

The Effects of Collagen Hydrolysate on Symptoms of Chronic Fibromyalgia and Temporomandibular Joint Pain

Gary B. Olson, D.D.S.; Sue Savage, M.B.S. JoAnn Olson, R.P.P.

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Address for reprint requests:
Dr. Gary B. Olson
3930 Eighth Street S.
Suite 202
Wisconsin Rapids, WI
54494-6511

ABSTRACT: Twenty (20) people who had medically diagnosed fibromyalgia for two to 15+ years participated in and completed a 90-day evaluation to determine effects of collagen hydrolysate on symptoms of chronic fibromyalgia, with twelve reporting temporomandibular joint pain. Collagen hydrolysate is a food supplement that is available without prescription, with no known side effects. Participants were evaluated initially and then at 30-, 60-, and 90-day periods. Final results were obtained and comparisons made. The average pain complaint levels decreased significantly in an overall group average, and dramatically with some individuals. It was concluded that patients with fibromyalgia and concurrent temporomandibular joint problems may gain symptomatic improvement in their chronic symptoms by taking collagen hydrolysate.

Dr. Gary Olson received his D.D.S. in 1976 from Marquette University School of Dentistry. He has been treating temporomandibular joint dysfunction, headaches, and related cervical pain for over 15 years. He was the Director of the Craniomandibular/Cervical Pain Center at St. Mary's Hospital in Milwaukee, Wisconsin, for two years from 1984-86. Dr. Olson maintained a private practice in Milwaukee from 1986-93 and then moved to Wisconsin Rapids where he currently practices. He provides treatment for TMD, headaches, and related cervical pain nonsurgically using conservative techniques recognized by American Dental Association and the Wisconsin Dental Association. Dr. Olson has lectured at national and international seminars and has published research findings completed with doctors at the Medical College of Wisconsin Milwaukee. He is a member of many pain-oriented professional organizations.

This study is a report of thirty (30) chronic fibromyalgia sufferers who were supplied collagen hydrolysate. Collagen hydrolysate is a food supplement made from a collagen protein formula which nutritionally feeds the body allowing it to support itself in maintaining lean muscle tissue. These individuals had tried various modalities of treatment to alleviate their symptoms and the reported levels of symptomatic complaints had plateaued with no further improvement despite repeated treatments. The symptomatic temporomandibular dysfunction (TMD) symptoms were treated without using a dental approach. Collagen hydrolysate helps the body to utilize fat and sugar effectively, as well as supports the body's natural mechanisms. A pain patient of Dr. Olson's reported that the Calorad (Nutri-Diem, Inc., Ste-Julie, Quebec, Canada) brand of collagen hydrolysate had effectively reduced her fibromyalgia symptoms, so the authors contacted the distributor, Essentially Yours Industries Corp (EYI). EYI referred them to the manufacturer, Nutri-Diem, Inc., and Medical Director, Jean-Louis Robillard, M.D., agreed to cooperate with the study by supplying product. The authors received no compensation of grant monies for this study.

Fibromyalgia Syndrome: Clinical Features

Fibromyalgia Syndrome (FMS) is characterized by widespread pain, multiple tender points, fatigue, poor sleep, feeling that extremities are swollen, and paresthesia. Data in recent years suggest FMS is part of a spectrum of syndromes which have been termed "dysfunctional spectrum syndrome" (DSS). Members of the DSS family include irritable bowel syndrome, chronic fatigue syndrome, fibromyalgia, temporomandibular dysfunction, tension-type headaches, migraine, and primary dysmenorrhea, among others. The most important pathophysiological mechanisms involved in DSS seem to be an aberration of neurohormonal functions.¹

