The Effects of Nutrition and Enzyme Therapy on Gastrointestinal Dysfunction

An Evidence-based Clinical Review from Transformation Enzyme Corporation

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ABSTRACT

Supplementation with digestive enzymes, probiotics, and herbal supplements along with dietary modifications has been used clinically for mitigating patient symptoms associated with gastrointestinal dysfunction. **Purpose:** To determine the effectiveness of a digestive wellness program as a therapeutic model for "leaky gut" symptoms. **Methods:** After baseline data and testing which included a symptom survey questionnaire, BOD POD® air-displacement plethysmography (ADP) body composition assessment, ELISA/ACT® Lymphocyte Response Assay (LRA), Cyrex™ Laboratories Intestinal Antigenic Permeability Screen, Genova Diagnostics (GDX) Lactulose / Mannitol Intestinal Permeability Assessment, Genova Diagnostics (GDX) GI Effects Comprehensive Stool Profile, and a comprehensive blood panel performed by Labcorp, participants were given a non-calorie restricted "Paleo" meal plan and enzyme supplement protocol of digestive enzymes, systemic proteases, probiotics, and an herbal support formula to follow for approximately 2 months. Data collection and testing was repeated at the end of the 2-month program. **Results:** The body composition test showed significant trends of weight loss (fat loss) and fat free mass gain. Participants cleared an average of 8.2 food reactions for a total average reduction of 42%. The intestinal permeability screen showed an overall 92% improvement. The stool analysis showed a strong trending toward a positive repopulation of predominant bacteria, and the markers of inflammation (lactoferrin) and immunology (fecal SigA) also showed positive trending. Based on the survey forms, all participants reported improvement of symptoms. **Conclusions:** Both the "leaky gut" symptoms and the underlying biological processes that cause those gastrointestinal symptoms improved within 63 day as a consequence of addressing diet and digestion through a nutrition and enzyme therapy program.

Key Words: DIGESTION, GASTROINTESTINAL DYSFUNCTION, LEAKY GUT, ENZYMES, NUTRITION

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"All Disease Begins in the Gut" – Hippocrates

INTRODUCTION

Diet and digestion are the foundation of wellness. Since 1990, Transformation Enzyme Corporation's (TEC) founder Dr. DicQie Fuller-Looney has shared her knowledge and experience with practitioners around the world. Transformation's approach is simple – when you correct the diet and support digestion, your patient's health will improve and he or she will feel better. This is where treatment of your patient begins.

TEC's goal for this study was to evaluate if a protocol of digestive enzymes, probiotics, and herbal supplements along with dietary modifications for a "leaky gut" could make a difference in patient outcomes and symptoms within 63 days.

To test this hypothesis, TEC partnered with Milton Bastidas, DC. Dr. Bastidas led the research team for this clinical study, and his clinic served as the primary study site.

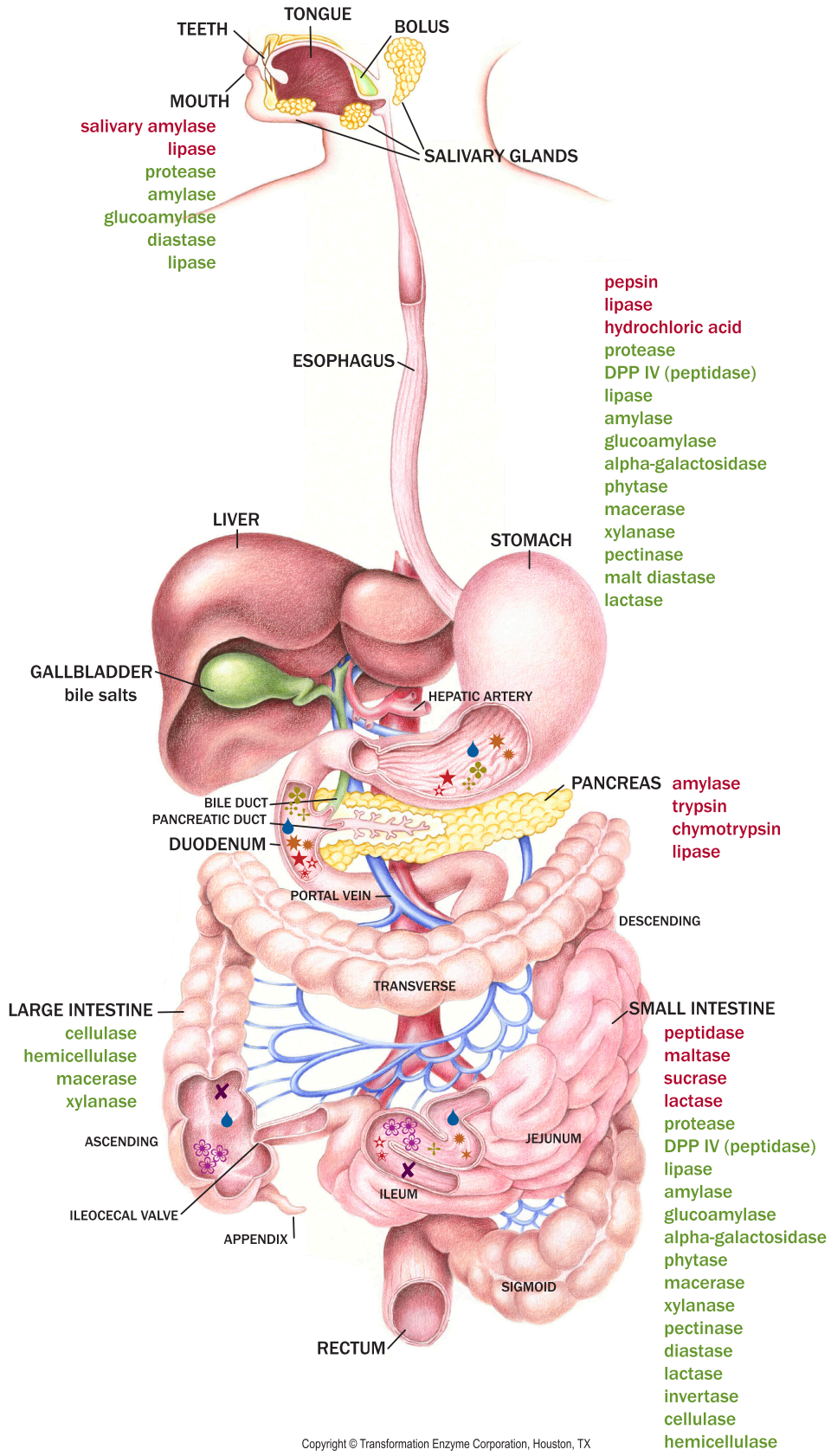
BACKGROUND

The health of every cell in the body depends on adequate nutrition. In order to supply adequate nutrients, foods must be selected in balanced proportions from whole food sources, they must be broken down into nutrients, the gastrointestinal lining must be permeable to these nutrients allowing them into circulation, and the immune system must be tolerant to these nutrients.

