

# THERAPEUTIC USE OF IGG FOOD SENSITIVITY TESTING AND ELIMINATION DIET AS AN EFFECTIVE APPROACH TO PATIENTS' CARE

## **CLINICAL STUDY OVERVIEW AND RESULTS**

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November 2022

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## INTRODUCTION

Food sensitivities have been on the increase over the past decades and estimates suggest that 60% of the population may have food sensitivities without knowing it [1].

The terms food allergy, sensitivity and intolerance are all commonly used interchangeably, however, they differ significantly. Although these terms all relate to an adverse physiological response to a particular food, the mechanisms by which this occurs are very specific to the type of food reactions in question. These can be categorised as either:

- Immunological i.e. involving the immune system which are either IgE (immunoglobulin E) or IgG (Immunoglobulin G) mediated. This type of food reactions is characterised by hypersensitivity and inflammatory responses to an immune-mediated reaction from the ingestion of an offending food [2]; or
- Non-immunological where there is no immune system involvement. These include histamine intolerance, enzyme deficiencies (e.g. lactose intolerance), fructose intolerance, amine and salicylates intolerances, among others [1].

Both food allergies and sensitivities are immune-mediated hypersensitivity reactions that involve two major types of reactivity, immediate (IgE mediated) and delayed (IgG-mediated). IgE mediates type I hypersensivity and IgG mediates type II and type III. Type III IgG hypersensitivity is immune complex mediated [2,3] and is involved in food sensitivity reactions discussed here.

IgG food sensitivities are immunologically mediated reactions to foods we ingest [4]. These sensitivities are often delayed and may take hours to days to manifest. Importantly, in some people these sensitivities may not always occur on a clinical level after consuming the food in question [1], as the severity of food sensitivity reactions also depends on the amount of food ingested and the frequency, as also observed in our study.

Sensitivity reactions occur when a certain food is ingested and antibody-antigen, also known as immune complexes, form with proteins in that food. Normally these complexes are eliminated by the immune system with no ill effects. However, if the immune or digestive systems are compromised, these complexes keep circulating in the blood and, when unable to be removed, can be deposited in tissues or organs causing an inflammatory response and/or tissue damage, subsequently producing symptoms [5]. Symptoms can last for several days or longer and are often intermittent, making it difficult to identify which foods the body is reacting to.

IgG is the most abundant antibody in normal human serum and it's the major antibody of the adaptive immune response. It has the longest half-life of all antibodies – 20-24 days [2]. It has the ability to modulate inflammation, bind antigens and mediate the anti-body dependent, cell-mediated cytotoxity [6]. Food sensitivity symptoms are dependent on which tissues, organs or body systems these immune complexes are deposited in, and can result in a wide range of indications.

In summary, delayed food reactions mediated by IgG antibodies are characterised by [5]:

- Onset of symptoms is delayed i.e. more than 24hr (24-72hrs+)
- Duration of symptoms chronic symptoms with constant exposure
- Amount of exposure required for immune reaction frequent exposure/ consumption
- Removal of foods decreases the IgG load and neutralises the inflammatory response



- Sensitivity diminished by avoidance
- Dose dependent overconsumption triggers IgG production
- Effects inflammation, tissue damage, immune activation

Immune-mediated food sensitivities are well recognised in clinical practice and have been implicated in a variety of disorders and symptoms. A large body of research in the past 10 years has indicated that food sensitivity is a frequent cause of a wide range of physical and mental conditions (this will be discussed further below).

However, the effects of the food specific IgGs on human health remain controversial. This aspect will be also discussed below. Notably, the vast majority of the previous clinical studies on food-specific IgG sensitivity typically focused on patients with a specific disease. In contrast, our clinical study covered a number of disease categories and symptoms across a wide age range, with the aim to assess therapeutic applications of IgG guided elimination diets in clinical practice.



### Objectives

This clinical study intended to validate the IgG food sensitivity testing for its ability to resolve or alleviate the causes and/or symptoms of our patients who reported a variety of complaints. These were broadly classified into six categories:

- Gut and digestive imbalances
- Skin disorders
- Weight loss
- Autoimmune disorders
- Hormone imbalances
- Other

Patients were classified into the above categories taking into account their chief complaint(s), as specified by them at an initial assessment. In addition to the chief complaint(s), the vast majority of patients also presented with multiple other complaints which were also recorded and monitored during the elimination diet protocol based on the IgG food sensitivity testing.

