

A Pilot Comparison of Two Massage Techniques in Fibromyalgia

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Clinical Inquiry Project Executive Summary

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Approximately five million people in the United States suffer from fibromyalgia (FM) (Lawrence et al., 2008). Massage is a common adjunctive therapy used to minimize symptoms in FM (Bennett, Jones, Turk, Russell, & Matallana, 2007). The purpose of this study was to test the feasibility and acceptability of myofascial release therapy (MFR) versus Swedish massage in women with FM. Also, qualitative interviews with the massage therapist were used to further explore the acceptability and feasibility of the interventions.

Twelve subjects received MFR or Swedish massage for 90 minutes weekly for four weeks. Feasibility and acceptability of the study were the primary specific aims of the study. The secondary outcome measures were the Fibromyalgia Impact Questionnaire Revised (FIQ-R), Modified Nordic Musculoskeletal Questionnaire (NMQ), and the Total Myalgic Score. Also, interviews of 3 massage therapists were conducted.

It was found that MFR and Swedish massage were acceptable for FM subjects. The results showed a greater reduction in symptoms in the MFR group and the Aickin separation test showed that further research is warranted (Aickin, 2004). The massage therapists agreed that massage therapy was an effective treatment for those with FM but they did not all agree that MFR was superior to Swedish massage for all with FM. The limitations of this study were the small sample size, the lack of randomization, short therapy duration, and lack of long-term follow-up. Future studies should include randomized controlled trials, longer follow-up, mechanistic studies, and interviews of patients in addition to massage therapists.

Description and Significance

Population, Epidemiology, and Background Knowledge

It is estimated that approximately 5 million adults in the United States suffer from fibromyalgia (FM) (Lawrence et al., 2008). FM affects both men and women, but research shows that women are at least 7 times more likely than men to have a diagnosis of FM (Wolfe et al., 1995). In addition, the prevalence of FM increases with age and appears to peak around the sixth decade of life (Weir, 2006; Wolfe et al., 1995).

FM is defined as a self-report of at least three consecutive months of widespread musculoskeletal pain with tenderness at a minimum of 11 of 18 specific soft tissue tender points on physical exam (Wolfe et al., 1990). Some of the other symptoms commonly experienced by those with FM include fatigue, stiffness, disturbed sleep, tenderness to touch, cognitive deficits, numbness and tingling of extremities, poor balance, impaired functional ability, anxiety, and depression (Bennett, 2009). Some of the common comorbidities associated with fibromyalgia include irritable bowel syndrome (IBS), migraine and tension headaches, interstitial cystitis, temporomandibular disorder, chronic pelvic pain, chemical sensitivities, and chronic fatigue syndrome (Arnold, 2010; Morris, Bowen, & Morris 2005).

Theoretical Framework

The complete etiology of FM remains unclear. Research has shown that there is an augmentation of pain processing in those with FM called central sensitization (Staud, Price, Robinson, Mauderli, & Vierck, 2004). Central sensitization occurs when there is repetitive and persistent nociceptive input, which leads to an increased excitability of the dorsal horn neurons of the spinal cord (Staud, Nagel, Robinson, & Price, 2009). The source of peripheral nociceptive input that leads to the initiation and maintenance of central sensitization in FM remains unknown

(Liptan, 2010).

Recent discoveries suggest that fascia could be a pain generator that leads to central sensitization (Rüster et al., 2005). Fascia is a fibrous connective membrane that envelopes, separates, or binds together muscles, organs, and other soft structures within the body (The American Heritage Medical Dictionary, 2007). Studies on FM muscle do not show consistent pathology but research does show that there are increased levels of collagen and inflammatory mediators in the connective tissue that surrounds muscle cells in those with FM (Rüster et al., 2005). Due to this emerging evidence, it is hypothesized that fascial dysfunction could be the source of peripheral nociceptive stimulus that leads to central sensitization in FM (Liptan, 2010). Therapies that target fascial dysfunction could help to reduce chronic pain by minimizing peripheral pain generation from fascia.

Description of the Problem

Due to the lack of a unifying pathophysiologic hypothesis on the cause of FM, treatments focus on symptom management and optimizing physical function, but the effectiveness of these treatments is limited. Only three medications (duloxetine, milnacipran, and pregabalin) have received FDA indication specifically for the treatment of FM (Di Franco et al., 2010). These medications have been shown to improve pain and other FM symptoms (Crofford et al, 2005; Clauw, Mease Palmer, Gendreau, & Wang 2008; Arnold et al., 2004). However, in the studies on the efficacy of these three medications, meaningful improvement in symptoms (e.g. pain) was defined as $\geq 30\%$ to 50% improvement (Crofford et al, 2005; Clauw et al., 2008; Arnold et al., 2004). Also, there are a number of common side effects of these medications. Some of these include insomnia, dry mouth, constipation, nausea, headache, dizziness, and/or somnolence (Crofford et al, 2005; Clauw et al., 2008; Arnold et al., 2004). Because of the limited efficacy,

cost, and side effects of these medications, adjunctive therapies (e.g. mild aerobic and flexibility exercise, cognitive behavior therapy, etc.) are generally employed to provide further relief.

One adjunctive therapy in FM is massage (Kalichman, 2010). Swedish massage is one type of massage and it includes a variety of techniques that involve superficial to deep pressure stroking of the body. It is designed for muscle and body relaxation. Studies have shown that Swedish massage can have beneficial short-term effects on fibromyalgia symptoms (Alnigenis, Bradley, Wallick, & Emsley, 2001; Sunshine et al., 1996). More recently, myofascial release therapy (MFR) has been employed due to its direct effect on fascia. MFR is a soft tissue therapy that includes a combination of manual traction and prolonged assisted stretching techniques that are theoretically designed to break fascial restrictions or micro-adhesions. Even though previous studies have shown that MFR results in improved FM symptoms and function with some long-term improvements, the effects of MFR in comparison to another manual therapy, such as Swedish massage, have not been conducted (Castro-Sánchez et al., 2011a; Castro-Sánchez et al., 2011b).

Importance to advance practice nursing

FM is a common condition and thus advance practice nurses should remain up-to-date on the diagnosis and management of this syndrome (Lawrence et al., 2008). Adjunctive therapies can be used to provide further symptom management but these are used less frequently than traditional pharmacological management. An internet survey of 2, 596 people with FM showed that some of the treatments most commonly used for FM included nutritional supplements, over the counter medications, and prescription medications (Bennett, Jones, Turk, Russell, & Matallana, 2007). Massage and other manual therapies are used much less frequently (Bennett et al., 2007). It is important that the tolerability and efficacy of adjunctive therapies, such as

massage, be investigated before they are recommended by providers. This study will provide important information for providers and medical researchers as this may give further rationale for third party reimbursement for adjunctive therapies and for future investigation of the critical role of fascia as a peripheral pain generator in FM.