When these steps take place, the cell has what it needs to function optimally and the body is well. A properly functioning gut therefore involves four key elements: selection, digestion, absorption, and delivery.

1. Selection of foods is the first component of a healthy gut. The appropriate foods must be received in a recognizable form. Whole foods as close to their natural state as possible and free of chemicals, pesticides, and preservatives are preferred. Paleo-style eating removes sugars, grains, legumes, and dairy. Foods that are allowed include fruits, vegetables, nuts, seeds, healthy oils, and animal proteins. Choosing organic and non-GMO food sources is encouraged.

2. Digestion means the mechanical and chemical breakdown of food takes place completely, starting in the mouth with thorough mastication and continuing in the stomach and small intestines. Endogenous and supplemental enzymes support the complete breakdown of all carbohydrates, proteins, and fats. The following diagram is an illustration of the digestive system showing where the various enzymes come into play and what they are responsible for digesting. Proper diet and digestive support further minimize allergens, toxins, and irritation of the GI lining.



Digestive Organs

mouth (teeth, tongue and salivary glands)
esophagus
stomach
liver
gallbladder (bile duct)
pancreas
small intestine (duodenum, jejunum and ileum)
ileocecal valve
appendix
large intestine (ascending, transverse, descending and sigmoid)
rectum

Endogenous Enzymes

salivary amylase (mouth)
pepsin (stomach)
lipase (mouth, stomach and pancreas)
hydrochloric acid (stomach)
bile salts (gallbladder)
amylase, trypsin and chymotripsin (pancreas)
maltase, sucrase and lactase (small intestine)
peptidases (small intestine)

Transformation™ Enzymes

protease (mouth, stomach and small intestine)
DPP IV (peptidase) (stomach and small intestine)
lipase (mouth, stomach and small intestine)
amylase (mouth, stomach and small intestine)
glucoamylase (mouth, stomach and small intestine)
alpha-galactosidase (mouth, stomach and small intestine)
phytase (stomach and small intestine)
macerase (stomach, large and small intestine)
xylanase (stomach, large and small intestine)
pectinase (stomach and small intestine)
diastase (mouth, stomach and small intestine)
lactase (stomach and small intestine)
invertase (small intestine)
cellulase (large and small intestine)
hemicellulase (large and small intestine)

Food Nutrients

- starches
  - disaccharides (maltase, sucrose, and lactose)
  - monosaccharides (glucose, fructose and galactose)
- proteins
  - peptides
  - amino acids
- fats
  - fatty acids
  - glycerol
- water

Microflora

- probiotic (friendly)
- potentially pathogenic

3. Absorption via intestinal permeability allows nutrients in and keeps toxins, pathogens, and large food molecules out. The healthy villi of the small intestines supply brush border enzymes for continued digestion and the hormones zonulin and ocludin to regulate the tight junctions. Zonulin signals the opening of the tight junctions while ocludin keeps them closed. This regulation allows for appropriate intestinal permeability. Actomycin is the muscular base onto which the villi adhere.

4. Delivery involves an immune system tolerant to nutrients received and a circulatory system able to deliver nutrients to the cell.

GGastrointestinal dysfunction is a very broad term that can involve a breakdown in any or all of the steps listed above. It can be called leaky gut, inflammatory bowel disease, irritable bowel syndrome, Crohn's, celiac, colitis, food allergies or sensitivities, constipation, diarrhea, GERD, etc.

According to the NIH[1], 20 percent of the US population experiences gastroesophageal reflux symptoms at least weekly and 211 million experience some form of gastrointestinal infection, with 60 to 70 million people affected by specific digestive diseases, including:

- 63 million with chronic constipation
- 20 million with gallstones
- 15.3 million with irritable bowel syndrome
- 3.6 million ambulatory care visits for abdominal wall hernia
- 2.8 million prescriptions for diverticular disease
- 2.1 million prescriptions for ulcerative colitis
- 1.9 million ambulatory care visits for inflammatory bowel disease

These are conditions of the gastrointestinal tract, but the effect they have on the entire body is profound. Research has linked gastrointestinal dysfunction to auto-immune disorders, compromised immunity, chronic fatigue, respiratory challenges, and skin lesions just to name a few. In fact, the list of symptoms your patient may exhibit beyond gastrointestinal dysfunction is infinite.

METHODS

Participants were screened to include those who had experienced chronic symptoms of gastrointestinal dysfunction. Qualified participants included those who reported any or all of the following symptoms in the last 6 months to a year:

- Abdominal pain associated with gas, bloating, cramps, diarrhea, or constipation
- Respiratory congestion, asthma, or allergies

[1]http://www.niddk.nih.gov/health-information/health-statistics/Pages/digestive-diseases-statistics-for-the-united-states.aspx

- Skin issues such as eczema, psoriasis, or skin rashes
- Muscle / joint pain or headaches / migraine
- Frequent infections or poor immunity
- Excessive fatigue

A total of 14 participants were selected. 12 began the study, with 9 completing the full 63-day program. The following is a list of procedures used to measure the progress of the participants.

Symptom Survey Questionnaire

The Symptom Survey Questionnaire is a list of questions designed to obtain information on the patient's overall health. It starts by asking the patient to list their 5 major health concerns in order of importance. The next section is a set of symptoms that the patient rates on a scale of 0 – 3 (0 for never having experienced, 1 for occasional occurrence, 2 indicating often, and 3 for always). In this section, the questions are geared toward understanding the status of different body systems, emphasizing digestion and metabolic function. The last section of the questionnaire deals with the patient's daily practices and habits in order to obtain information on his or her lifestyle.