### Design

The study included a cohort of patients who undertook food sensitivity testing (either one or two tests) <u>and</u> were closely monitored and coached for at least 6 months, utilising a tailored clinical methodology especially designed for the study – see details below.

### Methodology

Our study methodology was based on achieving optimal health results for patients. The sequential steps were organised into a clear and feasible sequence, where a patient and a practitioner worked closely together facilitating optimal health and wellness outcomes.

Assessment and monitoring

The initial assessment took 75-90 minutes to determine patients' chief complaint(s), other complaints and overall health level, nutrition status and limiting lifestyle factors. From then on patients were assessed and monitored regularly at least every 4-5 weeks on average for approximately an hour. All consultations were conducted via telehealth (Zoom).

Main assessment and monitoring steps included:

- Initial consultation: in-depth naturopathic health assessment using a tailored health questionnaire covering patient's health history combined with an assessment of main body systems, nutrition patterns and lifestyle habits.
- Identification, initial rating and prioritising of current complaints and symptoms prior to taking the IgG food sensitivity test.
- Referral for basic blood tests to assess overall health status and identify any key nutritional deficiencies of vitamins and minerals necessary for the body to function well.
- Referral for the IgG food sensitivities blood test.



- Test results interpretation, agreeing on the priorities and implementation steps.
- Complaints/ symptoms review at each consultation each patient was asked to record and rate their symptoms in a 'symptom tracker table' on a weekly or fortnightly basis. This was then reviewed and discussed at each consultation to remove any roadblocks as they arise. These included worsening of symptoms, making better food choices or supplementation adjustments.
- Frequency of consultations varied depending on a patient's needs, their nutritional literacy, ability to cook or work commitments. Consultations typically took place every 4-5 weeks.
- Tools and aids utilised throughout the elimination diet included:
  - Detailed nutrition guides covering food groups that needed to be eliminated for the 6 months on the elimination diet (e.g. gluten, diary, egg, yeast, soy)
  - Relevant food substitute lists e.g. gluten free flours, dairy alternatives, egg replacements
  - Best food preparation methods for optimum digestion and absorption
  - 'Safe' product lists and where to get them
  - Personalised, tried and tested recipes and menu plans covering all meals
  - Lifestyle modifications guidelines to support recovery including improving sleep, stress management, rest and relaxation, exercise, etc.

Second tests (retests) were performed between 6-8 months after the initial IgG food sensitivity test and after following the elimination diet for that period of time.

### **Statistical methods**

Changes in measured quantities between baseline and retest were tested using paired t-tests and paired Wilcoxon tests. Use of the t-test implicitly assumes normality of the differences between retest and baseline values. This was checked using the Shapiro-Wilk test when needed. A *p*-value less than 0.05 was regarded as indicating a statistically significant outcome. Statistical analysis was carried out in R version 4.2.1 [40].

### Settings

The patients were first seen by either Nicholas Greene at Greene Chiropractic, a wholistic chiropractic clinic in Sutherland, Sydney, or by Joanna Sochan, Nutritionist and Natural Therapist at Naturimedica. All patients were then referred to and worked with Joanna Sochan for the duration of the elimination diet.

Based on patients' chief complaint(s) and symptoms, the participants were broadly classified into six categories (as specified above). Patients' blood samples were analysed by the Australian Clinical Labs facility in Adelaide. To determine each participant's food sensitivities the study used the IgG FoodPrint test for 200+ foods developed by a UK-based Nutrition Cambridge Nutritional Sciences Ltd. The method used for analysis of patients' blood samples was the ELISA (enzyme-linked immunosorbant assay) testing for IgG-mediated food sensitivities.

Results of each food tested were reported **ELEVATED** (>30 U/ml), **BORDERLINE** (24-29 U/ml) or **NORMAL** (<23 U/ml) IgG antibodies levels, with a quantitative numerical value displayed adjacent to each food, representing the concentration of IgG antibodies detected (in U/ml) for each food. Sample report can be cited here [7]. A total of 200+ foods were tested, including 10 of the most



highly sensitive foods that were identified in the vast majority of tests performed: milk (cow), egg white, wheat, barley, soy, corn, cola nut, yeast, nuts and agar agar.

