAID 1R44AI177183-01, NIH/NIAID 1R41AI172572-01A1, Food Allergy Research and Education (FARE), Winston Wolkoff Integrative Medicine Fund for Allergies and Wellness, the Parker Foundation and Henan University of Chinese Medicine; received consultancy fees from FARE and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Bayer Global Health LLC; received royalties from UpToDate; received travel expenses from the NCCAM and FARE; share US patent US7820175B2 (FAHF-2), US10500169B2 (XPP), US10406191B2 (S. Flavescens), US10028985B2 (WL); US11351157B2 (nanoBBR); take compensation from her practice at Center for Integrative Health and Acupuncture PC; US Times Technology Inc is managed by her related party; is a member of General Nutraceutical Technology LLC.

Acknowledgements

The authors thank Henry Ehrlich and the researchers at the New York

Medical College for support during the planning and development of this research.

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