

Introduction

The purpose of the study is to evaluate an integrative mind-body protocol that has been specifically developed for mitigation of symptoms in Fibromyalgia (FM) patients.

The occurrence of this chronic pain disorder according to The National Fibromyalgia Association (n.d.-b):

affects an estimated 10 million people in the U.S. and an estimated 3-6% of the world population. While it is most prevalent in women—75-90 percent of the people who have FM are women—it also occurs in men and children of all ethnic groups. The disorder is often seen in families, among siblings or mothers and their children. The diagnosis is usually made between the ages of 20 to 50 years, but the incidence rises with age so that by age 80, approximately 8% of adults meet the American College of Rheumatology classification of fibromyalgia. (“Prevalence,” para. 1)

The uncertainty of the pathophysiology of fibromyalgia has made this condition frustrating for both patients and clinicians (Harris & Clauw, 2008). Using a patient survey, Choy et al. (2010) uncovered some of the frustrations encountered by the presenting FM patient. While some patients experienced symptoms for almost a year before consulting a physician, they were not actually diagnosed for an average of 2.3 years and had by then consulted with an average of 3.7 physicians. Some patients felt their own inability to communicate exact symptoms, the process of eliminating other conditions, and physicians’ various levels of understanding the syndrome were contributing factors to a delayed diagnosis. There are no lab tests or imaging techniques that provide conclusive evidence (Fürst, 2007), but rather, assessment depends on symptom severity (Clauw, 2009).

Many of the symptoms and comorbidities of FM have been designated as the primary cause of the illness. Research often supports the existence of a particular symptom, but does not prove that it serves as the primary etiology (Clauw, 2009; Leza, 2003; Lucas, Brauch, Settas, &

Theoharides, 2006). Comorbid factors might include, but are not limited to, affective disorders, irritable bowel syndrome, heat and cold intolerance (Buskila & Cohen, 2007; Goldenberg, 1989; van Houdenhove & Egle, 2004), depression (Tylee & Gandhi, 2005), and cognitive dysfunctions, such as “fibrofog” and working memory loss (Boomershine, 2012). The accumulation of research has led to inconsistencies, confusion, and ineffectual treatment plans (Häuser, Thieme, & Turk, 2010). Fibromyalgia has been notoriously unresponsive to allopathic medical treatments (Adsett, 2007; Simms, 1998; Turchaninov, 2006).

Although the etiology remains conjecture, recent advances and discoveries have helped to unravel some of the mysteries of pathways and dysfunctions in the pain analyzing systems evident in FM patients. Much research has focused on the hypersensitivity of the central nervous system’s (CNS) response to pain and the resulting altered transmission processes of that pain (Harris & Clauw, 2008). The theories of central disinhibition, central sensitization, and the dysfunctional response of the hypothalamus–pituitary–adrenal axis (HPA) dominate the central mechanisms hypothesis (Vierck, 2006).

“Pain signaling is a complex interaction between ascending and descending pathways between the spinal cord and brain” (Krypel, 2009, p. 7). These studies shed light on the whole body response to pain for the FM patient, but make no claim to define the etiology of these physiological events.

Some researchers look beyond the central nervous system’s changes and imbalances in the modulating pathways (Staud, 2004, 2006; Turchaninov, 2006; Vierck, 2006). These authors acknowledge the bidirectional relationship (Fig 1) of hypersensitive nociception input and

heightened central pain processing but do not believe it originates in the CNS. The focus of this group turned to a peripheral root source for the hyperalgesia.

Figure 1 summarizes the bidirectional distribution of clinical pain and hypersensitivity of FM patients.