Body Composition Assessment

Body composition refers to the sum total of lean tissue and fat tissue in the body. Lean tissue is composed of muscle, bone, and organs. Fat tissue is composed of three different categories: essential fat, storage fat, and non-essential fat. Essential and storage fat are both necessary for the body to function, while non-essential fat is considered excessive fat. Results are expressed as percentage of body fat and percentage of lean body mass. The BOD POD® Body Composition Tracking equipment is an air-displacement plethysmography (ADP) system. COSMED USA, Inc., is the owner of Life Measurement, Inc. (LMI), the provider of the BOD POD®.

Food Sensitivity Assay

The Lymphocyte Response Assay (LRA) by ELISA/ACT®, developed by ELISA/ACT Biotechnologies LLC (EAB), allows the monitoring of delayed hypersensitivity responses to over 490 common substances in our diet and environment. These tests identify reactive substances that may be provoking the patient's chronic condition. The LRA is more specific than other forms of testing in that it checks for type II (reactive antibody IgA, IgM, and IgG), type III (Immune complex), and type IV (T cell mediated) delayed sensitivity reactions to a number of substances through a blood draw.

Intestinal Antigenic Screen

The Intestinal Antigenic Permeability Screen by Cyrex™ Laboratories, LLC, identifies antibodies against the intestinal lining proteins Zonulin, Occludin, and Actomyosin. These proteins are responsible for the integrity of the tight junctions within the small intestines. When antibodies to these proteins are found in

the blood, it indicates increased intestinal permeability. This screening also looks for lipopolysaccharides (LPS) expressed by pathogens. When LPS antibodies are present, it indicates a strong immune response to endo-toxins, which can have a negative impact on intestinal permeability.

Lactulose / Mannitol Intestinal Permeability Assessment

The Intestinal Permeability Assessment test by Genova Diagnostics (GDX) directly measures the ability of two non-metabolized sugar molecules to permeate the intestinal mucosa. The patient drinks a pre-measured amount of lactulose and mannitol. The degree of intestinal permeability or malabsorption is reflected in the levels of the two sugars recovered in a urine sample collected over the next 6 hours. Increased permeability is indicated by elevated lactulose in the urine as the large molecule makes it through the intestinal wall into the blood stream and is excreted in the urine. Malabsorption is indicated by decreased mannitol in the urine because it does not make it through the intestinal lining and therefore is not excreted in urine.

Stool Analysis

The GI Effects Comprehensive Stool Profile by Genova Diagnostics (GDX) is a stool test for managing gut health and gives further insight into gut flora by identifying 24 commensal bacteria targets using PCR technology. It identifies parasites using O&P technology and provides biomarkers indicating levels of digestive and absorptive functions as well as potential issues with gut inflammation and immunology.

Blood Panel

The comprehensive blood panel performed by Labcorp (Laboratory Corporation of America®) was utilized to check for markers of inflammation, glucose, Hgb A1C, vitamin D, thyroid function, complete metabolic profile, CBC with differential, lipid profile, iron, TIBC, ferritin, and urinalysis.

Protocol

Day 1-21: Participants began with the following supplement protocol from Transformation Enzyme Corporation:

- 3 capsules of *DigestZyme* and 1 capsule of *PureZyme* with every meal*
- 3 capsules of *GastroZyme* following every meal*
- 3 capsules of *PureZyme* and 3 capsules of *Plantadophilus* at bedtime*

In addition to supplementation, participants were provided a booklet containing:

- Overview and explanation of "Leaky Gut"
- Detailed food list of acceptable foods

- 14-day menu to be rotated through 63 days
- Recipes
- 63-day journal

They were instructed to either use the meal plan as a guide or follow it exactly and record all meals that were consumed. Participants were also asked to document the supplements taken.

Weekly Follow-Up Survey

A clinic staff member made weekly phone calls to each participant with the exception of weeks 3, 6, and 9 when participants came into office for consultation. The following questions were asked:

- What day in your food journal are you on?
- Are you more or less comfortable in your gut during the day and/or at bedtime?
- Have your bowel movements increased, decreased, or stayed the same?
- Has your sleep pattern changed? Are you sleeping more or less?
- How is your energy throughout the day?
- Are you having difficulty with the diet? Any challenges?
- Are you having difficulty with the protocol?
- Overall, what changes in your health are you experiencing?

21-Day Consultation

Participants consulted with Dr. Bastidas in 21-day increments for a total of 4 consultations (i.e., the initial appointment plus 3 follow-up consultations). This made the program last a total of 63 days. During this consultation process, protocols were modified according to symptoms and patient feedback. If the patient was progressing well with a reduction in symptoms, they began a more therapeutic protocol consisting of the following Transformation Professional Protocol™ (TPP) formulas:

- 1 capsule of *TPP Digest* and 1 capsule of *TPP Protease* with meals*
- 1 capsule of *TPP Gastro* following meals*
- 2 capsules of *TPP Protease* and 1 capsule of *TPP Probiotic 42.5* at bedtime*

RESULTS

Weekly Follow-Up Survey

Participants reported the following observations in their weekly follow-up surveys via phone or email:

- ✓ With the initiation of diet change and enzyme protocol, there was more constipation reported in the beginning (this improved for most as the study progressed)
- ✓ Far less bloating and more comfortable at bedtime
- ✓ Better sleeping
- ✓ Improved energy
- ✓ Occasional signs and symptoms of detoxification, i.e., night sweats, bad breath, low energy, etc
- ✓ Regarding challenges with diet:
    - For those who do not eat vegetables, it was a challenge
    - Had to get used to planning and preparing / frequent shopping
    - Cooking was fun / cooking was hard
    - Giving up coffee was the hardest for most
    - Cravings lessened
    - Food was expensive
- ✓ Regarding the supplement protocol
    - It was easy / not a problem
    - Difficult to remember with busy schedule / travel
    - Forgot bedtime supplements

The most frequently asked questions included the following:

1. Can I eat a certain food?

   Answer – Is this a processed food? Take a look at the label and read the ingredients? Is this a "whole food in its most natural state"? (The replies were usually "no.")

