

Cutler Fibromyalgia Rehabilitation Program



Physicians can now refer their patients to the Cutler Fibromyalgia Rehabilitation Program

Cutler's Fibromyalgia Rehabilitation Program achieved outcome of 50-90% improvement in overall symptoms

- 'Primary care physicians can confidently diagnose fibromyalgia without the need for specialist confirmation, and the current practice of extensive investigations should be curtailed...Treatment must move away from the simple prescription of a drug, with incorporation of non-pharmacologic strategies in a multimodal approach... Treatments should therefore incorporate non-pharmacologic strategies with selected drug therapy, but without reliance on a single "ideal" drug.'¹
- '...Specialist consultation should be reserved for patients with atypical symptoms which might suggest an alternate diagnosis and is not required to confirm a diagnosis of FM...No advantage was observed when patients were followed in a specialist setting compared to primary care.'¹

CFGF Guidelines accepted by National Fibromyalgia Guidelines Advisory Panel & Endorsed by Canadian Rheumatology Association and Canadian Pain Society ¹

The Underlying Pathology of Fibromyalgia is a Multifactorial Disorder

- Abnormalities in Pain Processing
- Increased Intestinal Permeability
- Altered Gut Microflora
- Disturbance of Neuro-Endocrine-Immune System
- Altered Hypothalamic-Pituitary-Adrenal Axis
- Inflammation, Increased levels of Substance P and Cytokines
- Nutritional Deficiencies



'The pathophysiology of fibromyalgia (FM) is not completely understood. The disease is characterized by a central sensitization with an amplification of pain perception. A combination of interactions among external stressors, behavioral constructs, neurotransmitters, hormones, immune, and sympathetic nervous systems appears to be involved. It is known that the neuroimmunoendocrine system has a role in the pathogenesis of the disease and multiple abnormalities have been demonstrated in the peripheral and central nervous systems. Bidirectional mechanisms involving peripheral nociceptive input as well as abnormal central pain processing are involved. Hypothalamic-pituitary-adrenal axis alterations have also been shown with abnormal response to stress. Recent data highlight the putative role of cytokines in the pathogenesis of FM. The autonomic nervous system is implicated in the maintenance of the physiological homeostasis and sympathetic activity appears increased in FM. Neuropeptide Y and its receptors Y1 and Y2 seem to have a complex role in pain modulation.'

'Substance P is found at an elevated level in the cerebrospinal fluid of fibromyalgia (FM) patients.'

'Conclusions. The IPs [intestinal permeability] in primary FM and, unexpectedly, CRPS [complex regional pain syndrome] are increased. This study should stimulate further research to determine the implication of altered IP in the disease pathophysiology of FM and CRPS.'

'There is now, however, increasing experimental and clinical evidence to suggest that large antigenic molecules can penetrate the intestinal epithelial surface in quantities of no nutritional importance, but possibly immunological significance. In this review Allan Walker discusses our current understanding of small intestinal permeability to antigens and the potential importance of excessive absorption of macromolecules in mechanisms of immunologically mediated clinical disease.'

'Conclusion The higher levels of cytokines found in FM patients suggest the presence of an inflammatory response system (IRS) and highlight a parallel between the clinical symptoms and biochemical data. They support the hypothesis that cytokines may play a role in the clinical features of fibromyalgia. In addition, the similar cytokine patterns found in FM patients with different psychiatric profiles suggests that IRS impairment may play a specific role in the disease.'

'We focus on the example of an abnormal expansion of gut microbial flora into the small bowel...Fibromyalgia, a condition of musculoskeletal hypersensitivity, provides us with a fascinating model on the link between gut bacteria and somatic hypersensitivity.'

'The gut immune system has the challenge of responding to pathogens while remaining relatively unresponsive to food antigens and the commensal microflora. In the developed world, this ability appears to be breaking down, with chronic inflammatory diseases of the gut commonplace in the apparent absence of overt infections. In both mouse and man, mutations in genes that control innate immune recognition, adaptive immunity, and epithelial permeability are all associated with gut inflammation. This suggests that perturbing homeostasis between gut antigens and host immunity represents a critical determinant in the development of gut inflammation and allergy.'