### Study statistics

- Total initial IgG tests performed 98 patients
- Second (retest) tests performed 19 patients out of 98
- Patients who performed an initial test and were monitored for 6+ months (no retest )- 3
  patients
- Other 76 patients included:
  - $\circ$   $\quad$  Patients who followed the elimination diet on their own
  - Patients who had 1-2 initial consultations only with the Nutritionist
  - Patients who didn't follow the elimination diet

### Participants selection criteria

All patients were asked their verbal permission before being included in and participating in the study, and publishing of their cases study reports. Included in the study were patients who satisfied the following criteria:

- Patients who performed a minimum of two FoodPrint 200+ tests completed within 6 to 8 months of each other (19 patients) OR
- Patients who performed the initial FoodPrint 200+ test only and whose symptoms were monitored on a regular basis (minimum of three 3 consultations in 6 months) for at least 6 months on the elimination diet (3 patients)

Based on the above criteria, the study had n=22 participants. Out of all tests performed (98 tests = 100%), 22 patients (22.5%) fulfilled the selection criteria for study participation.

Patients age range was from 17 to 69 years, the group consisted of 13 females and 9 males.

Each participant was assigned into one category based on the nature of their chief complaint(s) as follows:

- Gut and digestive imbalances (6 patients)
- Skin disorders (5 patients)
- Weight loss (4 patients)
- Autoimmune disorders (3 patients)
- Hormone imbalances (2 patients)
- Other (2 patients)

Study participants presented with a wide variety of symptoms that included:

- Bloating, flatulence, abdominal pain and cramps, diarrhoea, constipation, reflux, intestinal parasites, leaky gut
- Excess weight, obesity, insulin resistance, blood sugar imbalances
- Eczema, hives (urticaria), psoriasis, histamine intolerance
- Painful periods, PMS, hot slushes, night sweats
- Fatigue and chronic fatigue



- Migraines and headaches
- Insomnia and other sleep disturbances
- Cognitive dysfunction, such as poor memory or concentration, brain fog; anxiety and depression
- Joint pain and muscle pain

### Intervention

The study reviewed the nutritional therapies and results of patients who were placed on an elimination diet for treatment of food sensitivities identified by the test. Based on an initial IgG test, foods causing ELEVATED IgG levels (>30 U/ml) were identified and eliminated from each patient's diet. Substitute foods were recommended based on the list of NORMAL foods (<23 U/ml) in patient's results.

The vast majority of patients was taking doctor prescribed medications as well as multiple supplements prior to starting the elimination diet. Generally, they continued taking them for the duration of the study. Some changes were made to supplementation, mainly related to providing additional digestive support in absorption of nutrients. Supplemental recommendations were based on:

- Blood test results for nutritional deficiencies
- Stool tests for gut motility imbalances, microbiome imbalances or having intestinal parasites affecting the nutritional therapy
- Symptoms not improving after around 3 months on the elimination diet indicating more support and investigations were required (e.g. addressing increased gut permeability i.e. leaky gut)

Progress and changes in patients' symptoms were obtained by the Nutritionist during monthly Zoom consultations. The patients were asked to quantify the severity of their symptoms by rating how much their chief complaint(s) and other symptoms had improved or worsened since the last consultation. Some patients also underwent specific, tailored detoxification protocols and/or took personalised oral supplements intended to strengthen the gut mucosal lining and improve digestion of nutrients, including probiotics.

At baseline and at an average of 6-8 months on the elimination diet, two IgG tests were performed on each patient's blood sample by the method of indirect enzyme-linked immunosorbent assay (ELISA). The second test was performed at least 6 months after the initial test, taking into account IgGs half-life of around 20-24 days, with residual effector functions of approximately two to three months [2] or longer. As explained above, IgG antibodies combined with antigens (food proteins), form immune complexes which may remain in circulation for an extended period [2]. The amount of time ultimately depends upon the magnitude of the antigen load (i.e. number of food sensitivities) and the efficiency of the immune system in clearing the immune complexes. For example in the case of cow's milk sensitivity, IgGs can last for up to 9 to 12 months according to Nutrition Cambridge Nutritional Sciences Ltd (IgG FoodPrint test developer).