Widespread musculoskeletal pain along with multiple tender points form the core features of FMS. Widespread pain has been defined in the American College of Rheumatology (ACR) criteria for the classification of fibromyalgia as the presence of pain in the axial skeleton (cervical or thoracic or lumbar or anterior chest region plus above the waist and below the waist, plus right and left sides of the body).² The ACR criteria definition of widespread pain has sometimes been misinterpreted to mean pain in all four limbs as well as the spine, although such a wide distribution of pain is indeed commonly reported to clinical practitioners.³ Pain is often regional initially and then spreads to multiple locations over months. Some patients may present with pain in one or two regions, such as the back, neck, or the chest area. Pain then becomes progressively widespread, severe, constant, nagging, and disabling in a majority of patients seen in a rheumatology clinic. Pain is the most common reason for consultation with a physician. Eighteen tender points were identified in the ACR criteria. Eleven of eighteen tender points satisfies tender point criteria (**Figure 1**).⁴

Yunus and associates have demonstrated that the number of tender points in FMS is not influenced by the psychological status of the patients. It is now clear that there is a generalized decrease in pain threshold in FMS: the so-called controlled points are significantly more tender in FMS than control groups.^{2,5-7} Such global tenderness provides an important clue to the pathophysiological mechanisms in FMS and suggests that an aberration of central pain mechanisms involving neuroendocrine dysfunctions is most important when explaining the widespread pain and tenderness that exists in fibromyalgia.³

Sufferers of symptoms related to DSS syndromes can benefit from centrally active drugs that modulate neurotransmitter or neurohormonal functions. Since it is likely that multiple neurochemicals with complex and interacting roles are operative in FMS,^{8,9} it is not expected that the

same drug will work in all the syndromes or even in all patients with the same syndrome. Wolfe, et al.¹⁰ described the general symptoms/associated symptoms of fibromyalgia.

Pain: The pain of FMS has no boundaries. People describe the pain as deep muscular aching, burning, throbbing, shooting and stabbing. Quite often, the pain and stiffness are worse in the morning and you may hurt more in muscle groups that are used repetitively.

Fatigue: This symptom can be mild in some patients and yet incapacitating in others. The fatigue has been described as "brain fatigue" in which patients feel totally drained of energy. Many patients depict this situation by saying that they feel as though their arms and legs are tied to concrete blocks, and they have difficulty concentrating.

Sleep disorder: Most FMS patients have an associated sleep disorder called the alpha-EEG anomaly. This condition was discovered in a sleep lab with the aid of a machine which recorded the brain waves of patients during sleep. Researchers found that FMS patients could fall asleep without much trouble, but their deep level (or stage four) sleep was constantly interrupted by bursts of awake-like brain activity. Patients appeared to spend the night with one foot in sleep and the other one out of it. In most cases, a physician does not have to order expensive sleep lab tests to determine if you have disturbed sleep. If you wake up feeling as though you have "just been run over by a Mack truck," what doctors refer to as unrefreshed sleep, it is reasonable for your physician to assume that you have a sleep disorder. It should be noted that most patients diagnosed with chronic fatigue syndrome have the same alpha-EEG sleep patterns, and some FMS-diagnosed patients have been found to have other sleep disorders, i.e., sleep apnea, sleep myoclonus (nighttime jerking of the arms and legs), restless leg syndrome, and bruxism (teeth grinding). The sleep pattern for clinically depressed patients is distinctly different from that found in FMS or CFS.

Irritable Bowel Syndrome: Constipation, diarrhea, frequent abdominal pain, abdominal gas, and nausea represent symptoms frequently found in roughly 40-70 % of FMS patients.

Temporomandibular Joint Dysfunction (TMD): This syndrome causes tremendous face and head pain in one quarter of FMS patients. Most of the symptoms associated with the condition are thought to be related to the muscles and ligaments surrounding the joint and not necessarily the joint itself.

Chronic headaches: Recurrent migraine or tension-type headaches are seen in about 50% of FMS patients and can pose a major problem in coping for this group.