2. When should I take a certain supplement? How many?

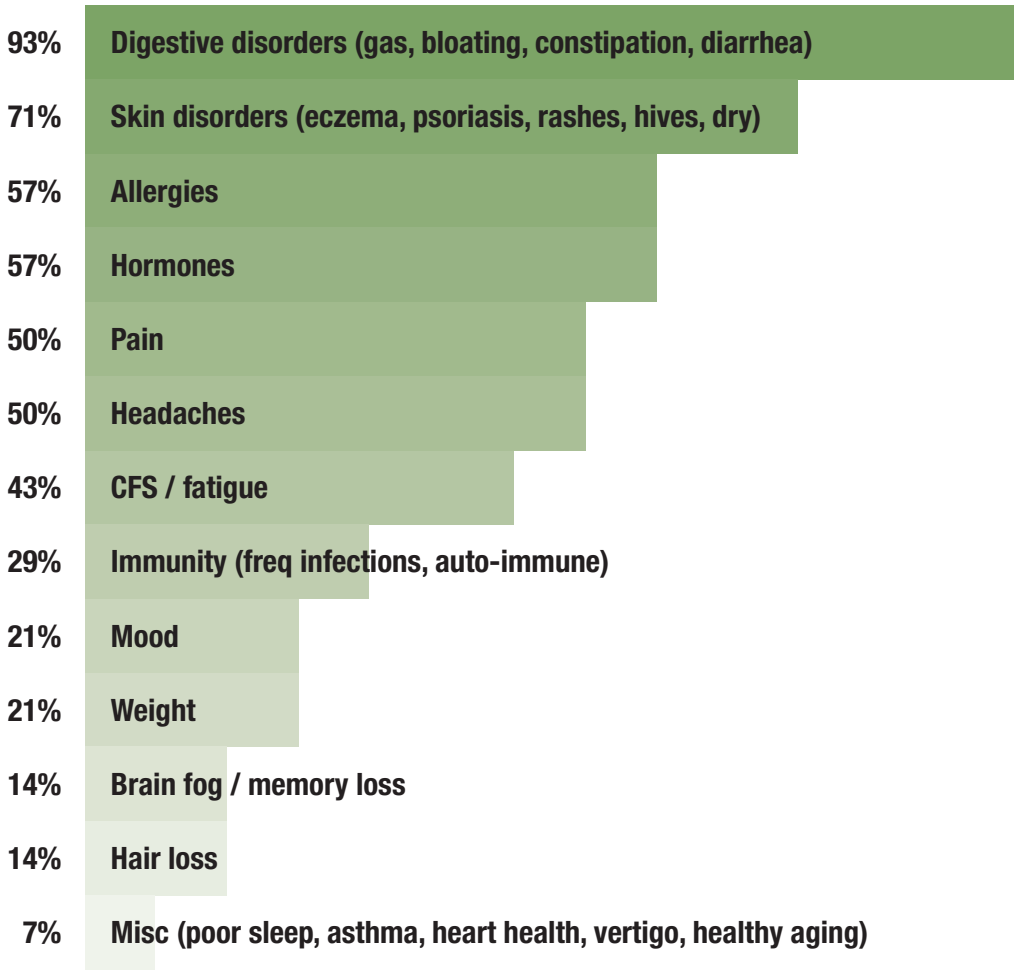
   Answer – review of the protocol and revised meal plan and journal template for clarification.

3. Why am I experiencing a certain symptom? (predominantly change in BM or typical signs and symptoms of detoxification)

Answer – As you change your diet and support the digestive process, your liver, gall bladder. and GI tract no longer have to work as hard. This is an adjustment phase and can be experienced as constipation. It will re-balance in a week or two. Firstly, maintain adequate fluid and fiber (i.e., vegetable) intake. Secondly, as you are cleaning up the diet, your body may begin to release toxins stored in tissues and fat cells. The only way to remove these toxins is via the lymphatic and blood streams for filtration by the detoxifying organs. This too should last only a short time.

Symptom Survey Questionnaire

The questionnaire asked for the top 5 health concerns in order of predominance. The following is an overview of the health priorities of the group. Given the nature of this trial and our target audience, it is not surprising that digestive concerns made the top of this list, followed by skin disorders, allergies, hormone imbalances, and pain/inflammation. This clearly illustrates that when gut dysfunction is a common denominator, any number of systemic imbalances may occur.



The following charts give an overview of the improvements in symptoms based on the survey done at the beginning of the trial compared to the survey completed on day 63 at the end of the trial. ***All participants reported some improvement in symptoms.***

Total Symptoms

	# symptoms	# improved	% improved
DK	102	96	94%
AV	71	62	87%
KP	107	93	87%
PB	20	17	85%
JD	73	49	67%
CV	101	53	52%
DM	74	38	51%
RL	132	41	31%
CP	73	11	15%

Symptoms rated 3 - always

	# symptoms	# improved	% improved
AV	15	15	100%
DK	37	34	92%
JD	10	9	90%
PB	7	6	86%
KP	51	43	84%
DM	14	10	71%
CV	28	14	50%
RL	8	4	50%
CP	44	10	23%

Symptoms rated 2 - often

	# symptoms	# improved	% improved
PB	5	5	100%
DK	51	49	96%
AV	24	23	96%
KP	24	21	88%
JD	29	24	83%
RL	40	28	70%
DM	26	16	62%
CV	36	19	53%
CP	20	1	5%

Body Composition Assessment

Body composition was obtained at the beginning of the study and at the end. The participants were asked to continue their current level of activity/exercise. They were given a meal plan and food list to follow but were not given a calorie restriction.

Overall, 8 out of 9 participants lost weight with an average weight loss of approximately 7 pounds. Notably, the 1 participant with weight gain was desiring a weight gain. Additionally, 6 of 9 participants showed a decrease in % fat and an increase in % fat free mass. This indicates a positive correlation between improved nutrient intake and absorption for a healthy body composition.