Both food sensitivities and chief complaints (and other symptoms monitored) were reassessed after the second test to determine if participants' complaints and symptoms improved with food elimination diet. Outcomes were based on the status of the patients' chief complaint(s). Overall improvement in other symptoms from baseline was also recorded.



### Results

Majority of patients who complied with the avoidance of foods identified by the IgG food sensitivity testing demonstrated a marked reduction in sensitivities, and all patient demonstrated a significant reduction in the initial chief complaint(s) as well as other symptoms reported before starting the elimination diet.

Number of IgG sensitivities detected showed a statistically significant decrease between baseline and retest values, by paired t-test (mean decrease = 7.14; 95%CI: 0.94 - 13.3; p = 0.026) and by paired Wilcoxon test (median decrease = 7.50; 95%CI: 0.0004 - 14.5; p = 0.045). A Shapiro-Wilk test application did not reject the assumption of normality of the differences between baseline and retest values (p = 0.497).

Chief complaint severity scores showed a statistically significant decrease between initial and retest values, by paired t-test (mean decrease = 6.95; 95%Cl: 6.16 - 7.75; p < 0.001) and by paired Wilcoxon test (median decrease = 7.00; 95%Cl 6.00 - 8.00; p < 0.001). A Shapiro-Wilk test application did not reject the assumption of normality of the differences between initial and retest values (p = 0.311).

### Discussion

At present, IgG food sensitivity testing and its effects of on human health remain controversial. There are more recent studies and evidence supporting its use, as well as other reviews and research stating that IgG food sensitivity testing is not strongly supported by research and the IgG testing lacks clinical validity and testing reliability [8,9,10,11,12].

For example, the American Academy of Allergy, Asthma and Immunology stated: "IgG antibodies to common foods can be detected in health and disease. This reflects the likelihood that circulating immune complexes to foods occur in most normal individuals, particularly after a meal and that they are found or considered a normal physiological finding." [8] This is important to acknowledge as some immune system prevalence and reactivity is always present and is considered normal. Therefore, not all detectable immune response is pathological in nature and, in our view and clinical experience, the reactivity level needs to be assessed individually for each patient taking into account the symptoms, digestive health and lifestyle factors, among others. This area would benefit from further research and study to clarify and explain the clinical evidence.

On the other hand, a number of more recent studies have suggested that food-specific IgG testing is clinically relevant, and that it can be involved in the development and progression of specific diseases. This is associated with the ability of the IgG antibody to form an immune complex with allergens in foods, and thus induce an inflammatory reactions in the body that manifest as various symptoms and diseases [13].

Examples of relevant studies supporting this view include the following conditions: irritable bowel syndrome [14,15,16,17,18], inflammatory bowel disease [19,20,21], migraine [22,23,24,25], depression and mental disorders [16,24,26], autoimmunity [27,28]. Studies show that the symptoms of these disease can be relieved or resolved by food-specific IgG-based diet recommendations [16,19,25,29].

A recent 2021 study compared the effectiveness of three different diet plans in treating patient with mixed IBS: low FODMAP diet, IgG based elimination-rotation diet and control group with a classic



diet recommended by an attending gastroenterologist [30]. The study concluded that the most effective diet in the treatment of patients with mixed IBS was the elimination-rotation diet based on the IgG-dependent food hypersensitivity test. The study showed that a personalised dietary approach based on the IgG testing is more effective in treating mixed IBS than generalised diet recommendations such as FODMAPs.

Other studies even suggest that food-specific IgG actually provides natural protection against food allergy [31,32]. The most direct evidence comes from an oral immunotherapy (OIT) study showing that OIT for peanuts can induce a remarkable increase in the plasma levels of food-specific IgG, which indicates the involvement of IgG in mitigating the symptoms and inducing food tolerance of allergic patients [31]. Food-specific IgG is also present in healthy subject [16,33] but this has not received much research attention to date. This remains one of the current controversies surrounding the IgG testing and needs further research.

Based on the literature review above, the volume of studies provides both research and clinical evidence in support of the use of IgG blood testing to determine food sensitivities.