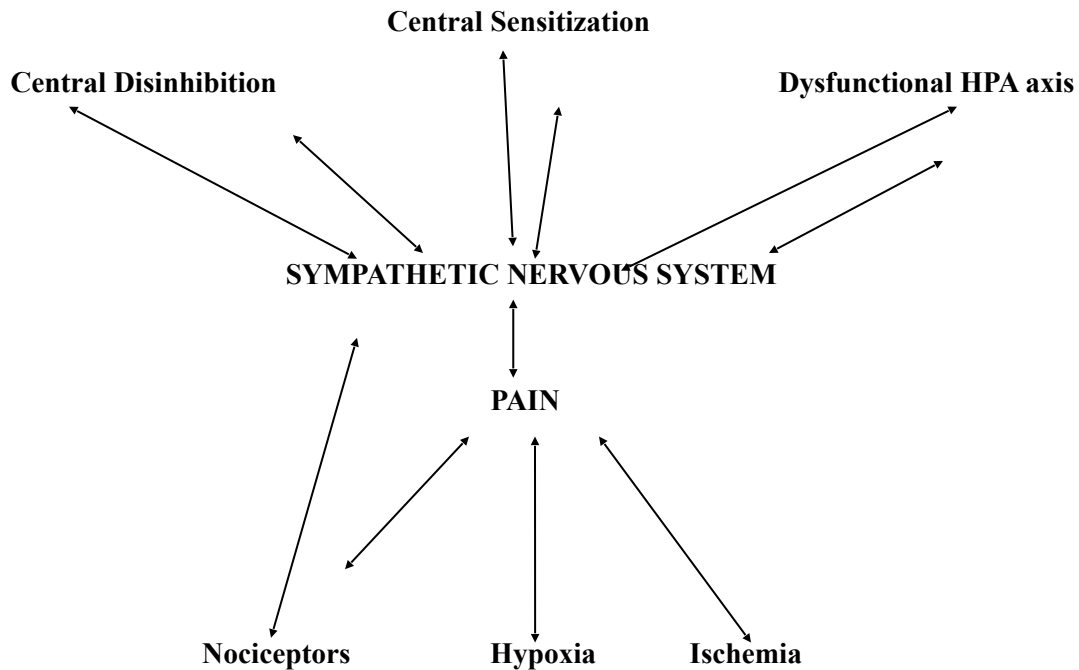


Figure 1. Bidirectional influences on FM pain.

The role of peripheral mechanisms in the changes of the CNS is subject to much conjecture. Some progress in understanding the relationship is made with the factors identified by Vierck (2006), which acknowledged that until a source is recognized in the CNS, peripheral mechanisms must be considered. In the systematic review of this study, (Mooney, 2015) *muscle pathology has been shown to have a clear origin and progression (Popelansky & Ivanichev, 1984) that explains many of the events leading to the hyperalgesia and, ultimately, the changes*

in the nervous system, soft tissue, viscera, emotions, and behaviors associated with FM. The onset of this muscle pathology occurs following physical or emotional trauma or stress.

The development and progression of muscle abnormalities offers an explanation for the peripheral mechanisms observed in patients with FM (Mooney, 2015). These events appear to be provoked by a physical and/ or emotional impact (Goldenberg, 1999; Ogden et al., 2006; Scaer, 2007; Staud, 2007), chronic overuse of a muscle group (Popelansky & Ivanichev, 1984), or a history of accumulated distress. *These circumstances set the stage for an unresolved stress response in the body or somatization and muscle pathology resulting in ischemia and hypoxia* (Levine, 1996; Ogden et al., 2006; Popelansky & Ivanichev, 1984; Scaer, 2007).

Selection of Intervention Protocol

The stages of muscle pathology have shown how hypertonic muscles restructure the body and brain drastically, altering physiological and psychological events. These events are created by the devastating systemic response to ischemia. It is imperative that one phase of the treatment protocol addresses the skeletal muscle component to relieve the comorbid factors associated with the dystrophic changes of the hypertonic muscle and the systemic influence of ischemia.

A second component considers the issues of releasing trauma from the body and redefining coping skills to begin altering the progressive course of FM. Managing stressful situations and reducing stress indicators found in the body can be the cornerstone of emotional/ body healing (Rogers, 1989).