% Fat

	before	after	difference
CP	50.3	45.5	-4.8
DM	45.4	41.2	-4.2
JD	27.7	23.6	-4.1
KP	25.2	21.8	-3.4
AV	24.5	22.4	-2.1
CV	34.4	33.5	-0.9
PB	33.3	34.6	1.3
RL	25.4	28.4	3.0
DK	44.7	48.2	3.5

% Fat-Free Mass

	before	after	difference
DK	55.3	51.8	-3.5
RL	74.6	71.6	-3.0
PB	66.7	65.4	-1.3
CV	65.6	66.5	0.9
AV	75.5	77.6	2.1
KP	74.8	78.2	3.4
JD	72.3	76.4	4.1
DM	54.6	58.8	4.2
CP	49.7	54.5	4.8

Body Mass (lb)

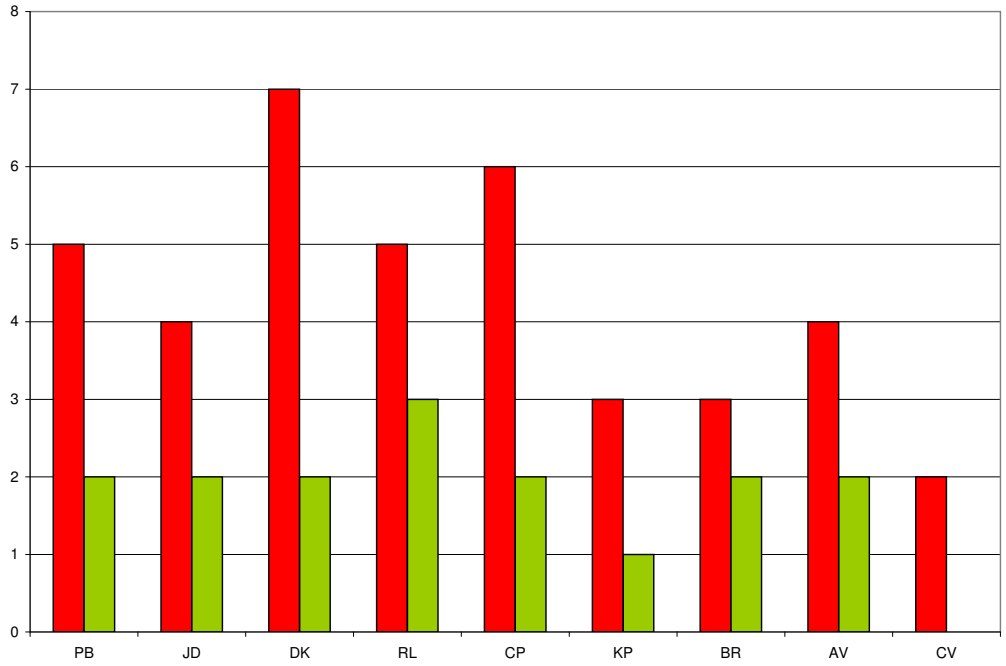
	before	after	difference
CP	205.617	185.336	-20.281
RL	204.000	186.000	-18.000
DK	260.000	252.809	-7.191
KP	124.429	118.431	-5.998
CV	161.546	155.825	-5.721
DM	199.658	195.990	-3.668
AV	171.497	168.370	-3.127
PB	142.851	141.921	-0.930
JD	135.459	136.698	1.239

Food Sensitivity Assay

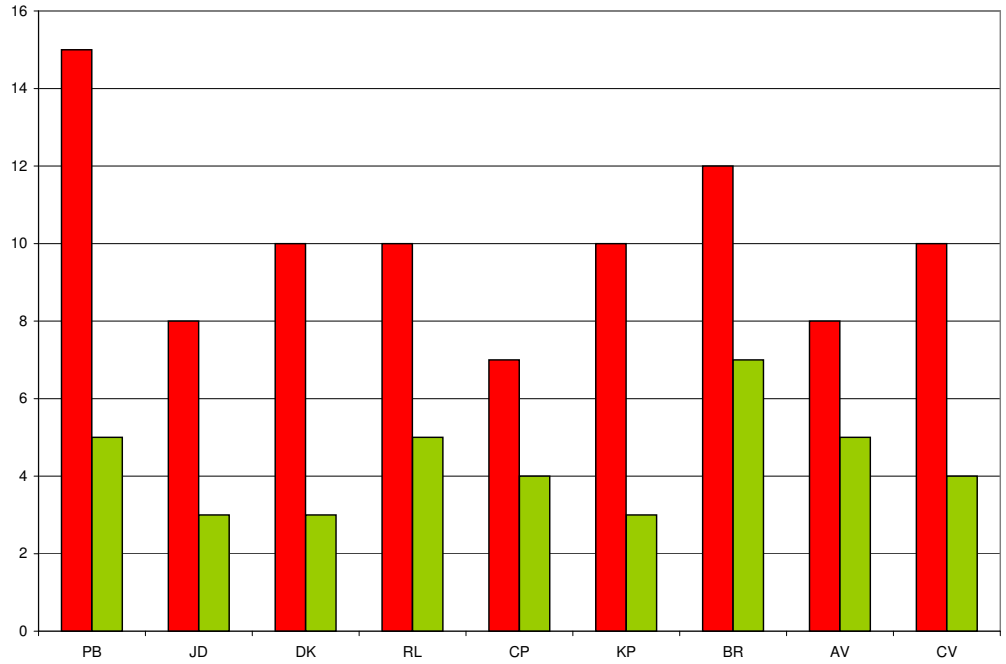
Many hypersensitive delayed allergy reactions are caused by specific components in food, poorly digested food presenting as non-food, and/or chemicals that enter the blood. Gut dysfunction and immune dysfunction illnesses include chronic nasal congestion, asthma, migraine headache, pain syndromes, weight management, personality changes, unexplained depression, thought disorders, and metabolically-based mood disorders. Identifying the reactants that cause these symptoms is not an easy task.

The following graphs illustrate the reduction of strong and moderate food reactions of each participant. The group as a whole had an average of 4.3 strong reactants and 10.0 moderate reactants at the onset of the study. At the end of the study, each participant had cleared an average of 8.2 foods for a total reduction of 41% and 43%, respectively. This indicates an overall decrease in food sensitivities in as little as 2 months as a result of the diet plan, avoidance of specific foods, and the enzyme protocol. This is significant because it usually takes 6 months to clear the food reactants with diet alone.