To date the vast majority of the clinical studies on food-specific IgG typically focus on patients with a specific disease, as discussed above. On the other hand, our study is much broader and included a group of patients who presented in clinic with a wide variety of symptoms and disorders.

It can often be difficult to identify underlying food sensitivities in clinical practice, as symptoms vary from patient to patient, including patients with the same condition. In addition, the food we eat has both chemical and immunological mechanisms [34] which adds to the complexity and difficulty to identify and confirm them by analysing symptoms alone. Importantly, it is believed that the tests examining IgG levels can be improved by utilising both raw and processed food antigens. At present, only raw food samples are used which doesn't reflect real life situations where most foods are processed [35].

While elimination diets without the use if IgG serum testing may be utilised by practitioners, the time-consuming nature of this process may prove challenging for both patients and practitioners. In our clinical experience utilising IgG food sensitivity testing produced better client compliance and engagement as well as monetary savings over the average 6-month therapy. It also decreased guessing and significantly helps to personalise nutritional therapy for each patient to achieve optimal health results.

In conclusion, much of the controversies surrounding the efficacy of IgG food sensitivity testing has arisen from indiscriminate use of the terms food allergy, food intolerance and food sensitivity. Use of the term 'food allergy' to describe IgG food reaction has created the impression that practitioners are equating IgE food allergies with IgG food reactions. This has led critics to dismiss IgG testing as lacking clinical efficacy because its results do not correlate with IgE tests. As a result, this led to overlooking the relevance of IgG food reactions by some practitioners and researchers as a separate clinical condition.

The continued controversies hinder the progress that can be achieved through appropriately designed elimination diets for a number of challenging health conditions. Our clinical study is one example of significant health benefits to be gained by patients who undergo IgG food sensitivity testing and elimination diets based on the test result.



### The study

The aim of the study was to assess the efficacy of IgG food sensitivity testing in order to guide food elimination diets to resolve or decrease various complaints and/or symptoms of the participants. In addition to eliminating the offending foods, it was recommended that some patients perform a short detoxification therapy and/or take supplements to enhance the digestion and gut wall integrity (i.e. decrease leaky gut syndrome that is associated with having food sensitivities) [36].

All participants reported a significant reduction of both the chief complaint(s) and the vast majority of other symptoms they reported at the start of the elimination diet – refer to data in Table 1. In the majority of patients, but not all, their IgG antibody production related to the offending foods decreased, and their symptoms either subsided or completely resolved.

The majority of the participants who followed the elimination of IgG dietary antigens, demonstrated a reduction in IgG sensitivity scores after the second test (retest) – refer to data in Table 2.

The initial tests and second tests (retests) of the FoodPrint 200+ IgG tests were compared at the conclusion of the study. The average time between the two tests was 6-8 months. Among the 22 patients, 100% demonstrated sensitivity to one or more of the 10 foods/ food groups that were identified as the most problematic in the study. The 10 food were: egg white (22 patients/100%), nuts (22/100%), barley (22/100%), wheat (21/95%), milk (20/91%), corn (20/91%), cola nut (20/91%), yeast (20/91%), agar agar (16/73%) and soy (12/55%).

Table 1 shows the comparison between the numbers of the initial IgG tests (baseline) in both the 'elevated' and 'borderline' categories. Figure 1 shows the comparison between the IgG sensitivities detected in the 'elevated' category in the initial (baseline) test and the second test (retest).

### Table 1

Number of IgG sensitivities detected - the initial (baseline) and second (retest) IgG test

Number of IgG sensitivities detected				
Patient	Initial IgG test (baseline)		Second IgG test (retest)	
	Elevated	Borderline	Elevated	Borderline
	GUT AI	ND DIGESTIVE	DISORDERS	•
1	33	15	21	10
2	33	9	29	6
3	34	4	21	4
4	25	5	18	3
5	23	10	34*	17*
6	42	8	59*	14*
SKIN CONDITIONS				
7	49	8	22	6
8	27	6	37*	5
9	27	2	25	5
10	16	11	20*	6
11	26	6	n/a	n/a
WEIGHT LOSS				
12	24	5	27*	4