The protocol components of Medical Massage and a movement class were specifically chosen to address the theories of trauma or accumulated stress and the somatic expression of FM explored in the Review of Literature (Mooney, 2015)..

Development of the protocol

Over a third of those finally diagnosed reported the chronic pain was not well managed by the current treatment (Choy et al., 2010). The various prescribed medications and physical therapies sometimes offer a 30–50% temporary relief from pain (Fürst, 2007). FM is considered to be treatment resistant (Rasmussen, Mikkelsen, Haugen, Pripp, & Forre, 2009).

Standard Treatment Strategies

The array of medications used to address symptoms of FM includes antidepressants, opioids, nonsteroidal anti-inflammatory (NSAIDS) drugs, muscle relaxants, anticonvulsants, sedatives, analgesics, and hypnotic agents (Han et al., 2011). Three of these pharmacological interventions include Duloxetine (DLX), milnacipran (MLN), and pregabalin (PGB). Because of the erratic results of the pharmacological interventions some authors suggest other forms of therapy with or without the drug treatments (Fürst, 2007; Jahan, Nanji, Qidwai, & Qasim, 2012; Littlejohn & Walker, 2002; Staud, 2010).

Some non-pharmacological studies support the recommendations and expand the options for more multi-component treatment strategies. These multidisciplinary approaches should actually treat pain, sleep disturbance, fatigue, and comorbidities such as hypotension and psychiatric disorders and include drug intervention. Although these programs show efficacy in coping with the lifestyle dictated by fibromyalgia, there appears to be a need for studies that are guided by specific theories about onset and/or expression of FM. The intervention evaluated here was developed to focus on two specific theories which perhaps will initiate another arena for research for FM.

The intervention is a result of several years of working with patients diagnosed with FM at a Medical Massage center and as a consultant for a local FM support group; listening to their detailed reports of daily symptoms; and assessing the futile standard treatments they had experienced. The multiplicity of the illness emerged in the diverse expression of symptoms, but common themes surfaced.

Each person interviewed reported lack of sleep, diffuse and/or localized algesia, depression, isolation, and an inability to live the active life he or she once had lived. Many described feelings of having to force themselves to work or interact socially, and of having a personal commitment to help others. Each specified a history of trauma or overwhelming stress. They all felt disconnected from their own bodies and out of control of their life choices and their personal well-being.

Using the information gathered from each patient, the specific treatment protocol was developed. The two major components of the protocol presented in this research—Medical Massage and gentle movement therapy—were chosen to address the symptoms, provide a proactive treatment plan, and create a supportive, motivating environment while addressing:

1. The somatic expression of trauma;
2. The development of hypertonic muscles and trigger points;
3. Resulting ischemia;
4. The limiting influence of adaptive movement patterns;
5. The cognitive and pathological influences on the mind and body of the patient with FM;
6. Pain.

The protocol was designed to reduce or resolve the impact of these six factors and was shown to be effectual in its clinical application with our patients.

Study Design

To address the research question and present the findings, the design of this study utilized a mixed method approach including a multiple case study (qualitative) and pre- and post-intervention measurements (or repeated measures) for quantitative data.

The focus in this particular multiple case study was both intrinsic and instrumental. The study relied on the experience of the individual case to answer the questions (intrinsic), but the study also served as an instrument to further understanding of FM (Stake, 1995).

Six individuals were asked to complete interviews, questionnaires, personal journals, and assist with progress notes. The participants previously diagnosed with FM by an attending physician using the American College of Rheumatology preliminary diagnostic criteria for FM (Wolfe, Clauw et al., 2010) were randomly selected from a large group of self-volunteers providing the critical cases. A copy of the diagnostic criteria was given to each volunteer and a suggestion was made to all volunteers to consult with their attending physician. Each person came into the study at a different stage or presentation of this syndrome and each was expected to respond differently to the intervention program. There were no exclusions in this study for factors such as age, culture, socioeconomic status, education levels, gender, or views of wellness or health. Volunteers presently taking an opioid medication or ketamine in any form were not included. Taking other medications or supplements was acceptable. Participants were asked not to add any new medications or treatments during the study. Also, patients under active chiropractic care were excluded.