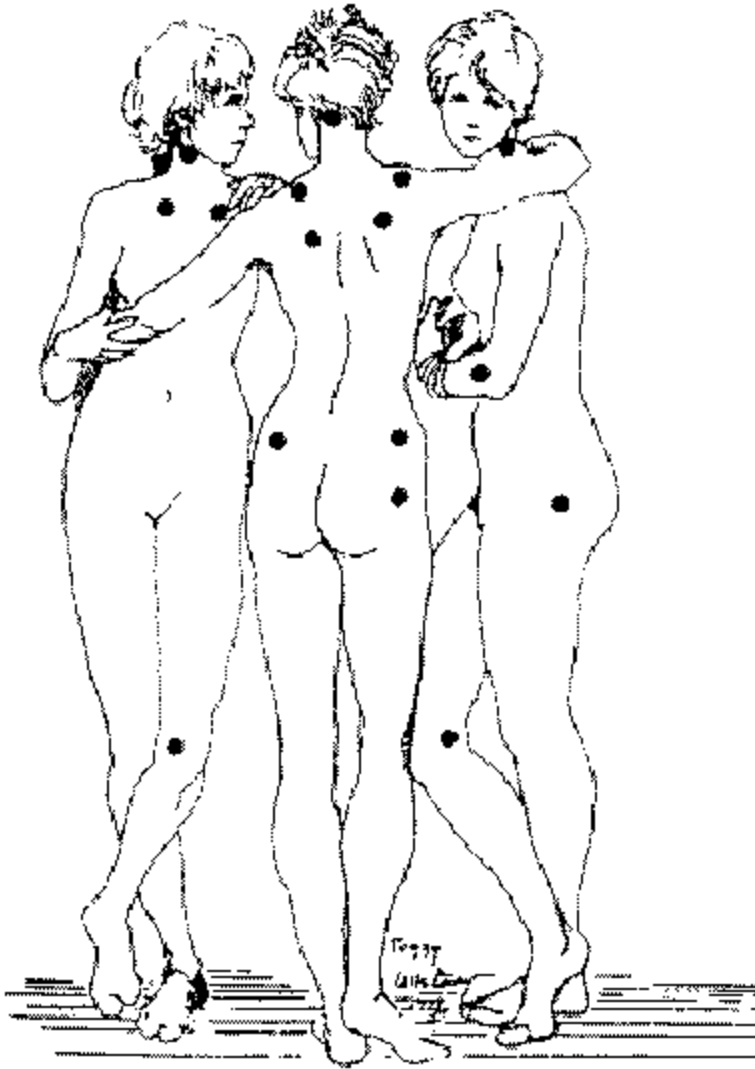


Figure 1

The eighteen tender points of the 1990 American College of Rheumatology criteria for the classification of fibromyalgia. Eleven of the 18 tender points satisfies the tenderness criteria. Points indicated on figure by black dots. (Figure used with permission: Lippincott, Williams & Wilkins, *The Journal of Arthritis and Rheumatism*, 1990; 33:160-172.)

Other common symptoms: Premenstrual syndrome and painful periods, chest pain, morning stiffness, cognitive or memory impairment, numbness and tingling sensation, muscle twitching, irritable bladder, the feeling of swollen extremities, skin sensitivities, dry eyes and mouth, frequent changes in eye prescription, dizziness, and impaired coordination can occur.

Aggravating factors: Changes in weather, cold or drafty environments, hormonal fluctuations (premenstrual/menopausal states), stress, depression, anxiety, and over-exertion can all contribute to symptom flare-ups.³

Materials and Methods

Thirty (30) individuals were selected on a first-come, first-serve basis after all members of the Wisconsin Rapids Fibromyalgia/Chronic Fatigue Support Group

were contacted by mail. Based upon previous reports, the average FMS drop-off rate is 40% in studies.¹⁰ The authors selected thirty people for this pilot study, so even if a 40% drop-off occurred, we would still have beneficial data to evaluate. None of the participants were in treatment for TMD problems at this office. Requirements for participation in the study were:

1. Must be diagnosed with fibromyalgia by a physician for at least one year;
2. No previous/current use of collagen hydrolysat products;
3. Complete medical history, fibromyalgia symptom history, and periodic updates;
4. Obtain permission from a medical doctor, if necessary, to participate if questions arose regarding other medications/medical conditions;
5. Subjects were given information and understood that collagen hydrolysat is a food supplement with no known side effects.