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13	52	15	52	8	
14	30	5	10	4	
15	27	9	n/a	n/a	
	AUT	OIMMUNE DI	SORDERS		
16	78	13	46	13	
17	31	8	38*	8	
18	12	3	8	1	
	HORMONE IMBALANCES				
19	22	7	25*	9	
20	15	8	n/a	n/a	
OTHER**					
21	46	11	25	4	
22	26	9	24	3	

\*IgG levels increased on the second retest (retest) compared to the initial test (baseline) \*\*Fatigue, inflammation, sleep disorder

n/a - no retest performed, however patients were monitored for 6 months

### Figure 1

### Number of elevated IgG sensitivities detected – initial (baseline) and second (retest) IgG results







As seen in Figure 1, only lines (7) slope up, illustrating the conclusions of the statistical tests presented in the Results section on page 9. The reduction of detected IgG antibodies is illustrated in 11 patients (61%). One patient recorded the same number of elevated antibodies in both tests. Seven patients (38%) recorded an increase of the IgG antibodies in the elevated category. Please note that three patients didn't perform the second test; therefore their data was excluded from analysis.

Notably, all patients experienced significant improvements of symptoms regardless of any increases in the number of the IgG antibodies – see Table 2 and Figure 2 below.

Likewise, patients in all six categories, regardless of the nature of their complaints, reported a significant reduction in both, chief complaint(s) severity and the severity of their other complaints and/or symptoms monitored throughout the study from baseline – see Table 2

Patients	Chief complaint severity score – initial	Chief complaint severity score – after 6-8 months	Rating of overall improvement from baseline (%)**	
	GUT ANI	DIGESTIVE DISORDERS		
1	9	1	90%	
2	8	0	95%	
3	9	0	100%	
4	10	4	60%	
5	9	2	80%	
6	7	1	50%	
		Category overall (average)	79%	
	S	KIN CONDITIONS		
7	8	2	80%	
8	8	1	70%	
9	9	0	100%	
10	10	1	95%	
11	10	0	90%	
		Category overall	87%	
WEIGHT LOSS				
12	8	1	75%	
13	8	2	70%	
14	10	0	90%	
15	6	0	95%	
		Category overall (average)	83%	
AUTOIMMUNE DISORDERS				
16	8	5	60%	
17	9	2	65%	
18	8	1	95%	
		Category overall (average)	73%	
HORMONE IMBALANCES				
19	8	2	80%	

Table 2 Comparison of the chief complaint(s) severity scores per category -Initial scores (before the intervention) and 6-8 months after the intervention

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20	8	3	60%
		Category overall	70%
OTHER (fatigue, sleep, inflammation)			
21	7	3	45%
22	10	3	80%
		Category overall (average)	63%

Severity scores explanation:

• Scale: 0 - 10

• 0 = complete resolution of chief complaint(s)

• 10 = severe complaint

\*\*Assessed and reported by each patient after 6-8 months on the elimination diet and after the second test (retest). Overall rating of improvement percentage reflects the <u>improvement of both the chief complaint and the</u> <u>other complaints/ symptoms listed initially and monitored during the study. See Figure 4 for illustration.</u>

All patients reported significant improvements in their chief health complaint(s) compared to baseline as illustrated in Figure 2.





As before, each line shows the movement of an individual patient. As can be seen, all the lines slope down, consistent with the statistical test results presented on page 9.

Severity scores explanation:

- Scale: 0 10
- 0 = complete resolution of chief complaint | 10 = severe symptoms



Data in Table 2 and Figure 2 shows the significant improvements in the chief complaint severity scores as reported by the patients before the initial test (baseline) and after the second test (retest). The differences seen between the two test results can be strongly presumed to be significant.

# Notably, 6 patients reported a complete resolution of severe chief complaint(s), i.e a score of 0, initially rated between 6-10.

Figure 2 also illustrates that patients with diverse range of symptoms such as gut and digestive disorders, blood sugar imbalances/ insulin resistance, excess weight, migraines, cognitive dysfunction, depression, menopause and PMS, eczema, psoriasis, urticaria and arthritis, among others; significantly improved or resolved their chief complaint(s) after eliminating the trigger foods identified by the IgG test.

This is an important finding that can be utilised in the clinical practice and for the overall patient management. It supports our rationale and the effectiveness of applying the IgG testing and the elimination diet based on the test results. There are a very few nutrition-based clinical tools, if any, that can be successfully utilised across a number of diverse health conditions and body systems.