The mixed method approach enabled the participants not only to rate the effects of FM on their daily lives and put a number to the pain, but to discuss the onset and progression of the FM and offer some insight into living with their illness.

Table 1 is a summary of data collecting instruments, time each was used, and reasons for selection.

Data Collection Instruments

Data Collection Tool	Time	Assessment / <i>Symptom domain</i>
Intake Interview	Before treatment protocol or the first week preceding the study	Qualitative Medical history Symptoms Medications Interventions Lifestyle Onset of problem Baseline
Personal Journaling	First week and continuing throughout the study	Qualitative Subjective self-report of pertinent daily behaviors, symptoms, changes, needs
Progress Notes	Sequential with intervention	Qualitative Therapist & participant report
Revised Fibromyalgia Impact Questionnaire (FIQR)	First week preceding study; Within 5 days following study	Quantitative Current Evaluation: <i>physical functioning</i> <i>socio-cultural impact, ability to perform mental tasks</i>
The Brief Pain Inventory (BPI)	First week preceding study; Within 5 days following study	Quantitative Self-report of <i>the intensity and the reactive dimension of pain</i>
Patient Global Impression of Change (PGIC)	Within 5 days following study	Quantitative <i>Overall improvement in pain and symptoms</i>
Exit interview	Within 5 days following study	Qualitative/Quantitative retake assessments subjective impressions

Table 1 Data Collection Instruments

Components of the Protocol

Medical massage. One phase of the intervention protocol consists of twelve, 40 to 60 minute treatments of Medical Massage. To elicit a clinical change for the participants with FM, the protocol intervention uses techniques of the Medical Massage modality to address the peripheral mechanisms.

The use of specific researched methods that include goals, techniques, and discriminate application according to the stages of the illness minimize confusion and enable the practitioner to replicate methods developed from clinical trials. The FM protocol used in this study adheres to the clinically approved principles and precise interventions of Medical Massage.

The role of the Medical Massage protocol in this effort is essential to:

- release the somatic manifestations;
- reset the autonomic nervous system;
- treat hypertonic muscles, tender points, trigger points;
- decrease pain;
- allow the participant to experience his or her own body in a positive way;
- restore normal blood flow to ischemic tissue;
- validate the participant's perception of the state of the body while creating a compassionate, safe, and nurturing environment
- address the chronic, persistent psychological aspects of FM.

Medical Massage protocol:

For purposes of replication and because the study was limited to 12 treatments of Medical Massage with a diverse group of volunteers the protocol could not be as individualized as private clinical sessions. However, areas of hyperalgesia and pathological symptoms were addressed for each participant with the appropriate Medical Massage protocol

Each session began with the participant lying prone in anatomical position, using a face cradle and a foot bolster of comfortable size. Attention to comfort, temperature, position, sounds, present pain levels, and areas of hyperalgesia was paramount. All factors for each individual and each session were recorded in treatment notes. A discussion of pressure and discomfort alerted the participant to be vigilant and control these factors throughout the session. Feedback is imperative to enable the practitioner to meet the goals of the treatment but also for the patient to have expression and control of personal needs.

Described here are the initial 2 sessions of therapeutic massage in the inhibitory regime (Turchaninov, 2006) applied only to the upper torso only. To avoid nausea, headaches, flu-like symptoms following massage reported by many FM patients this method was selected to accommodate the stage of FM and the years of accumulated metabolic 'waste' resulting from the ischemic condition. These initial sessions establish rapport, trust in the process, patient control, and enable the therapist to assess the tolerance and needs of each person for further treatment plans.

The practitioner should be aware that the goals listed previously apply to each session.