Table 1
Calorad (Nutri-Diem, Inc., Ste-Julie, Quebec, Canada) Fibromyalgia Research Project
Beginning of Study/End of Study

Patient #	Pain Level*		Fatigue**		Total sleep		Uninterrupted sleep		Irritable bowel		Chronic headache		TMD		Morning stiffness		Cognitive/ memory impairment		Numbness/ stinging sensations		Feeling of swollen extremities		
	beg	end	beg	end	beg	end	beg	end	beg	end	beg	end	beg	end	beg	end	beg	end	beg	end	beg	end	beg
1	4-9	2-5	50%	50%	7	8	4	5	6	6	6	4	8	5	10	8	5	3	2	5	4	4	
2	2-3	2-3	75%	75%	6	7	4	4	4	2	7	3	2	1	1	1	1	2	9	3	5	1	
3	6-7	6-7	75%	75%	7	7	2	3	3	6	7	5	1	1	7	3	1	1	9	8	1	1	
4	8-9	2-3	75%	50%	12	8	4	6	10	4	10	4	10	4	10	6	10	4	10	2	10	2	
5	6-7	2-3	75%	75%	6	8	4	6	9	4	1	1	1	1	8	3	7	3	7	3	10	10	
6	4-5	4-5	50%	50%	6	8	2	3	8	5	10	5	1	1	8	5	5	5	5	8	8	8	
7	4-5	4-5	25%	50%	12+	10	4	4	5	4	5	4	1	1	8	5	5	5	8	4	1	5	
8	8-10	6-7	75%	50%	5	5	3	3	6	4	10	9	9	5	9	7	8	3	8	6	7	5	
9	6-7	2-3	50%	25%	7	9	3	4	2	1	1	1	1	4	4	1	2	1	10	1	2	3	
....10	4-5	2-3	50%	75%	7	7	4	5	7	2	3	2	6	1	9	4	4	2	9	4	7	1	
11	6-10	6-7	0%	0%	6	5	3	3	5	2	10	4	10	4	7	4	7	2	1	1	2	1	
12	4-5	6-9	25%	50%	9	6	3	5	4	3	5	5	6	3	9	8	9	7	2	3	2	2	
13	4-5	4-5	75%	50%	7	5	3	2	6	2	7	4	4	2	9	6	8	6	7	4	9	5	
14	2-3	2-3	50%	75%	9	9	5	5	4	2	2	2	1	1	8	7	5	3	4	4	4	1	
15	4-5	4-5	50%	25%	7	8	5	5	6	6	2	2	5	2	8	10	9	4	4	2	2	1	
16	8-10	8-9	50%	50%	8	9	4	4	2	6	4	1	1	6	10	10	7	9	8	6	5	9	
17	4-5	2-3	50%	75%	6	5	3	5	10	4	5	5	1	1	10	4	10	3	10	1	3	2	
18	6-9	8-9	75%	25%	6	5	3	2	8	7	8	10	5	1	10	10	8	10	8	7	8	7	
19	4-7	2-3	25%	75%	6	7	2	7	9	3	5	3	1	1	10	3	7	3	8	2	9	3	
20	10	4-5	0%	50%	10	6	2	3	2	1	10	4	1	1	10	7	10	7	10	4	1	3	

* Pain levels based on a scale of 0-10; 0-1 = no pain; 2-3 = mild pain; 4-5 = discomforting pain; 6-7 = distressing pain; 8-9 = intense pain; 10 = excruciating pain.
 ** Fatigue based on percentage of normal, normal = 100% and complete exhaustion = 0%.
 ... Patient #10 was the only male test patient.
 Note: Nonpain symptoms based on a scale of 0-10 with 10 being worst and 0-1 being absent.