In the majority of cases, the number of patients' IgG food sensitivities increased with increasing severity of their complaints and/or symptoms, and the length of time they experienced them i.e. high IgG antibody levels reflected an increased number and intensity of symptoms. Patients reported feeling better overall when their number of IgG antibodies/ food sensitivities were low(er), suggesting that food elimination based on the IgG test results was an effective approach in patient care.

It's important to state that we were not aiming to eliminate all food sensitivities. Some of them are always present and change as we alter diet and lifestyle throughout life. Our clinical goals were to reduce the number of IgG food sensitivities to a level where the complaints and/or symptoms were either resolved or decreased to the lowest level possible for each patient.

Improvements comparison between the chief complaint (s) and overall improvements from baseline – Table 3 and Figure 3

	Figu	Figure 3.2	
Patients	Chief complaint severity score – initial	Chief complaint severity score – after 6-8 months	Rating of overall improvement from baseline
1	9	1	1
2	8	0	1
3	9	0	0
4	10	4	4
5	9	2	2
6	7	1	5
7	8	2	2
8	8	1	3
9	9	0	0
10	10	1	1
11	10	0	1

Table 3



12	8	1	3
13	8	2	4
14	10	0	1
15	6	0	1
16	8	5	5
17	9	2	4
18	8	1	1
19	8	2	2
20	8	3	5
21	7	3	5
22	10	3	2

Severity scores explanation:

• Scale: 0 - 10

• 0 = complete resolution of chief complaint

• 10 = severe symptoms

### Figure 3.1

### Chief complaint severity score comparison – initial and after retest



Notes: 6 patients reported a complete resolution of severe chief complaint(s) i.e. a score of 0. 2 patients reported a complete resolution of both chief complaint and other complaints. Therefore, the differences seen between the two test results can be strongly presumed to be significant. This was confirmed by the statistical analysis – see page 9.





Rating of overall improvement from baseline



- 0 = complete resolution of chief complaint(s)
- 10 = severe symptoms

As stated above, 39% of participants experienced increased IgG antibody levels compared to the initial test. Throughout the study, we noticed that in around 50-60% of cases, usually in clients with chronic, long-term conditions, despite the symptoms improving dramatically or even resolving completely, the retests showed a similar or sometimes even greater number of both, foods intolerances and well as increased sensitivity levels. Our clinical experience and research suggest that the most likely reasons for the increase of IgG antibodies can be linked to:

- Patients not adhering to the elimination diet sufficiently enough and consuming trigger foods (even in small amounts) before the inflammation levels had subsided and the immune system became less reactive. Research into IgG testing suggests that even small exposure can result in an enhanced secondary antibody response i.e. a rapid increase in antibody levels [37,38]. The first antigenic exposure leads to a slow and modest immune response, whereas repeated exposure, even many years later, leads to a rapid and exaggerated response that is two to three orders of magnitude greater than the primary [37]. Therefore, if an individual is exposed to even small amounts of their trigger foods, then this can result in an excessive IgG antibody response.
- Retesting too early in the process assessing IgG levels too early may produce elevated results due to the insufficient time for the antibody levels to decrease naturally [38].



Leaky gut condition not improving sufficiently – continued issues with increased intestinal
permeability could be another explanation why certain individuals still have elevated IgG
antibodies to trigger foods after 6 months of avoiding them. An increase in permeability of the
gut wall ('leaky gut') results in a process allowing larger molecules that would normally stay in
the gut to cross into the bloodstream and in the induction of IgG-dependent food sensitivity
[16].

Notably, it is essential to understand that it is not the elevated IgG antibodies as such that cause inflammation triggered by food sensitivities, but the deposition of antibody-antigen immune complexes within tissues of the body [39]. These immune complexes are created when IgG antibodies combine with the food protein antigen(s) for which they were created. This is a natural process managed by the immune system to expel of what it perceives as invading pathogens.

However, when these immune complexes accumulate more quickly than they are removed, they then can lodge in tissues, causing inflammation and subsequent symptoms. It may potentially be the main reason why, despite patients' who had elevated IgG antibodies to foods from their initial tests, their symptoms significantly improved with their removal from the diet. This would lead to a subsequent reduction in the formation of immune complexes and decrease in inflammation levels.