Purpose Statement and Desired Outcomes with Impact

The purposes of this pilot study were to test the feasibility and acceptability of MFR versus Swedish massage in women with FM and to determine if future research on MFR and FM would be warranted. In addition, qualitative interviews were conducted with massage therapists who commonly treat FM patients and use both manual therapies in order to further explore the tolerability, safety, and acceptability of the interventions from the provider's perspective. The specific aims of this project were to determine the feasibility and acceptability of a study on MFR and Swedish massage in FM, determine if further research on these manual therapies is warranted, and obtain the massage therapist's perspective on the use of massage in FM.

Clinical Inquiry Questions

1. Was the study feasible and acceptable?
2. Was further research on MFR and Swedish massage in FM warranted?
3. What were massage therapists' thoughts on the effectiveness and tolerability of both manual therapies in those with FM?

Synthesis of evidence

This section will cover the prevailing theory concerning central sensitization. Also, the role of fascial dysfunction as an etiology for central sensitization will be reviewed. A number of studies on FM and manual therapies have been conducted but few have focused on therapies that target fascial restrictions and adhesions. This section will also review the current evidence on

manual therapies and FM. Lastly, an explanation of the reasons for conducting this study is included in this section.

Central Sensitization and Fibromyalgia

A prevailing theory regarding the pathophysiology of FM is central sensitization (Staud, 2006). Central sensitization involves “increased synaptic efficacy established in somatosensory neurons in the dorsal horn of the spinal cord following intense peripheral noxious stimuli, tissue injury, or nerve damage” (Ji, Kohno, Moore, & Woolf, 2003, p. 696). Spontaneous pain, hyperalgesia (increased response to painful stimuli), and allodynia (pain in response to non-noxious stimuli) have been described as consequences of central sensitization (Staud et al., 2004). Central sensitization can also lead to the spread of pain sensitivity to non-injured areas (Ji et al., 2003). Evidence that supports central sensitization in FM includes the study by Gracely, Petzke, Wolf, and Claw (2002) and Staud et. al (2004).

In the study by Gracely et. al (2002), functional magnetic resonance imaging was used to compare responses to painful stimuli in healthy controls and subjects with FM. In those with FM, mild pressure resulted in subjective pain reports and cerebral responses that were similar to the effects of at least twice the pressure in the control subjects. Also, similar pressures in both groups resulted in less areas of activation and different regions of activation as seen on functional magnetic resonance imaging in the control group compared to the FM group. The results of this study support the hypothesis that fibromyalgia is “characterized by cortical or subcortical augmentation of pain processing” (Gracely et al., 2002, p. 1333).

Staud et al. (2004) demonstrated that there is temporal summation of second pain or wind-up of second pain. Wind-up of second pain is a result of an increase in the excitability of the dorsal horn neurons that results from repeated nociceptive input. Staud et al. compared wind-

up maintenance in 72 healthy controls to 104 subjects with FM. Wind-up of second pain was produced by applying a train of thermal pulses to the glabrous surface of the hands of subjects at a frequency of 0.3 hertz (Hz). The FM subjects experienced enhanced second pain for up to 120 seconds when stimuli of 0.16 Hz and 0.08 Hz were delivered. The healthy controls did not experience enhanced second pain. This study shows that for those subjects with FM, once wind-up occurs, enhanced sensitivity to pain can be maintained even with low stimulus frequencies, which is an indication of central sensitization in the FM subjects. Taken as a whole, these experimental studies suggest that peripheral pain may initiate or maintain central pain.

Fascia and Fibromyalgia

The results of a study by Ruster et al. (2005) indicate that fascial dysfunction could be a peripheral pain generator that leads to central sensitization in those with FM. Fascia is comprised of a number of different cells (e.g. fibroblasts) and extracellular matrix (ground substance, collagen and elastin fibers) (Stecco et al., 2006). The histological study by Stecco et al. (2006) found that deep fascia contains a variety of “both free and encapsulated nerve endings, especially Ruffini and Pacini corpuscles” (p. 1), which indicates that fascia is richly innervated.

Evidence of fascial dysfunction was demonstrated by Ruster et al., (2005). The results of this study show that the fascia of FM patients had more intensive staining of the (AGE) N^ε-carboxymethyllysine (CML) (marker for oxidative stress and tissue damage) and activated nuclear factor kappa B (NF-κB) (Ruster et al., 2005). NF-κB is a transcription factor that, when activated, leads to increased expression of cytokines, chemokines, growth factors, and adhesion molecules. The researchers of this study also found more intensive staining of AGE receptor (RAGE) and CD-86 positive monocytes and macrophages in the muscle interstitial connective tissue, fascia, of FM subjects when compared to the muscle of healthy control subjects. There

was stronger staining for collagen type I, II, and VI in the fascia of fibromyalgia patients compared to the fascia of healthy controls. Ruster et al. (2005) argue that AGE modification of proteins could cause an alternation of collagen metabolism and the stimulation of proinflammatory cytokines which could result in the development, perpetuation and spreading of pain that is seen in FM. It is thus argued that fascial dysfunction and inflammation could be a potent peripheral pain generator leading to central sensitization in those with FM (Liptan, 2010). There is an emerging body of evidence regarding therapies that may mitigate peripheral pain, thus reducing central pain processing dysfunction.

Massage and Fibromyalgia

There are a number of studies on the use of massage in the treatment of FM. Many of these studies show mostly short-term improvements in FM symptoms and/or function. Four randomized controlled trials and one single group feasibility study showed that massage resulted in the short-term reduction of pain, depression, and/or anxiety (Field, Delage, & Hernandez-Reif, 2003; Field et al., 2002; Gordon, Emiliozzi, & Zartarian, 2006; Lund et al., 2006; Sunshine et al., 1996). The study by Lund et al. (2006) also found that the positive results of massage (decrease in pain and indications of emotional reaction) were seen in some subjects in the massage group one month after treatment cessation. A second randomized controlled study and one single group feasibility study showed that those treated with massage experienced a short-term decrease in the number of tender points and/or enhanced physical functioning (Field et al., 2002; Gordon et al., 2006). In addition, a short-term increase in the number of hours slept, reduced difficulty with sleep, decreased fatigue, and/or decreased stiffness were also seen in two randomized controlled studies on fibromyalgia and massage (Sunshine et al., 1996; Field et al., 2002).