The study participants were given a 30-day supply of the Calorad (Nutri-Diem, Inc., Ste-Julie, Quebec, Canada) brand of collagen hydrolysate and instructed to take one tablespoon with a glass of water just before going to sleep. They were advised to take no food or other beverages except water for three hours before taking the supplement. After 30 days they returned to fill out a symptomatic update form and receive a second 30-day supply. After 60 days another symptom report was obtained and another 30-day supply given. At the end of 90 days, a final survey form was completed. Patients were not coached. No controls were used in this initial investigative study. The ages of the participants ranged from 31 to 75 years old. Their duration of illness was 2–15 years, with the average being 5.35 years.

Previous modalities tried by the participants included: varied pillows, 8; medications, 18; food supplements, 10; exercise, 20; newsletters, 8; counseling, 5; an active support group, 12; herbal supplements, 13; physical therapy/chiropractic care/massage, 16; acupuncture, 1.

Results

One male and nineteen females completed the study. All reported data is based upon this group of 20. Thirty people began the study and only three were noncompliant. The others had to stop during the study because: couldn't sleep, moved, home burned down, medically too ill, assault, and hospitalized. Twenty participants completed the 90-day study and the results follow. **Table 1** shows both the beginning and end of study symptomatic responses. The only side effects reported were due to not eating and stomach jumpiness or loose stools, attributable to continued problems with hyper-irritable bowel. The people needing food beforehand were advised to have up to one cup of fresh fruit up to one hour before taking collagen hydrolysate, and those with loose stools were told to cut their dosage to one teaspoon and increase from there to the one tablespoon dosage per Nutri-Diem recommendation. No other side effects were reported.

Participants were instructed to change no current medications, food, or activities. The only change incorporated into their daily life was the addition of the collagen hydrolysate food supplement at bedtime as directed.

Discussion

In general, collagen is the building block of the soft tissues in the body. These tissues include all of the organs, skin, arteries, veins, lymph vessels, joint cartilage, and all of the muscles of the body. We are constantly involved in

a game of *catch up* to do repairs. Through the years, we lose lean muscle mass, have less demand for energy, and our metabolism adjusts and decreases. Therefore, it follows that providing the body with the collagen it needs for repairs and growth may help deficient areas to improve health.

According to Tim O'Shea, D.C., from California, a nutrition expert and chiropractor, it has been postulated that when the Calorad brand of collagen hydrolysate is absorbed on an empty stomach, it avoids anabolic competition from other amino acids, fatty acids, monosaccharides, sugars, and other absorbable elements. The concentrated effect of select amino acids in the blood-stream allows targeting of specific organs, in this case, the endocrine system. Calorad (Nutri-Diem, Inc., Ste-Julie, Quebec, Canada) has a specific amino acid formulation that targets the production of new collagen and thus supports natural function by providing in abundance long chain and branched chain amino acids necessary for connective tissue production (personal communication dated 8/18/99).

The proprietary formulation differs from other collagen supplements which are made from hydrolyzed collagen, not collagen hydrolysate. Collagen hydrolysate has a longer peptide chain composition (personal communication dated 1/24/00 from M. Hittner, Family Natural Foods, Wisconsin Rapids, WI).

This study used numerical symptomatic reporting of evaluated symptoms. When a patient goes to his/her doctor, 90% of treatment is based upon symptomatic complaints. Results reported are symptom changes reported and do not address personal or other medical conditions that could also affect responses. These aggravating factors could involve symptoms with emotional factors and chronic pain, medical illnesses that can be co-morbid symptom contributors, menstrual cycle effects, as well as changes in weather that may be occurring at the time of reporting. Most studies of medication/treatment trials do not state if the evaluations were done in the winter or summer months. Fibromyalgia sufferers are worse in the winter and better in the summer.¹⁰ This study was done during the period January to April, 1999. Also important is the fact that over 50% of the participants in the study were taking other prescription medications and over-the-counter drugs. Yet, it is important to also remember that these fibromyalgia syndrome sufferers had experienced reported symptoms an average of 5.35 years, so any notable improvement is significant to report.