The pressure of all strokes must be comfortable for the patient and below the pain response threshold. With every session this threshold was reassessed for each contact area. Please refer

to Therapeutic Massage (Turchaninov, 2000) for the definition and proper technique of each stroke.

Step 1: Addressing the whole back from sacrum to cervical and across shoulders apply long gentle, bi manual effleurage strokes. This allows the practitioner to activate the parasympathetic response, initiate a state of relaxation, and assess the contact areas for pain thresholds. Using full hand effleurage strokes (Turchaninov, 2000) cover the entire back from sacrum to cervical for several minutes The strokes should be consistent, smooth, and non aggressive. It is important to next address the paravertebral muscles on each side with the Big Fold stroke. Begin on the most affected side with the Big Fold technique first then move to the least affected side and apply the same.

Step2: Remaining on the least affected side and working across the body apply the effleurage strokes to the neck and shoulder from medial to lateral. Continuing in the inhibitory regime add a full hand friction moving down the neck, across and to the point of shoulder. Adjust pressure to what is comfortable, maintain contact, and follow with effleurage. The practitioner then physically moves to the least affected side to continue addressing that shoulder, scapula and upper thoracic area with general effleurage and non-specific friction strokes. Maintaining contact return to other side and work across the body again with raking effleurage and friction from thoracic to lumbar between ribs.

Step 3: Effleurage and friction through the lumbar and sacral area. Move up the back again with the Big Fold. Move again to the same side and effleurage the entire side of the back.

Big Fold the paravertebrals on the opposite side then repeat steps 1 through 3 on that side of the back.

Step 4: Finish the posterior by addressing the whole back again from sacrum to cervical with effleurage strokes. The patient often comments that this feels as if the parts are reconnected to the whole.

Step 5: Turn to supine position. Apply effleurage and friction to arms, shoulders, neck, and complete gentle facial massage.

Movement. The second component in the protocol is an 8-session program of structured movements. The movement class is a group activity, meeting for 1 hour a week for six sessions. The movement group meets simultaneously with the medical massage interventions. In a clinical

setting the movement class would include other mind/body interventions such as guided imagery and visualization.

Inclusion of movement therapy in the fibromyalgia protocol. The formation of hypertonic muscle pathology creates muscle tension that results in new muscle patterns which limit range of motion and normal function (Hanna, 1988).

Acknowledging the influence of somatization stress or trauma and musculoskeletal dysfunctions on the pathology of FM supports the clinical relevance of the movement portion of the protocol. Exercise and aerobics have been studied for use with patients with FM, but the focus has not been to restructure the cortical maps, release the trauma, or to alter the pathological progression (Häuser, Thieme et al., 2010).

For patients with FM restricted movement patterns limit life choices, sense of safety, and well being (Ogden et al., 2006). To restructure the brain map into a more productive movement pattern, it is necessary to expand and refine attention through slow, exact movements (Feldenkrais, 1977).

In order to disrupt the restricting somatotropic pattern the precise movement of each area of the body must be done slowly, with deliberation, while focusing on the sensation of the movement. Comparing the left to the right side, noticing the changes as each movement progresses to the next step, and resting completely between each movement reorganizes the brain while repairing the body (Daly & Ruff, 2007).

Physiologically, results of the slow methodical movement show a rebalancing of agonistic and antagonistic muscles, a decrease of effort in synergistic muscle groups, and a significant reduction in muscle hypertonus. For example, as the patient slowly and methodically

moves the legs in a precise pattern the threshold of the muscle spindle receptors are reset but in a careful, nurturing manner. The patient is then able to adjust the movement to the new threshold and increase the range of motion without creating any muscle tension. As the range of motion increases, with cautious adjustments, the muscle tension is reduced and so is the associated, devastating ischemia (Feldenkrais, 1977; Turchaninov, 2006).