A two condition, repeated measure with reverse-order counterbalancing study on water Shiatsu (Watsu), another form of massage therapy, showed significant differences between baseline and completion of Watsu therapy in physical function, bodily pain, vitality, and social function (Faull, 2005). A separate study with a single group feasibility design by Bazzichi et al. (2010) showed that FM patients treated with massage experienced short-term improved heart rate variability (decreased sympathetic and increased parasympathetic tone) and enhanced joint flexibility after treatment.

Field et al. (2002) found that massage resulted in decreased substance P, a neuropeptide associated with pain transmission, in those treated with massage. Another randomized controlled study measured 24-hour urine concentrations of corticotropin releasing factor-like immunoreactivity (CRF-LI), a “key physiological mediator of the endocrine, autonomic, and behavioral responses to stress,” (Lund et al., 2006, p. 166). The results of this study illustrate that after 6 weeks of twice weekly massage treatments, the 24-hour urinary concentrations of CRF-LI decreased.

There have also been studies on a specific manipulation technique called manual lymph drainage therapy in fibromyalgia. As explained by Asplund (2003), Manual lymph drainage therapy is a “rhythmical translational movements of the skin in the flow direction of the lymph vessels” (p. 193) and is proven to be an effective way to mobilize fluid in different lymphedema conditions. The single group design study by Asplund (2003) showed improvements in pain, stiffness, sleep, sleepiness, and well being during the treatment with manual lymph drainage therapy and decreased pain, sleep, stiffness, and enhanced well being two months after treatment cessation. Five months after treatment cessation improvements in pain and sleepiness remained (Asplund, 2003).

Connective tissue massage is much like other forms of massage but the therapist starts at the center of the body and works towards the periphery to affect arterial blood flow (Brattberg, 1999). Also, connective tissue massage is thought to detach dense connective tissue that occurs in diseases with chronic inflammation, whereas in classical massage, muscles are treated. The randomized controlled study (waitlisted control) by Brattberg (1999) found 10 weeks of treatment with connective tissue massage resulted in a pain relieving effect of 37%, a decrease in depression and use of analgesics, and an improvement in quality of life. Three months after treatment, approximately 30% of the pain relieving effect was gone and after 6 months the pain was back to approximately 90% of baseline (Brattberg, 1999).

Connective tissue manipulation is a massage technique that involves stroking defined zones of the body with fingertips in a certain sequence (Çitak-Karakaya, Akbayrak, Demirtürk, Ekici, & Bakar, 2006). In their randomized controlled study, Ekici, et al (2009) found that both connective tissue manipulation and manual lymph drainage therapy resulted in improvements in pain, health status, and health-related quality of life at the end of the treatment program but manual lymph drainage therapy was found to be more effective than connective tissue manipulation according to some subitems of the FIQ (morning tiredness and anxiety) and the total FIQ score. In addition, another study found that CTM resulted in improvements in tissue tenderness, sleep disturbance and general pain intensity after the treatment sessions (Çitak, Akbayrak, Akarcali, & Demirtürk, 2001). Lastly, an observational prospective cohort study of 20 females with FM who underwent CTM combined with electrotherapy therapy and high-voltage pulsed galvanic stimulation showed that the FM subjects experienced a decrease in pain intensity, impact of fibromyalgia on functional activities, and complaints about nonrestorative sleep after the treatment sessions (Çitak-Karakaya et al., 2006). It is difficult to determine if the

CTM used in this study resulted in these benefits or whether it should be fully or partially attributed to the other non-massage therapies.

Two studies that examined Swedish massage showed positive short-term results in those with FM. A randomized controlled pilot study that compared Swedish massage to standard physician care with or without follow-up telephone calls was conducted (Alnigenis, et al., 2001). Subjects were randomly assigned to one of the 3 groups: the standard care group with physician visits at 0, 4, 10, 16, and 28 weeks, the standard care with the same visit schedule plus follow-up calls from the research nurse, or the Swedish massage group with massage visits at 0, 1, 2, 3, 4, 6, 8, 13, 20, and 24 weeks using a standardized protocol (Alnigenis et al., 2001). This study showed modest but significant improvements in the Arthritis Impact Measurement Scale (AIMS) for mobility ($p = 0.05$) and the Rheumatology Attitudes Index ($p = 0.06$) (measures “learned helplessness”) in the Swedish massage group at 4 weeks but benefits were not seen long-term (28 weeks).

An addition study on Swedish massage in FM also showed improvements symptoms. The study by Sunshine et al. (1996) compared Swedish massage to transcutaneous electrical stimulation (TENS) and sham TENS. Each of the 30 adult subjects with FM was randomly assigned to one of the groups and each had 30 minute bi-weekly therapy sessions for 5 weeks (Sunshine et al., 1996). Both the Swedish massage group and the TENS group reported a decrease in anxiety and depression after the therapy session on the last day but the massage group also showed these changes on the first day (Sunshine et al., 1996). In addition, only the Swedish massage group showed improvements in dolorimeter and self-reported pain. Lastly, the Swedish massage group reported less pain, stiffness, fatigue and difficulty with sleeping at the last treatment session (Sunshine et al., 1996).

There are only two studies on myofascial release therapy in fibromyalgia and one on osteopathic manipulative treatment (OMT). OMT includes myofascial release techniques and is thought to release restrictions of soft tissue (Dodd et al., 2006). In a pilot study (control group repeated measure design) that included a protocol with multiple therapeutic modalities, MFR was assessed, but attribution is difficult given the many techniques used in this study (Gamber, Shores, Russo, Jimenez, & Rubin, 2002). The results of this study show that OMT in conjunction with medication showed that OMT combined with medication was more effective in treating FM symptoms than standard care alone. The reduction in fibromyalgia symptoms with OMT combined with standard care shows promise that this multidisciplinary approach could be an effective way to manage FM but it is difficult to determine what technique resulted in improved symptoms because of the number of manual techniques used.

A study on the benefits of MFR in fibromyalgia was conducted by Castro-Sánchez et al. (2011a). In this study, 74 FM patients were randomly assigned to either myofascial release therapy or sham treatment. The intervention included weekly 90-minute MFR sessions or weekly 30-minute sessions of disconnected magnetotherapy over a 20-week period. This randomized controlled clinical trial showed that immediately after the treatment and one month after treatment cessation, anxiety levels, quality of sleep, pain, and quality of life were improved in the experimental group over the placebo group. However, 6 months after treatment cessation, significant ($p < 0.05$) differences were only seen in the quality of sleep index.