Sleep reporting in research studies is at times questionable. However, the presence of alpha EEG sleep anomaly

has been interpreted as an arousal or a physiologic correlate of the complaint of light and un-refreshing sleep; an index of a non-restorative sleep. Consistent with this notion, fibromyalgia patients undergoing treatment showed significant correlations of symptoms with measures of sleep alpha EEG. Furthermore, in a recent study, fibromyalgia patients showed more alpha EEG sleep than healthy controls.¹¹

In addition, a greater number of pre- and post-sleep pain patients were more likely to rate themselves as not having enough sleep, feeling less rested with more fatigue and sleepiness than the control subjects. While fibromyalgia patients did not indicate more vigilance during their sleep, they were better able to:

Recall in the morning their awake behavioral signaling; and

Estimate their total time asleep as measured by their sleep EEG.¹¹

Based upon this information, the authors were confident using self-reporting assessment of sleep changes.

In spite of those possible neutralizing factors, very noticeable changes were noted. At first glance, the results (**Table 1**) were varied. Some people improved dramatically while others did not change. The most notable average improvement (**Table 2**) was a 25% decrease in overall reported fibromyalgia pain. Also observed was improvement in non-interrupted sleep from 3.35 hours to 4.2 hours. This is a 25% improvement and allowed deeper sleep to approach more restful sleep levels.

Further review of **Table 2** reveals a 36% overall improvement in irritable bowel syndrome and 34% improvement in chronic headaches. Morning stiffness

improved by 32% and cognitive/memory impairment improved 35%. Other average changes showed an improvement of 11% in numbness/tingling sensations. TMJ average change was 39% improvement. Reported fatigue levels did not change beyond a 2.5% improvement.

More in-depth review of **Table 1** shows different results, however, in regard to TMJ problems. Eight people did not have TMJ complaints to start. Of the twelve who did have TMJ complaints, two did not improve and actually worsened. Ten participants improved noticeably. The interesting positive results regarding TMJ complaints thus reveals that the collagen hydrolysate appears to be a beneficial food supplement for reducing TMJ problems. None of the people received TMJ treatment via routine dental modalities of care. The authors postulate that changes in sleep and a decrease in muscle and ligament pain provided symptomatic relief to TMJ discomfort by decreasing overall body stress, similar to the overall adaptation/accommodation breakdown reported by Fonder and Sleye.¹²

Table 1 draws attention to participants #4, #5, #10, #17, and #19. These five people had remarkable improvement reports in most areas including sleep. This fact brings the authors to a summary of results that each person's response to collagen hydrolysate is based upon the individual experience, and closer scrutiny of **Table 1** shows significant changes occurred. Our interpretation of the study results is that given the skeptical attitude of these FMS patients, plus the longstanding, well-documented nature of their disorder, we concluded the reported improvements are unlikely to be attributable to an expectancy effect.

Table 2
Calorad (Nutri-Diem, Inc., Ste-Julie, Quebec, Canada) Fibromyalgia Research Project
Group Averages*

	Beginning	30 days	60 days	90 days	Ave. chg.	Results
Pain level (based on 0-10 scale)**	6.8	5.8	4.85	5.1	-1.70	25% decrease
Fatigue	50%	48.75%	51.25%	52.5%	-2.50%	2.5% decrease
Total Sleep	7.45	6.9	7.4	7.1	-0.35	0.5% hr. decrease
Uninterrupted sleep	3.35	3.95	4.1	4.2	0.85	25% deeper sleep
Irritable bowel	5.8	5.25	4.25	3.7	-2.10	36% improvement
Chronic headache	5.9	4.95	4.5	3.9	-2.00	34% improvement
TMD (jaw) muscles & ligaments	3.75	3.65	2.5	2.3	-1.45	39% improvement
Morning stiffness	8.25	6.45	5.9	5.6	-2.65	32% improvement
Cognitive/memory impairment	6.4	5.0	4.4	4.15	-2.25	35% improvement
Numbness/tingling sensations	6.95	4.6	3.7	3.9	-3.05	44% improvement
Feeling of swollen extremities	5.0	4.1	3.6	3.7	-1.30	26% improvement