Levine (1996) tapped into the individual's innate ability to overcome the residual effects of trauma. "Everything we need awaits inside" (Levine, 1996, p. 10) and can be accessed through movement or a series of exercises that discharge the "frozen energy" (Levine, 1996) of trauma or anxiety and encourage body awareness

Movement goals include:

- awareness and release of restrictive patterns;
- awareness and release of pain patterns;
- providing a proactive response to stress;
- reconnecting to the body;
- reorganizing the cortical maps (Hanna, 1990-1991; Mahncke, Bronstone, & Merzenich (2006);
- awareness of personal somatic responses to stress/trauma, and reducing muscle tension.

Results

Quantitative Data and Analysis

Revised Fibromyalgia Impact Questionnaire

The FIQR is composed of 21 items investigating three domains: function, impact, and symptoms. Each item is graded on a 0 to 10 numeric rating scale (NRS) with 10 representing the worst of the item. The lower score reflects a higher quality of life (QoL) or the inverse being the higher score indicates more severe FM symptoms (Bennett et al., 2009).

For the participants in this study ($N = 6$) there was a statistically significant difference between the scores for the FIQR domains at the base measurement and the end scores post-intervention. Further Cohen's d effect size value ($d = 0.85$) suggested a high practical significance of this change. The statistical results suggest all participants experienced relief from some of the symptoms that limited normal daily activity and each participant's ability to function in everyday tasks was enhanced; each participant perceived that the ability to function had increased; and these participants experienced a reduction in the symptoms associated with FM.

The total FIQR demonstrates the maximum impact of FM on the patient (Williams & Arnold, 2011). In this study, to determine the efficacy of the protocol to reduce symptoms of FM for this volunteer group, the results showed there was a significant difference in the total scores between the pre-intervention total (T) score ($M = 56.50$, $SD = 14.00$) and the post-intervention total score ($M = 39.66$, $SD = 14.14$); $t(5) = 8.68$, $p < .001$. The Cohen's d effect size value ($d = 1.20$) suggested a high practical significance. These results suggest that the protocol reduced some of the symptoms that the FIQR measured and overall enhanced the quality of life (QoL) for these participants.

Table 2

Statistical Results for the FIQR Determined From the Mean Scores (N = 6)

Pre-Intervention/Baseline			Post-Intervention				
FIQR	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>t</i> (5)	Sig.	ES
Function	16.66	5.85	11.66	6.28	7.82	.001	0.85
Impact	13.84	3.92	8.50	4.14	8.00	<.001	1.36
Symptoms	26.67	7.55	20.17	7.63	4.33	.007	0.86
Total	56.50	14.00	39.66	14.14	8.68	<.001	1.20

Note. Mean and standard deviation (*SD*) of each domain, *t* (degrees of freedom=5), Sig. = significance level (2-tailed), and the Cohen's *d* effect size (ES).

Brief Pain Inventory (BPI)

Although the BPI long form contains a total of 32 items, the measurement uses a mixture of item types and can be administered as a self-report questionnaire or as an interview. The BPI is used to measure the severity and interference of pain in everyday life. For the participants in this study ($N = 6$) there was a statistically significant difference between the scores for the BPI-S domain at the base measurement ($M = 6.00$, $SD = 1.90$) and the BPI-S at the end score ($M = 4.17$, $SD = 1.60$); $t(5) = 2.60$, $p = .048$ as shown in Table 3. Further, the Cohen's effect size value ($d = 0.96$) suggested a high practical significance.

Table 3

Statistical Results for the BPI Determined From the Mean Scores (N = 6)

Pre-Intervention/Baseline			Post-Intervention				
BPI	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>t</i> (5)	Sig.	ES
Interference	6.83	1.72	4.66	1.61	7.05	.001	1.20
Severity	6.00	1.90	4.17	1.60	2.60	<.048	0.96

Note: Mean and standard deviation (*SD*) of each domain, *t* (degrees of freedom = 5), Sig. = significance level (2-tailed), and the Cohen's *d* effect size (ES).