Another study by Castro-Sánchez et al. (2011b) showed that MFR did improve a number of FM symptoms. In this study, 86 subjects with FM were randomly assigned to an experimental group where they underwent twice-weekly 1-hour sessions of MFR or 30 minute sham electrotherapy treatment sessions over a 20-week period. After 20 weeks of therapy the MFR

group showed significant ($p < 0.05$) improvements in tender points, McGill Pain Questionnaire score, physical function, and clinical severity. After 6 months post-intervention, the MFR group had a significantly ($p < 0.05$) lower mean painful tender points in a number of areas, and significantly improved ($p < 0.05$) pain score, physical function, and clinical severity. After one year, the experimental group showed significant ($p < 0.05$) improvements only in painful points at second left rib, and left gluteal muscle, affective dimension of the MPQ, number of days feeling good, and clinical severity.

Summary

There are currently no studies that have compared MFR to other forms of manual therapies and comparing 2 active interventions within a parallel design can help to control for multiple treatment effects (e.g. placebo effects, Hawthorne effect, etc.). The study as tested (MFR and Swedish massage in a parallel design) fills this critical gap. Comparing therapies that are aimed at releasing fascial restriction (e.g. MFR) to other types of massage therapy (e.g. Swedish massage) could help to determine the role of fascia in producing fibromyalgia pain and guide further research on the pathology of fibromyalgia (Liptan, 2010). Moreover, the voices of the interventionist providing these treatments have not been elicited and this study will fill this gap also. Lastly, there are currently very few proven treatments for FM and there is need for future research to determine the most effective treatments that work to minimize symptoms and maximize function in those with FM.

Methods

This quasi-experimental feasibility study compared MFR versus an active massage condition, Swedish massage, in women with FM. Additionally, qualitative interviews were used

to gather information from the massage therapist about their experiences using various massage techniques with FM clients.

Quantitative

Sample.

There were a total of 12 subjects (8 MFR and 4 Swedish). Formal power analyses were not required because efficacy was not being tested in this study. All were women with a diagnosis of FM. The inclusion criteria was a diagnosis of FM by 1990 American College of Rheumatology Criteria for the Classification of Fibromyalgia (Wolfe et al., 1990)., ages 21 years of age or older, and able to read and speak English. The exclusion criteria included a current participation in any manual therapy (e.g. massage, chiropractic, or physical therapy), an unwillingness or inability to maintain a steady course of FM treatment for 3 months prior to the study or during the study (e.g. exercise and medication), planned surgery during the study period, uncomfortable receiving massage therapy from a male massage therapist, and a score of 27 or greater on the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977).

Description of intervention and setting.

Two types of manual therapies were used in this study. These included MFR and Swedish massage. Eight subjects received MFR and four subjects received Swedish massage. Both manual therapy sessions were 90 minutes and occurred on a weekly basis for 4 weeks. Two licensed massage therapists and one physical therapist with training in MFR and/or Swedish massage provided the treatments per standardized protocol. The MFR therapy session included 90 minutes of prolonged assisted stretching of painful soft tissue areas of the neck, back, arms and legs. The Swedish massage included 90 minutes of moderate pressure stroking of the neck, back, arms and legs. All treatments were provided at each therapist's respective offices.

Measures and data collection procedures.

Data from the subjects was collected at a pre-intervention visit, before each of the 4 treatment sessions, and 2 weeks post-intervention. All questionnaires were filled out on paper. The principle investigator (PI) administered the questionnaires at the pre-intervention and post-intervention visit and the massage therapists administered the questionnaires prior to each treatment session. All subjects in this study were consented prior to data collection and treatment. Demographic data was collected prior to the initiation of treatment at a pre-intervention session. This included the subject's age, gender, race, ethnicity, marital status, education level, and income level. In addition, the number of years since the patient was diagnosed, how long they have had FM symptoms, if they experienced a trigger for FM, a history of other related medical problems, smoking status, experience with massage, if the patient is working, and if they have filed for disability due to FM were also collected at the pre-intervention session. Mood was also measured at the pre-intervention visit with Epidemiologic Studies Depression Scale (CES-D), which is a 20 item scale used to measure depressive symptoms over the past week (Radloff, 1977). The scores range from 0 – 60 and a higher score indicates an increased burden of depression. A score of 27 or more is indicative of major depression.

Feasibility and acceptability of the study were the primary specific aims of the study. Feasibility was measured by determining the time it took to recruit patients, the number of visits each subject attended, and the questionnaire completion rates. Acceptability of the intervention for the study subjects was measured by the rate of adverse events, questionnaire and visit completion rates, attrition, and adherence rates.

There were three secondary outcome measures. The Fibromyalgia Impact Questionnaire Revised (FIQ-R) was one of the secondary outcome measures and was conducted at the pre-intervention session, prior to each massage session, and 2 weeks after treatment cessation. The FIQ-R has 21 individual questions and all of the questions are based on an 11-point numeric rating scale and are answered in the context of past 7 days (Bennett et al., 2009). The three domains covered in the FIQ-R are function, overall impact, and symptoms (Bennett et al., 2009). Higher scores indicate greater negative FM impact. The FIQ-R has been extensively validated.

There were two other measures used in this study. One was the calculation of the Total Myalgic Score, which was assessed by a physician who specializes in fibromyalgia at the pre-intervention and post-intervention visit. The Total Myalgic Score is a standardized physical exam where the examiner exerts 4 kg/cm² of pressure for 3 seconds to 18 tender points and scoring ranges from 11 to 54 with a higher number indicating more tenderness (Wolfe et al., 1990). A modified version of the Nordic Musculoskeletal Questionnaire (NMQ) was conducted at baseline, before each treatment session, and 2 weeks post-intervention. This is a standardized questionnaire that is used to analyze musculoskeletal symptoms and is often employed in ergonomic or occupational health (Kuorinka et al., 1987). This validated tool was used to assess musculoskeletal complaints at different regions of the body and was adapted for this study and was used to rate pain in 7 different body regions. These regions included the neck, shoulders, upper back, arms, lower back, upper legs, and lower legs. Pain is rated as mild, moderate or severe pain and scores range from 0-21, with higher scores indicating greater pain.

Design and data analysis.