'For many nutrition deficiencies, a direct cause and effect of different symptoms and diseases has been established...Less well recognized are the effects of nutritional deficiencies on chronic disease, especially acute and chronic neuromuscular diseases.'

Cutler's Fibromyalgia Rehabilitation Program achieved outcomes of 50-90% improvement in overall symptoms

Time course for Improvement in Symptom Severity: Figure 2

Treatment Duration (months)	0	1mo.	2mo.	3mo.	4mo.	5mo.	6mo.
Pain	0	19.9	37.5	41.2	55.8	58.1	60.0
Fatigue	0	16.2	34.2	40.4	54.0	64.0	70.3
Mental Energy	0	16.3	58.1	56.2	57.8	61.2	63.6
IBS	0	36.7	45.3	66.5	75.0	70.9	78.7
Sleep Problems	0	20.4	35.1	56.7	62.6	65.5	70.3

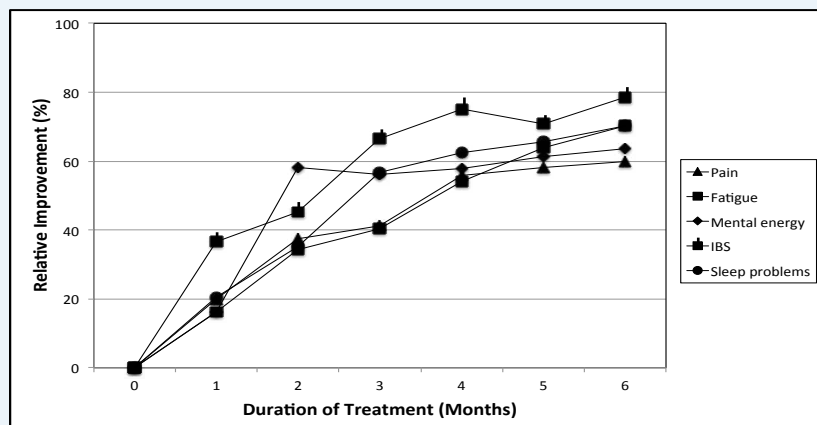


FIGURE 2. Monthly assessments of improvement in severity of wide-spread muscle pain, fatigue, mental energy, irritable bowel syndrome, and sleep problems for patients enrolled in the Fibromyalgia Rehabilitation Program. Mean SSRS scores are indicated.

Time course for Improvement in Symptom Severity: Figure 3

Treatment Duration (months)	0	1mo.	2mo.	3mo.	4mo.	5mo.	6mo.
Stiffness	0	6.25	25.9	37	45.5	51.1	58.2
Memory Problems	0	13.0	29.8	35.5	47.6	47.6	51.4
Anxiety	0	35.3	44.3	47.4	52.6	57.9	56.2
Depression	0	21.8	39.5	47.9	60.5	61.3	65.5
Tension Headache	0	27.2	32.5	54.5	62.7	70	70.9
Joint Pain	0	25.0	31.0	40.0	50.6	57.5	58.4

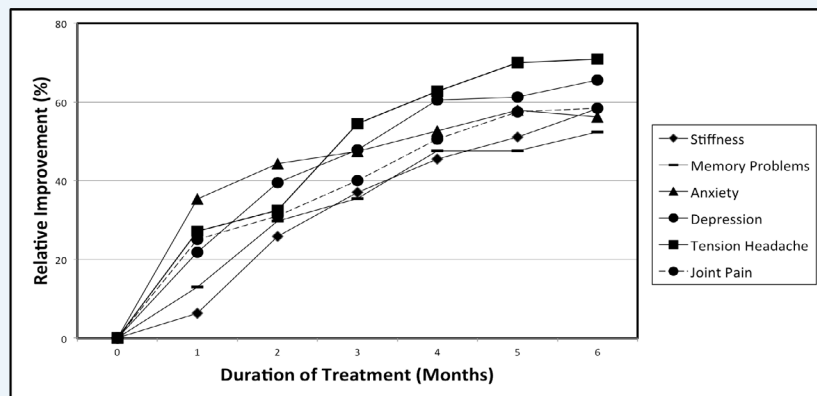


FIGURE 3. Monthly assessments of improvement in severity of stiffness, memory problems, anxiety, tension headache and joint pain for patients enrolled in the Fibromyalgia Rehabilitation Program. Mean SSRS scores are indicated.