* When more than one number was given, the higher number was always used for averaging.

** Pain levels based on a scale of 0-10: 0-1 = no pain; 2-3 = mild pain; 4-5 = discomforting pain; 6-7 = distressing pain; 9-9 = intense pain; 10 = excruciating pain.

Note: Nonpain symptoms based on a scale of 0-10 with 10 being worst and 0-1 being absent

Conclusions

In this pilot study, 20 participants took the Calorad (Nutri-Diem, Inc., Ste-Julie, Quebec, Canada) brand of collagen hydrolysate at bedtime for 90 days. Review of the averaged data shows that this food supplement provided notable improvement in symptomatic complaints. When reviewing individual responses rather than those of the averaged group, very significant changes occurred. TMJ complaints were notably improved in those who had been diagnosed with TMJ problems.

The results of this preliminary study of a chronic fibromyalgia population are promising. These participants had tried many other modalities of treatment and were *stuck* with little hope of further improvement. However, study results have shown that a food supplement may provide notable improvement. These results show that further objective collagen hydrolysate studies need to be conducted, perhaps under a more controlled approach utilizing outcome measures which include the Fibromyalgia Impact Questionnaire, Self-Efficacy Questionnaire, and other more detailed tests.¹³ Further research may show what effect this food supplement provided to stimulate improvement in a fibromyalgia population who had little hope of improvement.

The authors postulate that collagen hydrolysate may be one of the neurohormonal protein/amino acid complexes necessary for balanced neuroendocrine function. This mechanism of individual protein keys has already been proven by Dr. Gunter Blobel, the 1999 Nobel Prize in Medicine winner. His work over three decades has proven that proteins become building blocks for the cells, while others function as enzymes catalyzing thousands of chemical reactions as specific as ZIP codes, helping them find their correct locations within the cells and providing normal function.¹⁴

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Ms. Sue Savage, M.B.S., received her *Medical Business Specialist certification from the State Medical Society of Wisconsin in 1996. She is the Administrative Assistant to Dr. Gary Olson and provides nutritional counseling to pain patients. She has used her college background to establish her own business, Healthy Concepts, based upon her special interest in natural products for healthy living. At Healthy Concepts she also provides nutritional counseling, aromatherapy, and is an herbal body wrap technician, as well as a certified instructor for the Herbal Body Wrap, Inc.*

Ms. JoAnn Olson, R.P.P., is a *Registered Polarity Practitioner, Cranio Sacral Therapist, and Reiki Master. She practices and teaches at Whole Person Unlimited, her private practice in Mosinee, Wisconsin. For the past 25 years she has pursued studies in the natural health field. She is certified in Herbology, Iridology, Bio-Mechanics, Muscle Response testing, Foot Reflexology, and Touch for Health. Other studies include acupressure, shiatsu, aromatherapy, yoga, therapeutic touch, and fascial tissue unwinding. She studied with renowned authors Bernie Siegel, M.D., author "Love, Medicines & Miracles," Dr. Alan Siegel, author of "Polarity Therapy, The Power that Heals," and Live Food Therapy with Dr. Ann Wigmore. Professional memberships include American Polarity Therapy Association, International Association of Health Care Practitioners, Reflexology Organization of Wisconsin. The Reflexology Research Project, Associated Bodyworkers, and Massage Professional. Wisconsin Natural Food Associates, and National Health Federation..*