A quasi-experimental design was employed in the quantitative portion of the study. The subjects were not randomly assigned to either treatment. The rationale for choosing a feasibility

and acceptability paradigm over a randomized controlled trial, which would have been ideal, was due to limited funding, a short timeline, and lack of a project director.

Data was entered by the PI and Doctor of Nursing Practice (DNP) student and was stored electronically in a password protected file. Data analysis included a conditional change score analysis. In addition, separation tests were used to determine if further research was justified (Aickin, 2004).

Protection of human subjects and ethics.

The procedures and protocols for this study were approved by the institutional review board (IRB). Consent was collected prior to the administration of questionnaires and the initiation of treatment. The subjects were explained the possible risks (loss of confidentiality, emotional discomfort from being partially unclothed, increased pain during the massage session) and benefits (possible decrease in FM symptoms). All questionnaires were placed in a locked box at the therapist's office. Identifying data were kept in a separate log from de-identified research data.

Qualitative

Sample.

A convenience sample of 3 massage therapists was identified. All subjects had at one time or another used both Swedish massage and MFR when treating FM patients. The eligibility criteria for the massage therapists included an active massage therapy license, trained in Swedish massage and MFR, and experienced with using both techniques with FM patients.

Description of intervention and setting.

Each massage therapist was interviewed using a structured interview guide. The interview questions were reviewed by two doctorally prepared nurses with extensive research

experience (one was an expert in qualitative research). Based on the feedback from the nurse researchers, a structured interview guide of 8 questions was developed (see table 1). All interviews were conducted at each therapist's respective offices. The interviews were digitally recorded and the audiotapes were transcribed verbatim. The transcriptions were compared to the digital recordings to ensure accuracy.

Data collection procedures.

The massage therapists were informed of the study purpose and requirements prior to the initiation of the interview. Demographic information (age, sex, years of experience as a massage therapist, if they have had training in MFR and Swedish massage, percentage of patients with FM, and if they receive out-of-pocket and/or insurance payments for massage services).

Design and data analysis.

A qualitative descriptive approach as described by Sandelowski (2000) and conventional content analysis according to Hsieh and Shannon (2005) were used for this study. The transcriptions were read by a doctoral nursing student and two doctorally-prepared nurses in order to determine key ideas and recurrent themes (Pope, Ziebland, & Mays, 2000). After an initial reading of all the transcripts, each researcher reread the transcripts and made notes and first impressions on each transcript. As the transcripts were read again, empirical codes were assigned to each of the key ideas and recurrent themes (Hsieh & Shannon, 2005; Gibson & Brown, 2009). Then each of the three researchers sorted the codes into categories (Hsieh and Shannon, 2005). After the codes and categories were found from each interview, similarities and differences among the interviews were then identified by each researcher. After the common themes and differences across the interviews were identified, excerpts from the interviews were selected to give an example of each common theme and difference of opinion. The three

researchers met in three group sessions to discuss the identified themes, categories, similarities and differences among the interviews and the quotes for each theme and difference of opinion.

Multiple validation strategies were employed in this study. The use of multiple sources and methods was one strategy suggested by Creswell (2007). In addition, peer review for the formation of the interview guide and the data analysis was used to provide an external check of the research process (Creswell, 2007).

Protection of human subjects and ethics.

IRB reviewed the procedure and protocols for this portion of the study. The potential risk of participating in this study (loss of confidentiality) and the potential benefit (increased public knowledge of the use of massage therapy to treat FM) were explained to the massage therapists prior to the interview. The identities of the massage therapist were kept anonymous. The interview transcripts were shared with only two members of the research team. The audiotape, transcription, and field notes had only the subject's number and no further unique identifying information. A master list of subject number and name was kept in a separate password protected file.

Dissemination Plan

The findings will be reported at health care conferences and in applicable journals. The preliminary results and final results were presented as a peer reviewed poster at Oregon Health and Science University (OHSU) P.A.I.N. day (February 28, 2012, Portland, Oregon, USA) and Western Institute of Nursing (WIN) Research Conference (April 19, 2010, Portland, Oregon, USA) respectively. Please see table 2 for the timeline of this project.

Results

Quantitative

All 12 subjects completed the massage intervention: 8 in the MFR group and 4 in the Swedish massage group. On average, the subjects were 34.5 years of age ($SD=5.5$). The average time since diagnosis for the subjects was 2.6 years ($SD=0.9$). Table 3 depicts baseline demographic data for all of the subjects.

Feasibility and acceptability of the study were determined in a number of ways. Recruitment was completed in less than 2 weeks. Of the 12 subjects, 9 completed all of the questionnaires and went to all 6 visits. All of the subjects attended all 4 MFR or Swedish massage visits despite the subjects' baseline tenderness to touch. The mean Total Myalgic Scores at baseline were high, at 31.9 ($SD=7.7$) and 36.3 ($SD=3.1$) in the MFR and Swedish massage groups, respectively (Wolfe et al., 1990). In addition, there were no adverse events.

The Aickin separation test was used to determine if further research on MFR and FM was warranted. The Aickin separation test showed that the primary outcome, FIQ-R total change score (see figure 1), for those in the MFR group trended (mean = 10.14, $SD = 16.2$) in the hypothesized and positive direction compared to the Swedish massage group (mean = 0.33, $SD = 4.93$) (Aickin, 2004).

In terms of clinical significance, 62% of the MFR subjects showed ≥ 14 percent reduction in the FIQ-R total score compared to only 25% in the Swedish massage group. A ≥ 14 percent change in the FIQ total is considered clinically significant (Bennett, Bushmakin, Cappelleri, Zlateva, & Sadosky, 2009). Three subjects in the MFR group had ≥ 30 percent reductions in the FIQ-R total, which corresponded with reductions in pain measured by the modified NMQ. Most of the reduction in pain was noted in the neck and upper back regions.

Qualitative

Three massage therapists were interviewed for this portion of the study. The first massage therapist who was interviewed has been working as a massage therapist for 3 years and approximately 78% of his patients were being treated for FM. The second massage therapist has been practicing massage therapy for 10 years and about 7% of her patients were being treated for FM. The third massage therapists had practiced massage for 16 years and approximately 10% of his patients were being treated for FM. All 3 massage therapists have been trained in MFR and 2 of the 3 massage therapists have been trained in John F. Barnes' Myofascial Release Approach[®]. One massage therapists only used MFR but used Swedish in the past, one used mostly MFR and at times would end the session with Swedish massage or other massage techniques, and the third used a combination of Swedish, MFR and other massage techniques when treating FM patients.