Number of Foods "Strongly" Reacted to (before / after)



Number of Foods "Moderately" Reacted to (before / after)



Cyrex® Antigen Test

Results from the Intestinal Antigenic Permeability Screen are reported as in range, equivocal, or out of range. An equivocal result represents the range between negative and suspicious low positive results.

In considering the participants who completed before and after testing, 7 of 7 out-of-range values (shown in red) showed improvement. Additionally, 4 of 5 equivocal values (shown in blue) showed improvement. ***This represents an overall 92% improvement for this intestinal permeability screen.***

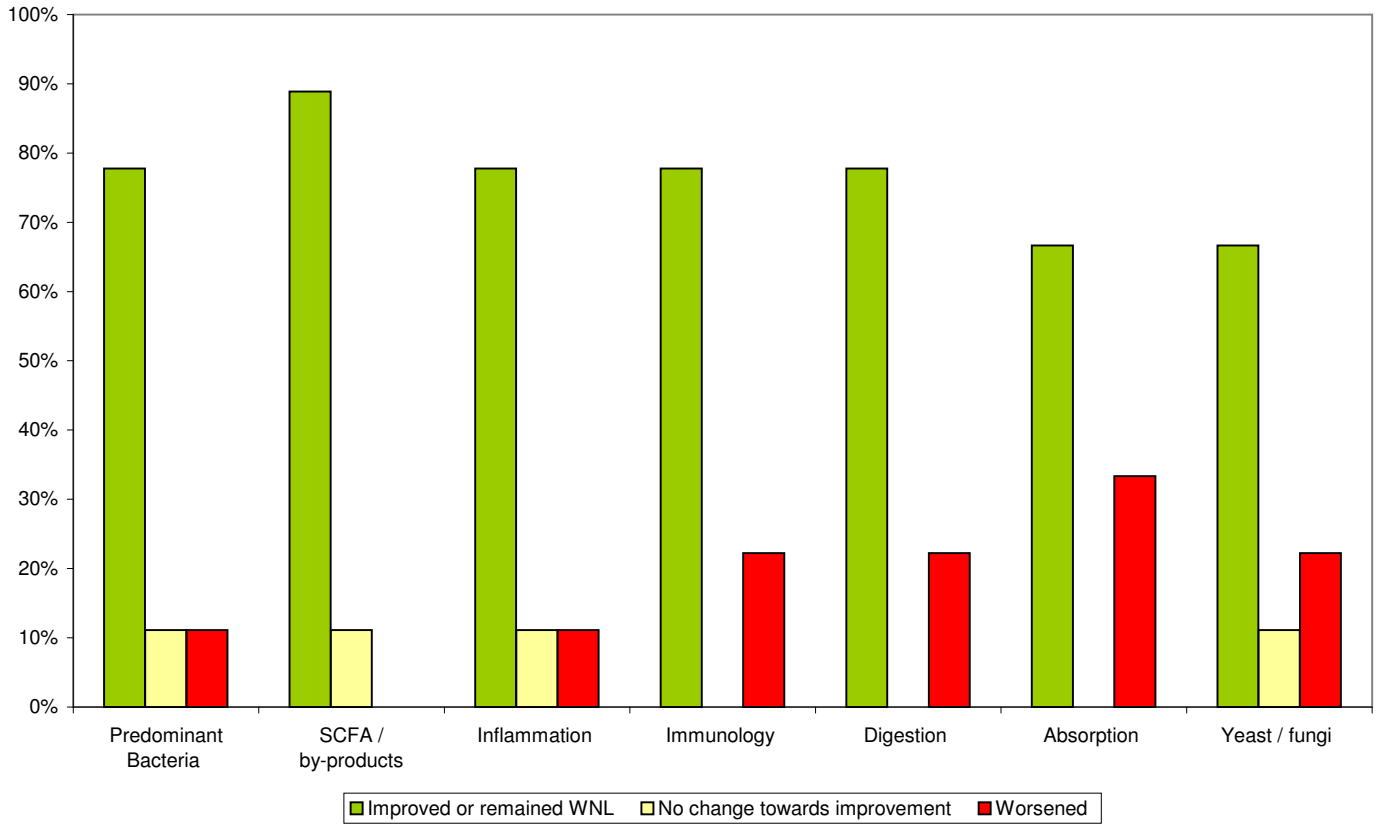
		CV		JD		AV		CP		PB		DK	
	ref. range	before	after	before	after	before	after	before	after	before	after	before	after
Actomyosin IgA	0.0 - 20	9.52	10.52	4.73	8.28	21.20	17.49	7.23	11.24	11.85	10.85	9.56	14.35
Occludin/Zonulin IgG	0.2 - 1.5	1.52	1.51	1.18	0.47	0.64	0.59	1.04	0.76	0.94	0.91	0.58	0.35
Occludin/Zonulin IgA	0.1 - 1.8	0.82	0.41	1.06	0.60	1.50	0.56	0.98	0.52	2.01	0.74	1.06	0.45
Occludin/Zonulin IgM	0.1 - 2.1	1.09	1.22	1.68	0.92	2.58	2.17	2.68	2.04	2.98	2.57	0.90	0.36
Lipopolysaccharides (LPS) IgG	0.1 - 1.6	1.10	1.41	0.76	0.89	0.90	0.67	0.74	0.70	0.65	1.00	1.97	1.67
Lipopolysaccharides (LPS) IgA	0.1 - 1.8	0.76	1.15	1.33	1.99	0.59	0.81	0.76	0.63	1.03	1.04	1.08	1.13
Lipopolysaccharides (LPS) IgM	0.1 - 2.0	0.89	0.85	0.56	0.78	0.76	0.64	1.45	1.36	2.81	2.70	1.09	0.84

Lactulose/Mannitol Intestinal Permeability Assessment

The results of the test were inconclusive.

Stool Analysis

The analysis of the before and after GI effects stool profiles was a bit more challenging due to the fact Genova Diagnostics revised their procedures midway through our trial. The parameters and values we obtained in our baseline stool samples did not match those at the end of the trial. Therefore, a general comparison has been done to show overall trending results in the categories assessed.