Patients' Global Impression of Change (PGIC)

The PGIC was administered post-intervention providing the participants an opportunity to report any clinical changes. Hurst and Bolton (2004) outlined and noted on the PGIC questionnaire the interpretation of this subjective outcome measurement:

- A significant, favorable change is a score of 5–7
- No significant change is a 1–4 response.
- Note, this is a dichotomous scale (5–7 = yes; 1–4 = no).
- A 2-point change is significant from their last reported score.

The subjective assessment and scores for the PGIC are individually reported in Table 4

Table 4

PGIC Scores

PGIC	JA	LB	MJ	GR	JK	DB
1 No change/worse						
2 Same						
3 Some change						
4 Better						
5 Some noticed difference				x		
6 Definite improvement	x	x	x		x	x
7 Impressive difference						
Score	6	6	6	5	6	6
Degree of Change	1	2	2	3	2	4

The scores of 5 and 6 reflect individual significant changes (Hurst & Bolton, 2004) for each participant after the intervention. The degree of change is shown with a Likert scale of 1 (much better) through 10 (much worse). Four of the participants indicated a significant change of 2 or less since the beginning of the intervention. The subjective assessment and scores for the PGIC are individually reported in Table 4.

Qualitative Data and Analysis

For the qualitative inquiry in this mixed method research a case study approach provided an in depth understanding of the experience of each participant. Common themes that related to the research question, “How efficacious is a specific theory-based approach, including Medical Massage and movement therapy, in reducing the symptoms of patients with fibromyalgia?”

added another dimension to the quantitative results. The focus on key issues or themes began within each case followed by a thematic cross-case analysis.

The themes were then discussed and the effects of the protocol on the quality of life summarized within each theme. Some responses to the exit question “How would you describe the change (if any) in symptoms, activity, and quality of life?”

- had a better understanding of her own body, her pain patterns, and was not as fearful or hopeless. The pain reduction was substantial. pain might be exaggerated by the fear. ...and expected to continue this treatment.
- the improvements were considerablelearned some of the activities and thoughts that exacerbated her condition.
- she had some doubts about feeling well after a treatment in the beginning. she noted soreness but no flu-like symptoms. After several sessions she found herself going into a “trance-like state.”

Each participant noticed some changes in at least one area of her life. For most it was a reduction in pain, and for some, it was a renewal of sense of self. It seemed to them that any positive change gave them more hope and power, therefore increasing the quality of life.

Conclusion

The results of this theory-based protocol for the treatment of FM, including Medical Massage and a precise, gentle movement therapy, showed a statistically significant effect on the mitigation of symptoms for the participants ($N = 6$) with FM. It is important to reiterate that the protocol evaluated in this study is based on the theory that muscle pathology is a key peripheral mechanism, and that trauma plays a critical role.

Although the central theory of FM currently prevails and there is an abundance of evidence for central processes being affected in FM, the importance of certain peripheral

mechanisms has been recognized. Vierck (2006) credits “abnormal peripheral input(s) for development and maintenance of this condition (FM)” (p. 242), which necessitates a better understanding of the mechanisms to develop and document adequate therapies.

The statistical results provided preliminary evidence that the protocol may be effectual in improving functional deficits and symptoms of FM. The general improvements noted in the significant statistical findings of the study included a decrease in pain and muscle tension; less depression and anxiety; and an increased ability to function, set goals and limits.

The qualitative summary of each theme reflected that although the time allowed for this study was limited, participants experienced a substantial reduction in pain and therefore an increase in the QoL. One participant made the comment that “we cannot heal without addressing both the mind and the body parts of this illness” (JK). We might clinically transfer this information to other treatment plans for patients with FM.

This study also may be a springboard to further investigation of the progression of muscle pathology discussed here as the “abnormal peripheral input(s) for development and maintenance of this condition (FM)” (Vierck, 2006, p. 242).

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