A number of common themes and differences of opinion were identified from these interviews. Conventional content analysis was used to identify common themes, and differences of opinion, and 5 common categories. These categories included; the perceived etiology of FM, the efficacy of massage in FM, the effects of massage 24 to 48 hours post-massage, how long it took for massage therapy to work and how long it lasted, and general impressions about massage in those with FM.

Perceived etiology of fibromyalgia.

The exact cause of FM remains unknown but the massage therapists shared their opinions that were formed from their knowledge of research on this subject and their clinical experience. Two massage therapists believed physical and/or emotional trauma played a role in the development of FM. According to one massage therapist, "...trauma is definitely an aspect of the disease." Some examples of traumas that increase an individual's risk for FM that were shared by the massage therapists include; car accidents, post-traumatic stress disorder, and abuse. In

addition, all three massage therapists discussed the role of adhered or stuck fascia in causing pain in those with FM. One discussed her thoughts about a possible “loop of stickiness” that can result in pain in those with FM. Another massage therapist described the fascia in those with FM as a “straightjacket” and said that

their fascia seems to have clamped down on their bodies, to put it in a very general way, and that fascia has thickened and makes it difficult for them to move, breathe, and is also closing down on pain sensitive structures.

Efficacy of massage.

All of the massage therapists agreed that massage therapy was an effective treatment modality for those with FM. One massage therapists described his personal experience treating his wife who has FM. He stated massage therapy, specifically MFR, “changed our lives... my wife no longer needed a cane to walk.” Another described his experience during many first MFR sessions by saying, “they feel marked improvement most of the time after that first session.”

The massage therapists shared the positive effects of both Swedish massage and MFR. All three massage therapists believed that Swedish massage and/or MFR resulted in decreased anxiety. One massage therapist described his patient’s response to Swedish massage, “they feel good when they leave, they all feel relaxed when they leave.” Another massage therapist described the “anxiety relief” and also explained that

sometimes part of any body work [MFR] can illicit emotional releases. Emotional releases are often part of the subconscious holding pattern and as a client can release some emotion through sometimes what’s called an unwinding, a freedom of movements, sometimes they’ll cry, sometimes laugh. Any emotions that have been held on can seem to be very cathartic once that release happens.

The massage therapists also described a decrease in pain relief with both types of therapy. Two massage therapists described the short-term pain relief with Swedish massage. One stated that two days after the treatment her patients are

ready to take on the world. They can do their housecleaning, they can see their friends, they can go back to work...they can do...all those things that they need to do, that they've been putting off because it hurts too much...

This massage therapist stated that this improvement in pain usually lasted for 2-3 days. In addition, all 3 therapists agreed that those with FM experienced pain relief with MFR and two believed the pain relief lasted longer in those treated with MFR versus Swedish massage. One stated that:

Swedish really made them feel good when they left, but didn't give them any kind of lasting benefit...The myofascial release...I've been able to take my fibro patients and be able to space their sessions out. My once a week people become two weeks, then three weeks, then once a month.

Improvements in movement and range of motion were also noted by all the massage therapists. According to one massage therapists, Swedish massage and MFR resulted in, "increased function and range of motion." Another described the feedback he got from his patients. He stated,

A big thing I get is...I'll get messages in the phone "I had to adjust my mirrors in the car." That's a big one. I'll get that at least once a month... That's a fun one. I just love that one.

Lastly, 2 of the massage therapists believed that MFR therapy resulted in improvements in digestive issues (e.g. IBS) experienced by those with FM. According to one massage therapist,

“myofascial release is huge with helping the digestive problems... the myofascial release around the abdomen, getting rid of that crunch down, helps tremendously.”

Effects of massage 24 to 48 hours post-massage.

All of the massage therapists described the symptoms experienced by patients 24 to 48 hours post-massage. They describe a short-term soreness and/or ill feeling that many feel after both MFR and Swedish massage. One therapist described the post-massage period by stating, “they will typically have a day of feeling awful the next day, that’s not uncommon at all with fibro.” Another described the pain after a session of MFR. He stated, “It’s a different kind of hurt. Sometimes they’re relieved just to have a different hurt... if you ever had chronic pain, you’ll understand how that could be a good thing.”

How long it took to work and how long it lasted.

There were differing opinions on how long it took Swedish massage and MFR to take effect and how long it lasted. One massage therapist stated that after a massage that included both MFR and Swedish massage her patients experienced one day of feeling ill and then began to feel relief from symptoms about 24 hours post-massage and this lasted for about 2 to 3 days. The massage therapist explained that the symptom relief does not last as long after the first treatment but after multiple treatments the symptom relief, “often... will extend, it’ll be, you know, one good day and then that will last longer and longer.”

The effects of MFR alone were explained by the other 2 massage therapists. One massage therapist described the immediate effects of MFR that many of his patients experience. He stated, “...they will feel marked improvement most of the time after the first session.” According to one massage therapist the time length of symptom relief is much less with Swedish massage compared to MFR. He stated, “Swedish never lasted more than a couple of days. But the longer I

do myofascial release, the longer the benefits last. People I've been treating for several years now, I might not see but every couple of months." In addition, two of the massage therapists described their general course of treatment using MFR for those with FM. According to one massage therapist,

a healthy patient can come an hour and a half once a week or sometimes at the beginning, I'll see them an hour and a half twice a week for two weeks and then start to spread that out more... sometimes it will go to an hour twice a week and then an hour once a week... some patients start feeling well enough that they don't need to see me at all... I like to taper someone down to seeing me only if symptoms come back or get worse.

The massage therapist who used combination therapy stated that the course of treatment varies with every patient.

General impressions.

There were a number of general impressions about massage and the use of massage in FM expressed by the massage therapists. Four general impressions were repeated by all or at least 2 of the therapists. The first was that massage therapy resulted in a flushing or release of toxins, which could be a cause of the soreness and flu-like symptoms many experience soon after a massage. According to one therapist, FM patient's "...lymph nodes are just loaded up with crap." She went on to say, "Honestly, I think that's their fluish kind of feeling. They're sometimes hurting and I think it may be that, you know, we push a lot of stuff through their lymph nodes and they're just inundated." Another therapist stated, "...they're ill that night, they're ill the next day- too much flushing toxins released into their system."