A total of 9 participants completed before and after stool tests. The stool analysis shows a strong trending toward a positive repopulation of predominant bacteria following the 9-week protocol. As the microbiome improves, so will the metabolism of SCFA (short chain fatty acids) as seen in the graph above. The markers of inflammation (lactoferrin) and immunology (fecal SigA) also showed positive trending in the majority of participants. In looking at digestion and absorption, most participants experienced improvement, but a few appeared to have difficulty with the high-fat, paleo-style meal plan as indicated by higher than normal levels of fat, triglycerides, and cholesterol detected in the stool. Lastly, no parasites were identified in any of the stool samples, and 3 samples revealed ongoing yeast imbalances.

Blood Panel

The overall results for the comprehensive blood panel were unique to each individual. We did not see any significant trends in the parameters of this study, therefore the data was inconclusive. Further research on nutrients that have reached a sub-clinical level may be able to demonstrate how specific supplementation can help bring such levels back to healthy range. Specific notations have been made in the case study, available upon request.

CONCLUSION

The goal for this study was to determine whether a protocol of digestive enzymes, probiotics, and herbal supplements along with dietary modifications for a "leaky gut" could make a difference in patient outcomes and symptoms within 63 days.

By comparing the test results before and after introduction of the program, we found that both the symptoms and the underlying biological processes that cause those symptoms improved as a consequence of addressing diet and digestion.

This clinical trial therefore demonstrates that Transformation's program can successfully be used as a therapeutic model for mitigating patient symptoms associated with gastrointestinal dysfunction.*

Symptoms	Improved
Body Composition	Improved
Food Sensitivities	Improved
Antigen Testing	Improved
Stool Analysis	Improved
Lactulose/Mannitol	Inconclusive
Blood panel	n/a

While multiple methods of assessing the health of the gut were utilized, it is not suggested that all tests are required. The various tests were chosen to provide different perspectives on each participant and to speak to a broad audience of practitioners who utilize a variety of testing methods to assess their patients. However, regardless of the test method or level of dysfunction involved, the majority of participants clearly experienced improved results.

The symptom survey results were key findings of this study. Regardless of the results of lab tests, a patient must feel better in order to continue with the program. Based on the survey forms, all participants reported improvement of symptoms.

For optimal compliance, most treatment protocols should therefore begin with Transformation's complete program of diet and enzyme therapy for at least the first 2 months.* After this initial protocol, the patient can continue on a maintenance protocol of digestive enzymes, systemic proteases, and probiotics.* Additional support formulas can be included with the ongoing protocol as needed based on lingering symptoms.*

Addendum:

CASE STUDY

The following is a detailed review of one of the participants in this study.

45 year old female, 5'11", 135 lbs, fitness instructor / nutritional therapist, single, no children; complaining of excessive hair loss, low energy, digestive problems, and hormonal imbalance; interested in fat loss / increased muscle mass. The participant's baseline data and testing was completed. She was then given a non-calorie restricted "Paleo" meal plan and enzyme supplement protocol to follow for approximately 2 months. Data collection and testing was repeated at the end of the 2-month program.

The participant's initial **Symptom Questionnaire** revealed the most notable symptoms to be depression / lack of motivation; abdominal intolerance to sugars and starches; craving sweets during the day; alteration in bowel regularity; excessive belching, burping, or bloating; lower bowel gas and/or bloating several hours after eating; hormonal imbalances; thinning of hair on scalp, face, or genitals, or excessive hair loss; diminished sex drive; and outer third of eyebrows thinning. These were all rated by the participant as level 3 on a scale of 0 to 3, meaning severe.

Of these 10 severe symptoms, 9 had improved by the end of the study for a 90% improvement in the worst symptoms. According to the final Symptom Questionnaire, the following key symptoms, initially reported as constant and severe, were now ranked at level 0 or level 1, indicating rarely experienced:

- Depression/lack of motivation
- Abdominal intolerance to sugars and starches
- Crave sweets during the day
- Alteration in bowel regularity

The participant also reported 29 level 2 (moderate) symptoms. By the end of the study, 24 of these had improved for an 83% improvement in that category. These symptoms which received lower rankings (level 0 or level 1) in the follow-up survey included the following:

- Difficulty digesting fruits and vegetables
- Stool undigested, foul smelling, mucous-like, greasy, or poorly formed
- Unexplained itchy skin
- Weight gain
- Poor bowel function
- Eating sweets does not relieve cravings for sugar
- Cannot fall asleep
- Poor muscle endurance
- Alternating constipation and diarrhea
- Gas immediately following a meal

- Sense of fullness during and after meals
- Dry or flaky skin and/or hair
- Overall sense of bloating
- Agitated, easily upset, nervous
- Under high amount of stress
- Tired, sluggish
- Require excessive amounts of sleep to function properly
- Mental sluggishness
- Increased ability to eat sugars without symptoms
- Acne
- Facial hair growth

The total number of symptoms initially reported (whether mild, moderate, or severe) was 73, of which 49 of these had improved for a 67% overall improvement in symptomology.

The participant was given a **comprehensive GI effects stool analysis kit** provided by Genova Diagnostics (GDX) which evaluates targeted biomarkers to assess gut function. The test gives insight into gut flora by identifying 24 Commensal Bacteria targets using PCR technology, identifies pathogenic bacteria and yeast/fungi, identifies parasites using O&P technology, and gives biomarkers indicating levels of digestive and absorptive functions as well as potential issues with gut inflammation and immunology.

The participant's initial stool collection showed intestinal flora mostly within the 1st and 2nd quintile. The final stool collection showed intestinal flora mostly within the 3rd and 4th quintile. This demonstrates a positive shift of predominant gut flora to the healthy ranges.

As the gut flora improves, so does the short chain fatty acids (SCFA) produced by them, which is a product from bacterial fermentation of dietary polysaccharides and fiber. N-butyrate is one of the SCFAs produced, taken up, and used to sustain normal activity of colonic epithelial cells and has also been shown to lower risk of colitis and colorectal cancer. A healthy balance of GI microbes depends on production of SCFAs by one species to allow the normal growth of another one in a complex cross-feeding network. This participant's total SCFA numbers also made a positive shift from 36 mM/g to 46 mM/g. This improvement demonstrates how when more beneficial bacteria are present, more SCFAs are produced.