In addition to the significant improvements of chief complaint(s) in all participants, their other symptoms listed initially along the chief complaint(s) either resolved or significantly decreased – see Figure 4. We monitored the improvements in all reported symptoms by asking all participants to self-assess their overall health improvements by estimating an overall percentage improvement from baseline. Refer to Table 2 for details.

Overall improvements of all complaints or symptoms - see Figure 4 below





Overall improvements rating of all complaints or symptoms (%)



Figure 4 illustrates the following findings:

- 1. 13 patients (59%) achieved at least 80% improvement in overall complaint(s) and/or symptoms
- 2. 20 patients (91%) achieved at least 60% improvement in the overall complaint(s) and/or symptoms

Data analysis across all patient categories is presented in Figure 5 (refer to data given in Table 2).





Average overall improvement from baseline per category (%)



Category data analysis: Percentage improvements of combined chief complaint(s) and other monitored symptoms compared to baseline:

- 1. Patients in all categories achieved at least 63% improvement from baseline
- 2. Patients in the skin category achieved the most significant improvements 87%. Notably, 40% of patients in this category achieved a complete resolution of symptoms
- 3. Very good results were achieved in the following categories:
  - a. Weight loss 83% improvements with 50% achieving a healthy weight
  - b. Gut and digestion 79% improvements with 33% achieving complete resolution of symptoms

### **Study limitations**

This was an observational study rather than a randomised clinical trial. It relates therefore to a particular study population and may not generalise to other contexts.

Confounding variables in the current study included:

- Some patients took either pharmaceutical drugs or natural supplements (many self-prescribed) to alleviate symptoms
- Socioeconomic challenges prevented some patients from obtaining different foods and sustaining themselves on the recommended dietary program



• The level of the patient's knowledge and interest about their condition, symptoms and nutrition may affected their compliance. To overcome this, the participants were regularly seen, coached and supported in all aspects of the implementation of the elimination diet, and provided with supplemental support, when deemed appropriate to optimise their health and results.

Further clinical studies with larger patient populations are warranted with a revised methodical approach to control for confounding factors and biases, where possible

### Conclusions

Despite the controversies surrounding IgG food sensitivity testing discussed above, more recent research and clinical studies suggest a link between IgG food sensitivities testing to identify possible food triggers, in order to develop personalised elimination diets for a wide variety of conditions and symptoms.

Our study demonstrated that patients' health and wellbeing markedly improved when their food sensitivities decreased as a result of following a tailored elimination diet, demonstrating that food removal based on the IgG test results could be an effective approach to patients' care. Patients who complied by avoiding foods in the elevated category (most patients removed all foods in the elevated and borderline categories) experienced significant improvements in their chief complaint(s) and other symptoms or complaints.

While traditional elimination diets are often utilised by practitioners, these are time consuming to implement and require patient's daily commitment and discipline to notice, record and self-monitor potential food triggers. This process often proves challenging for both patients and practitioners. Therefore, IgG testing should be considered as an efficient, timesaving and cost-effective alternative.

Overall, the study results support the validity of the IgG tests in identifying the severity of food sensitivities and its effectiveness as a tool in clinical therapy, including the resolution and/or management of symptoms related to food sensitivities in the six diverse health categories utilised in the study.

Given the plethora of treatments and various formulations (conventional and natural) to alleviate or resolve symptoms of bloating, abdominal pain, diarrhea, constipation, fatigue, migraines, headaches, depression, joint pain, eczema and urticaria, among others, the study has demonstrated a solid supportive data for considering the use of IgG food sensitivities tests in clinical interventions supporting patients with diverse symptoms and in lowering total inflammatory load.

As shown in our study, to make it effective, food sensitivity testing needs to be supported by working with patients on an individual basis and support them in implementation of the elimination diet. Therefore, future clinical studies are important to undertake although it may be challenging to conduct double-blind studies because of the individuality of such treatments.

Despite the efficacy of the IgG testing in showing the correlation between the magnitude of the IgG response and the reduction of symptoms after avoidance of the elevated foods, unanswered questions remain and need to be investigated further.



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