There was a difference of opinion on the depth of pressure that should be used with FM patients. One therapist believed that light pressure caused a flare of FM symptoms and deep

pressure is preferred in those with FM but the other two felt the opposite was true. One therapist stated, “light pressure often send them... into a flare up” and believed those with FM prefer “deep, even, whole-handed pressure.” The other two massage therapists believe light pressure is preferred by those with FM and deep pressure can cause a flare of symptoms. One therapist stated, “Deep tissue work I found can set off flares of fibromyalgia symptoms and it not to be effective in my own personal treatment.”

Two of the therapist discussed cost as a barrier to the use of massage by those with FM. The massage therapists stated that many of their patients pay out-of-pocket for massage. According to one therapist, the frequency of treatment differs for everyone “especially in this economy, with their ability to pay and their insurance.” Another therapist also said that the frequency of treatment “varies [based] on their budget... none of them are insured right now. They’re all out of pocket.”

Lastly, all agreed that every FM patient is unique and they require individualized treatment. One therapist explained, “everybody is very different. Fibro is unique that way.” This therapist also reported, “there are the people that you’re not able to help at all, but that happens in everything.” Another discussed how she individualizes the treatment for every patient. She stated, “I’ve learned not to make a one size fits all massage, you have to think on your toes every time and be present.”

Discussion

Findings

This study adds novel data to FM literature. First, both MFR and Swedish massage were found to be safe, tolerable, acceptable, and feasible to patients despite tenderness at baseline. Recruitment was completed in less than 2 weeks, which indicates a high interest by the target

population. All of the subjects attended all of the massage visits but only 9 of the 12 subjects had complete data from all 6 data collection points. The questionnaire and visit completion rates were related to the feasibility of the PI also being the project director. The adherence rates for the 4 massage sessions and the lack of adverse events indicate that both interventions were acceptable for the FM patients.

In addition, the results showed that MFR was superior to Swedish massage in improving FM symptoms and function. Also, the Aickin separation test showed that the FIQ-R total change score for those in the MFR group trended in the hypothesized direction compared to the Swedish massage group and future research is warranted.

All of the massage therapists agreed that massage therapy was an effective treatment modality for those with FM. The massage therapists but did not agree in regard to whether MFR was universally superior to Swedish massage for all FM patients.

Context

The findings from both the quantitative and qualitative parts of this study had some similarities and differences compared to the previous studies on Swedish massage in FM and MFR in FM. The study by Sunshine et al. (1996), which had a larger sample size (30 subjects) than this study but a similar dose of therapy, compared Swedish massage to TENS and Sham TENS in those with FM. The results of this study showed significant short-term improvement in dolorimeter scores and short-term significant decreases in anxiety, depression, pain, stiffness, number of nights with difficult sleep, and fatigue after the last therapy session. Unlike this study, the study by Sunshine et al. (1996) did not measure affects of the therapy in a post-intervention visit. Overall, the results of the study by Sunshine et al. (1996) differed from the results of the quantitative portion of the current study, where Swedish massage showed minimal effectiveness.

The findings of this study were similar to what was mentioned by one of the massage therapists interviewed in that Swedish massage could result in a short-term reduction in a number of FM symptoms.

Another pilot study on Swedish massage in FM compared to usual care was conducted by Alnigenis et al. (2001). In the study by Alnigenis et al. (2001), the subjects who were assigned to the massage group had 45 minute Swedish massage treatments delivered using a standardized protocol at weeks 0, 1, 2, 3, 4, 6, 8, 13, 20, and 24 weeks. Attrition in all groups in this study was a problem and after 4 weeks, 24 subjects of the original 37 remained, and after 28 weeks, only 16 subjects remained in the study. It is possible that the drop out rate could be related to the longer length of the study. The results of the study by Alnigenis et al. (2001) showed a trend toward improvements in the RAI, learned helplessness, and AIMS mobility score at week 4, but the improvements did not remain long-term (28 weeks). Similar to the quantitative portion of this study and to what 2 massage therapist shared, the study by Alnigenis et al. (2001) showed that the effects of Swedish massage in regards to improvement in FM symptoms and function are minimal and short-term.

The findings from both portions of this study on the effects of MFR in those with FM were similar to those from previous studies by Castro-Sánchez et al. (2011a, 2011b). The studies by Castro-Sánchez et al. (2011a, 2011b) had a larger sample size (86 and 64 subjects) and treatment dose (30 to 40 hours). In one study by Castro-Sánchez et al. (2011a), 5 of the 64 originally enrolled in the study dropped out prior the end of the study and in the other study by Castro-Sánchez et al. (2011b), 8 of the 94 subjects originally enrolled in the study dropped prior to the completion of the study. The results of both studies by Castro-Sánchez et al. (2011a, 2011b) show that after 20 weeks of MFR, improvements in painful tender points, pain score,

physical function, quality of sleep, quality of life, anxiety level, and clinical severity of disease were achieved. Castro-Sánchez et al. (2011a, 2011b), looked at the long-term effects of MFR in those with FM and found that after one month post-intervention, improvements in anxiety levels, quality of life, quality of sleep, and pain remained. Then, 6 months post-intervention, improvements in quality of sleep, number of painful tender points, pain score, and clinical severity of disease were noted. In Castro-Sánchez et al., (2011b) a decrease in painful tender points, an increase number of days feeling good, and an improvement in clinical severity of the disease remained after 1 year post-intervention. Similar short-term positive effects of MFR were found in this study.

Financial Considerations

Research has shown that the direct medical costs for those with FM are about 2 times the costs for those without FM (Thompson et al., 2011). It was determined by Thompson et al. (2011) that the medical costs over a 4 year period for those with FM were \$15,759 and without FM were \$7,774 (Thompson et al., 2011). Also, the results of this study indicated that those with more severe disease incur significantly higher medical costs compared to those with more mild disease (Thompson et al., 2011).

MFR is costly and is not often covered by insurance in the U.S but the massage therapists interviewed for this study revealed that many FM patients who use MFR are able to space their treatments at increasingly longer intervals. According to the therapists, many people taper down the therapy dose to only at the times they have symptoms and thus there is a potential for a decrease in cost of care with the use of massage and specifically MFR. Future research should assess the cost impact of MFR in those with FM.