The participant also exhibited moderate Trophozoites (Dientamoeba fragilis and Endolimax nana) on initial testing, which did not show up on the second test after the prescription of an anti-parasitic drug. It should be noted that even though the second test did not show infection with parasites, the test is not 100% accurate for sensitivity or specificity, meaning a possible infection is still possible and therefore other markers should be used in context of the participant's clinical presentation.

The digestion markers in the stool shown by levels of Elastase 1, Triglycerides, Putrefactive SCFA, and vegetable fibers also demonstrated a shift to improvement. Elastase 1 stayed constant from 249 ug/g at baseline to 228 ug/g upon final testing, demonstrating sufficient pancreatic function as long as it remains

above 100 ug/g. Triglycerides found in the stool moved from 131 mg/dL (high) to 113 mg/dL (normal is less than 181 mg/dL), signifying that fats were being digested more efficiently. Putrefactive SCFA's moved from 2.5 mM/g to 4.1 mM/g, showing a slight increase although remaining within normal limits (it should be less than 7.4 mM/g). Presence of vegetable fibers in the stool should be none / few, and anything above also represents mal-digestion. The participant went from moderate levels to rare levels upon second test, which indicates an improvement in digestion.

Absorption markers were also reported in this test as Long Chain Fatty Acids (LCFAs), Total Fat, and Cholesterol. High levels of Total Fat and/or Cholesterol in the stool indicate mal-absorption, whereas high LCFAs indicate either fat mal-absorption due to pancreatic or biliary insufficiency or acute bacterial infection that produces intestinal cell wall destruction. The participant's LCFAs improved from 17.2 mmol/L to 10.6 mmol/L (optimal levels are below 9.1 mmol/L). The Total Fat also improved from 21.1 mmol/L to 14.1 mmol/L (optimal levels are below 12.9 mmol/L). Cholesterol remained within normal limits. All markers therefore showed a shift towards improvement absorption, which correlates with the participant's improved clinical presentation and symptomatology.

As the stool test gave markers related to gut function, another test performed in our study was the Cyrex™ Labs **Intestinal Antigenic Permeability Screen** (array 2), which tests for antibodies against Actomyosin, Occludin / Zonulin, and Lipopolysaccharides (LPS). These tight junction proteins (Actomyosin and Occludin / Zonulin) and endotoxins expressed on the cell membranes of pathogens (LPS) give information on the integrity of our gut barrier. When antibodies are present, it represents a leaky gut through the intestinal cells or between the intestinal cells.

The majority of the antibodies to intestinal junction proteins all normalized as follows: Actomyosin IgA remained within normal limits from 4.73 to 8.28 (ref range 0.0-20); Occludin / Zonulin IgG decreased from 1.18 (equivocal) to 0.47 (ref range 0.2-1.5); Occludin / Zonulin IgA remained in range at 1.06 to 0.60 (ref range 0.1-1.8); IgM decreased from 1.68 (equivocal) to 0.92 (ref range 0.1-2.1); LPS IgG remained in range at 0.76 to 0.89 (ref range 0.1-1.6); and LPS IgM remained in range from 0.56 to 0.78 (ref range 0.1-2.0). In fact, the participant's array 2 showed improvement in all but one antibody: IgA for LPS went from 1.33 (equivocal) to 1.99 (out of range) (ref range 0.1-1.8) which signifies a present LPS immune reaction affecting the intestinal integrity and correlates with the stool test finding of a parasitic infection.

The participant was given a **Lymphocyte Response Assay** by ELISA/ACT®, which checks for delayed type- II, III, and IV immune hypersensitivity reactions to 315 substances from foods, molds, preservatives, additives, and toxic minerals / metals. Upon initial testing, strong reactive items were coffee, benzaldehyde, mango, and dieldrin. The moderate reactive items were corn, haddock, D&C red #33, squash, maple sugar, cranberry, corn sugar food group, FD&C red #2, and 1,2 dichlorobenzene.

The final test showed the strong reactive items to be only FD&C red #2 and dieldrin. The moderate reactive items only showed squash, cranberry, and mango. The items that no longer reacted upon second testing were coffee, benzaldehyde, corn, haddock, D&C red #33, maple sugar, and 1,2 dichlorobenzene. These findings show a definite improvement in tolerance of the immune system to environmental antigens as we lessened the toxic load in the digestive tract through our enzyme protocol.

The participant was also given a **comprehensive blood panel** through Labcorp to note any changes

in blood markers. The most notable changes were: cholesterol from 223 to 190 (ref range 150-199), triglycerides from 51 to 45 (ref range 75-100), LDL from 134 to 114 (ref range less than 100), serum iron from 192 to 113 (ref range 85-130), iron saturation from 57% to 39% (ref range 15%-55%), Hgb from 13.2 to 12.4 (ref range 13.5-14.5), WBC's from 4.3 to 4.6 (ref range 5-8), monocytes from 11 to 9 (ref range less than 7), eosinophils from 4 to 5 (ref range less than 3), free T3 from 2.9 to 3.3 (ref range 3-4), vitamin D 25(OH) from 33.4 to 24.7 (ref range 50-100), BUN from 20 to 14 (ref range 13-18), and BUN/creatinine ratio from 24 to 19 (ref range 10-20). With the exception of Hgb and vitamin D, these results show improved absorption and utilization of nutrients and support to the liver and kidneys.

The participant was given a **body composition analysis** through a mobile BOD POD® that uses Whole Body Air Displacement Plethysmography (ADP). Body composition refers to the sum total of lean tissue and fat tissue in the body. Lean tissue is composed of muscle, bone, and organs. Fat tissue is composed of essential fat, storage fat, and non-essential fat. Essential and storage fat are both necessary for the body to function, while non-essential fat is considered excessive fat. Results are expressed as percentage of body fat and percentage of lean body mass.

The participant's percentage of fat decreased from 27.7% to 23.6% and the percentage of fat-free mass increased from 72.3% to 76.4%. Actual fat mass dropped from 37.5 lbs to 32.2 lbs, while actual fat free mass increased from 98 lbs to 104 lbs. The participant's body mass showed a desired weight gain of 135.4 lbs to 136.7 lbs. As evidenced by these findings, the participant successfully gained muscle mass and lost fat mass, thereby improving overall body composition.

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