

Effectiveness of a Tailored Dietary Program in Subjects With Fibromyalgia

Jan Patenaude¹, Gustavo Zarini², Michael McLean², and Susan Linke³

¹Food Sensitivity Solutions, LLC; ²Oxford Biomedical Technologies, Inc.; and ³Food Sensitivity Specialists LLC

Objectives: We examined the effects of the Lifestyle Eating and Performance (LEAP) program to alleviate fibromyalgia-related symptoms.

Methods: The retrospective study included de-identified data of 33 subjects with fibromyalgia. Dietitians used the in-vitro Leukocyte Activation Assay-MRT (LAA-MRT) blood test results to develop the tailored LEAP program for each subject. The LAA-MRT measures white blood cells reactivity to scale the degree of an adverse immune response to 150 food and food-chemical antigens. The LEAP program is based on the principles of the oligoantigenic dietary approach which is built in a nutritionally balanced manner and takes into consideration the subject's eating habits. Body Mass Index (BMI) was calculated as weight in kg/height in m². A symptom survey was used to evaluate the severity and frequency of 13 domains of symptoms associated with fibromyalgia. The survey was quantified on a scale of 0 - 4 with a range score from 0 to 248 points. Descriptive statistics and linear mixed models were performed using SPSS version 25. The study

received approval from an independent Institutional Review Board (IRB).

Results: Subjects' age was 47.7 ± 12.4 years, BMI of 27.9 ± 3.8 kg/m², and 29 (88%) were female. The follow-up time seen by the dietitian was 76.0 ± 60.7 days. Linear mixed models indicated a significant reduction in overall mean (standard error) scores of fibromyalgia symptoms pre- versus post-intervention (98.3 ± 5.7 vs. 54.2 ± 6.3 , $P < 0.001$) and for each of the 13 domains [constitutional (12.9 ± 0.8 vs. 7.0 ± 0.8 , $P < 0.001$); emotional/mental (12.9 ± 1.0 vs. 7.5 ± 1.0 , $P = 0.001$); head/ears (6.7 ± 0.8 vs. 4.3 ± 0.6 , $P = 0.018$); skin (3.5 ± 0.6 vs. 1.9 ± 0.3 , $P = 0.030$); nasal/sinus (9.3 ± 0.7 vs. 5.6 ± 0.8 , $P = 0.002$); mouth/throat (4.7 ± 0.7 vs. 2.2 ± 0.3 , $P = 0.004$); lungs (3.4 ± 0.7 vs. 1.5 ± 0.4 , $P = 0.026$); eyes (6.2 ± 0.6 vs. 3.9 ± 0.6 , $P = 0.009$); genitourinary (2.2 ± 0.3 vs. 1.1 ± 0.2 , $P = 0.017$); musculoskeletal (12.5 ± 0.7 vs. 8.1 ± 1.0 , $P = 0.001$); cardiovascular (1.7 ± 0.3 vs. 0.9 ± 0.2 , $P = 0.046$); digestive (15.3 ± 1.2 vs. 7.6 ± 1.2 , $P < 0.001$); and weight management (6.8 ± 0.7 vs. 2.4 ± 0.5 , $P < 0.001$)].

Conclusions: This study showed the beneficial improvements in fibromyalgia symptoms by the LEAP program and the potential as a tailored dietary option in the clinical management of fibromyalgia.

Funding Sources: Oxford Biomedical Technologies, Inc.

BACKGROUND

- Fibromyalgia is a complex and chronic disabling condition of undetermined etiology and pathophysiology.
- The condition is described by generalized pain, sleep disturbance, cognitive impairment, fatigue, headache, and gastrointestinal symptoms.
- Diet plays a critical role in the clinical course of fibromyalgia and overall quality of life.
- Individuals with fibromyalgia reported aggravation of symptoms following the intake of certain foods and chemical additives.
- Currently, nutritional interventions have not provided robust evidence for the treatment of fibromyalgia.
- Additionally, existing studies have not explored the role of tailored dietary interventions to manage fibromyalgia.
- Tailored interventions offer new perspectives that could improve the condition symptomatology.

OBJECTIVE

- We examined the effects of the Lifestyle Eating and Performance (LEAP) program to alleviate fibromyalgia-related symptoms.

METHODS

- The retrospective study included de-identified data of 33 subjects with fibromyalgia.
- Dietitians used the in-vitro Leukocyte Activation Assay-MRT (LAA-MRT) blood results to develop the tailored LEAP program for each subject.

METHODS (cont'd)

- The LEAP program is based on the principles of the oligoantigenic approach built in a nutritionally balanced manner considering the subject's eating habits. Body Mass Index (BMI) was calculated as weight in kg/height in m².
- A symptom survey was used to evaluate the severity and frequency of 13 domains of symptoms associated with fibromyalgia.
- The survey was quantified on a scale of 0 - 4 with a range score from 0 to 248 points.
- Descriptive statistics and linear mixed models were performed using SPSS version 25.
- The study received approval from an independent Institutional Review Board (IRB).

RESULTS

- Subjects' age was 47.7±12.4 years, BMI 27.9±3.8, and 29 (88%) were female. The follow-up time seen by the dietitian was 76.0±60.7 days (Table 1).
- Linear mixed models indicated a significant reduction in overall mean (SE) scores of fibromyalgia symptoms pre- versus post-intervention (98.3±5.7 vs. 54.2±6.3, P<0.001) and each of the 13 domains (Table 2).

Table 1. Baseline Characteristics	N=33 M±SD
Age (years)	47.7±12.4
Gender (F) n (%)	29 (88%)
BMI (kg/m ²)	27.9±3.8
Time follow-up (days)	76.0±60.7

Table 2. Measures Pre- and Post-Dietary Intervention

Symptom Survey Score	Pre-LEAP program M±SE	Post-LEAP program M±SE	P-value
Constitutional	12.9±0.8	7.0±0.8	<0.001
Emotional/mental	12.9±1.0	7.5±1.0	0.001
Head/ears	6.7±0.8	4.3±0.6	0.018
Skin	3.5±0.6	1.9±0.3	0.030
Nasal/sinus	9.3±0.7	5.6±0.8	0.002
Mouth/throat	4.7±0.7	2.2±0.3	0.004
Lungs	3.4±0.7	1.5±0.4	0.026
Eyes	6.2±0.6	3.9±0.6	0.009
Genitourinary	2.2±0.3	1.1±0.2	0.017
Musculoskeletal	12.5±0.7	8.1±1.0	0.001
Cardiovascular	1.7±0.3	0.9±0.2	0.046
Digestive	15.3±1.2	7.6±1.2	<0.001
Weight management	6.8±0.7	2.4±0.5	<0.001

CONCLUSION

- This study showed the beneficial improvements in fibromyalgia symptoms by the LEAP program and the potential as a tailored dietary option in the clinical management of fibromyalgia.
- Furthermore, the LEAP program based on LAA-MRT shows promise for future large-scale pragmatic investigations in fibromyalgia.