Scientific Study Results published by Cutler in
Today's Therapeutic Trends, The Journal of New Developments in Clinical Medicine
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Results

Following completion of the study period, the medical evaluator determined that all patients showed improvement ranging from 50% to 90%, based on patients' self-assessments. Typically, subjects reported a reduction in symptoms, including a decrease in widespread and localized pain, reduced IBS symptoms, improved mood, and more restful sleep patterns. An increase in energy level was often noted as well. Improvement in day-to-day functioning and mood were corroborated by independent spouse interviews.

Methods

Patients were referred to the Fibromyalgia Rehabilitation Program by a family physician or medical specialist (e.g., rheumatologist, neurologist) who had made the diagnosis of fibromyalgia. This initial diagnosis was based on a comprehensive physical examination by the referring physician, a thorough medical history, appropriate blood testing, and other diagnostic criteria relevant to myalgias. During initial screening, the participating social worker made the determination as to whether a referral for psychological counselling was indicated, and met with the patient and family members to establish that she was able and willing to complete the full 6-month rehabilitation program. Overall results of the initial assessment were then reviewed by an independent specialist in internal medicine prior to acceptance of the subject into the study.

Standard components of the Fibromyalgia Rehabilitation Program include patient education; dietary modification and use of a selected combination of nutraceuticals; lifestyle changes; patient calendars and questionnaires designed to measure fibromyalgia symptoms and their impact on overall patient function; and regularly scheduled follow-up visits. Doses and intensity of use of the standard treatment components were adjusted in accordance with indications and complaints, as well as patient response to treatment.

Following a psychosocial assessment, the social worker recommended initiation of psychological counselling, participation in fibromyalgia support groups, and/or other behavior modification strategies as appropriate. Patients were also encouraged to develop or strengthen their emotional support networks. Depending upon the extent of symptoms, energy levels and responsiveness to treatment, patients could be encouraged to increase their intensity of physical activity with approval of the referring physician. The nursing staff contacted each patient monthly or bi-monthly for a follow-up interview, which included administering the Symptom Severity Rating Scale. After 6 months, the program team evaluated each individual patient to determine whether treatment should be continued. Several patients who had experienced a less pronounced response to the rehabilitation program agreed to the continuation of treatment for up to one year.

Patient Evaluation

Patient response to the program was evaluated by three measurement criteria:

- an exit interview and assessment by an independent medical evaluator;
- the Symptom Severity Rating Scale (SSRS) (see Table 2); and
- the Fibromyalgia Impact Questionnaire (FIQ), a standardized instrument widely used to study fibromyalgia syndrome.

The SSRS, developed by Cutler Clinics, was administered at least once a month throughout the duration of treatment and served as a primary endpoint of the study at 6 months, and at the end of treatment (up to 12 months). Each item is rated on a scale of 0 (no impairment) to 10 (the most severe or greatest impairment). The SSRS is composed of 20 questions assessing the health status of patients with fibromyalgia syndrome. Of these, 8 measure varying aspects of pain identified in fibromyalgia patients, 2 focus on fatigue, others evaluate aspects of memory problems, symptoms of irritable bowel syndrome (IBS), tension and migraine headaches, and 4 assess other frequently reported symptoms, including restless legs/leg pain, cold sensitivity, painful/ sore feet and frequent urination.

As a second endpoint measure, the FIQ was administered to patients upon completion of treatment. This standardized scale assesses several areas of fibromyalgia-associated impairment (depression, anxiety, generalized pain, stiffness, fatigue), as well as measuring ability to function in home activities and work performance. Both questionnaires were administered verbally by the program staff in a semi-formalized setting, to ensure the absence of any questioner influence on patients' responses.

TABLE 2. Symptom Severity Rating Scale (SSRS) items.

- | | |
|-------------------------------------|---|
| 1. Widespread pain in muscles | 11. Varying degrees of depression |
| 2. Pain in joints | 12. Decreased mental energy |
| 3. Muscle pain when you are resting | 13. Memory difficulties |
| 4. Muscle pain with repetitive work | 14. Tension headaches |
| 5. Muscle pain when exercising | 15. Migraine headaches |
| 6. Stiff muscles | 16. IBS-related problems |
| 7. Tender points | 17. Frequent or urgent urination |
| 8. Decreased sense of energy | 18. Painful or sore feet |
| 9. Sleeping problems | 19. Intolerance to cold or cold extremities |
| 10. Varying degrees of anxiety | 20. Restless legs syndrome or leg aches |

Time Course for Improvement in Symptom Severity

Figures 2 and 3 illustrate the progressive improvement in mean symptom severity scores as measured by the SSRS at monthly intervals throughout the study. The reduction in symptoms associated with these 11 indicators of fibromyalgia can be observed throughout the 6-month study, with symptom improvement being measurable as early as 1 month after initiating treatment. The greatest relative symptomatic improvement occurred within the first 4 months of participation in the Fibromyalgia Rehabilitation Program, and was then generally maintained, but with a subsequent tapering off of further improvement.

Statistical Analysis

Primary analyses involved comparisons of baseline and 6-month symptom severity data from the SSRS, and of baseline and endpoint data on the SSRS and FIQ upon termination of patient treatment. Due to the relatively small sample size and non-parametric distribution of differences, a more conservative test, the sign test (M statistic), was employed. A significance level of 0.05 was selected. The data were analyzed in SAS version 8.12.

Symptom Severity

Baseline assessment showed that study patients reported from 13 to 20 symptoms of pain and multiple co-morbid conditions on the 20 item SSRS (mean: 17.5 symptoms/conditions per patient). In 95% of the study subjects, at least one complaint completely resolved within 6 months (mean: 5.6 complaints resolved; range: 0-15).

The Cutler Fibromyalgia Rehabilitation Program

Treats Fibromyalgia Patients with a Multidisciplinary/Multimodal Approach Based On the Following Guidelines

2012 Canadian Guidelines for the Diagnosis and Management of Fibromyalgia Syndrome

'Current evidence indicates that there is no single ideal treatment...Management of persons with fibromyalgia should be centered in the primary care setting with knowledgeable healthcare professionals, and ideally, where possible, this care may be augmented by access to a multidisciplinary team...' ²

'Ideal management is a multimodal approach combining non-pharmacologic and pharmacologic treatments, with the understanding that fibromyalgia symptoms fluctuate over time and seldom completely disappear. No single treatment outperforms others, so a multimodal approach is best...' ¹

'Non-pharmacologic interventions such as relaxation, distraction, exercise and cognitive behavioural training play an important role in modulating descending pain mechanisms...It is essential that non-pharmacologic therapies be incorporated in a treatment plan...Non-pharmacologic strategies form an integral part of multicomponent therapy, which currently has the best evidence for effect in treatment of fibromyalgia. These interventions can include education to improve a patient's self-efficacy and coping mechanisms, as well as exercise, psychological interventions such as cognitive behavioural therapy, and multidisciplinary therapy. Non-pharmacologic interventions should be incorporated into every patient's treatment plan.' ¹

The Fibromyalgia Syndrome: A Clinical Case Definition for Practitioners. (2003)

Document supported by Health Canada

'...the standard treatments have not provided significant relief from symptoms...Many patients with FMS are unusually sensitive to medication given in the usual doses...Balanced Diet- Patients should be encouraged to: Eat a Balanced, Nutritious Diet. Patients who are tired and in chronic pain may require higher nutrient intake to encourage the healing process. Pain reduction and energy enhancement may be achieved in selected patients with a nutritional program of lowered carbohydrates, adequate monounsaturated lipids, and adequate protein in every meal. Patients with hypoglycemia may benefit from food low on the glycemic index. Patients should avoid foods to which they are sensitive or that aggravate pain... integrate other health care providers into the treatment programs ...While each individual has a unique biochemistry and unique needs for various nutrients, those with chronic illnesses may require additional nutrients to support the repair process.' ¹¹

Physicians can now refer their refractory Fibromyalgia Syndrome patients to *Cutler's Multidisciplinary Team* for a consultation.

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