Situation Analysis

As with all research projects, this study took much time and effort from all investigators who were involved in the study. The course of the project began with the organization of the data from the quantitative portion of the study that was collected in the previous year. A DNP student and committee member spent time organizing and inputting the data so that it was ready for analysis. This data was then analyzed by a statistician. At this same time, a review of the literature on massage in FM was conducted the DNP student. This took over a month to accomplish because many of the articles had to be ordered through the library. After the literature was reviewed it was determined that the impression of massage therapists in FM treatment had not been studied. A proposal to interview massage therapists who use MFR and Swedish massage in the treatment of FM patient to add to the quantitative data was written, presented, and approved. After hearing from the IRB, massage therapists were recruited and the interviews were conducted by the DNP student. It took over a month to do all of the interviews because of time conflicts. Then the DNP student and two doctorally prepared nurses on the committee reviewed the transcribed interviews to determine common themes and form categories of themes. The researches met as a group three times over a month long period to discuss this analysis. The DNP student then wrote up a final report with the results from both the quantitative and qualitative portions of the study.

Multiple lessons were learned during this research process. First, I learned to allot many months for the literature review process and IRB review process. Second, it is important for the statistician to specify how they would like the data inputted so that the necessary data can be easily found. Third, conducting even a small research study without a project director and with limited funding can be time consuming and difficult. Fourth, transcribing interviews is a long process and a transcription services is worth the investment but the transcripts should be

compared to the recordings to ensure accuracy. Lastly, it takes much skill to elicit data in qualitative research and assistance from those skilled in qualitative data analysis is essential. Lastly, peer review is an essential part of the analysis process.

Limitations

There are many limitations in this study that must be mentioned. The first was that this was a small convenience sample. There were 12 participants in the quantitative portion of the study and 3 in the qualitative portion. In addition, the study was limited by a lack of randomization. Also, the lack of a long-term follow-up (1 month or longer post-intervention) was another limitation to this study. Lastly, the short duration of treatment, a total of 6 treatment hours compared to 30-40 treatment hours in the studies by Castro-Sánchez et al. (2011a, 2011b) was another limitation of this study. Nonetheless, the dose tested in this study did reveal clinically significant differences between massage techniques indicating that a shorter course of treatment may be effective. Due to the limitations of this study, further research on MFR in FM should be conducted before generalizing the results to all FM patients.

Conclusions

The current therapies for FM are limited, costly, associated with a number of side effects, and lack efficacy. Massage is commonly used as an adjunctive therapy to help minimize the debilitating symptoms associated with FM and maximize physical functioning. The results of this study show promise that both Swedish massage and MFR are acceptable, tolerable, and safe therapies for those with FM. The results also show that MFR was superior to Swedish massage in improving symptoms and function in those with FM. In addition, the Aickin separation test showed that the FIQ-R total change score for those in the MFR group trended in the positive direction compared to the Swedish massage group and that future research is warranted. Also, all

of the massage therapists agreed that massage therapy was effective in those with FM but they were not in agreement as to whether MFR was universally superior to Swedish massage for all FM patients. Future studies should include randomized controlled trials on MFR in FM with a longer follow-up period. Mechanistic studies should be conducted to further determine the role of fascia as a peripheral pain generator that leads to central sensitization in FM and the affect of MFR on fascia. Also, further qualitative research that includes interviews of both the patient and therapists with a larger sample size should also be conducted. A more in-depth exploration would be valuable to better understand the lived experience of those with FM who use massage therapy for symptom management. Overall, the results of the study show promise that MFR could help those with FM by minimizing their symptoms, maximizing their physical functioning, and ultimately improving their quality of life.

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Table 1

Interview Questions

Question number	Question
1	Tell me about your experiences treating people with fibromyalgia.
2	What types of massage techniques have you found to be more effective for treating fibromyalgia patients?
3	Based on your experiences with working with people with FM, how would you compare Swedish massage and Myofascial release therapy for symptom/pain relief?
4	Tell me about patients' positive and negative responses after treatment with Swedish massage? With myofascial release therapy?
5	What is a typical course of treatment based on Swedish massage?
6	What is a typical treatment course using myofascial release therapy?
7	What have you learned from treating people with fibromyalgia?
8	Is there anything that you would like to add about massage therapy and fibromyalgia?

Note. Structured interview guide question.

Table 2

Timeline for project

Month(s)	Activity
August, 2011	Literature Review, Write Proposal, Input data from Quantitative portion of the Study
September, 2011	Write Proposal, Meet with Dr. Kristin Lutz and Dr. Cheryl Wright to discuss interview guide, Analyze Quantitative Data
October, 2011	Proposal Defense
November, 2011	Apply for IRB
December, 2011	Conduct Interviews
January, 2011	Transcribe Interviews, Analyze Qualitative Data
February, 2011	Analyze Qualitative Data (includes meetings with Dr. Kim Jones and Dr. Cheryl Wright discuss data analysis), Poster Presentation of preliminary data at OHSU P.A.I.N day
March, 2011	Write Results and Discussion Section and Send to Committee for Review, Poster Presentation at WIN Research Conference
April, 2011	Finalize Final CIP Report and Presentation
May, 2011	Finalize Final CIP Report and Presentation,

Turn in Final CIP Report May 9th, Present CIP
on May 23rd

Note. Timeline for clinical inquiry project.

Table 3

Demographic data from both intervention groups

Demographics	% of subjects
Marital Status	
Married/domestic partnership/long-term live-in partner	50
Divorced/Separated	30
Never married	20
Race	
Caucasian	100
Hispanic	20
Education Level	
High school	20
Trade/technical school/community college	20
Some College	30
College	10
Post-graduate education	20
Income	
< \$9000	20
\$40,000-\$49,000	20
\$50,000 - \$59,999	20
\$60,000-\$69,999	10
\$70,000-\$79,000	20
\$100,000-\$199,999	10
Length of time with FM symptoms	
1 to 5 years	60
6 to 10 years	10
> 10 years	30
Length of time since diagnosis	
0 to 6 months	20
7-12 months	10

13 months- 4 years	50
5 to 10 years	10
> 10 year	10
Trigger for FM	
Motor Vehicle Accident	40
Viral illness	10
Other physical trauma (e.g. fall or injury)	20
None	30
Comorbid conditions	
TMD	40
Endometriosis	20
Migraine	50
Sleep Apnea	30
Restless leg	20
interstitial cystitis	10
IBS	50
Diabetic neuropathy	10
Arthritis	10
Tried Massage in the past	
Yes	90
No	10
Experience with massage	
Massage made pain worse during and after massage	10
Pain relief during but benefits last only a few hours	70
Pain relief during and pain relieving effect lasted for several weeks	10

Working Status	
Yes	50
No	50
Disability Benefits	
Yes	10
No	90
Smoking Status	
Former Smoker	30
Current Smoker	0
Non-smoker	70

Note. Demographic data from the 10 subjects who completed the questionnaire

^a All subjects had more than one comorbid condition

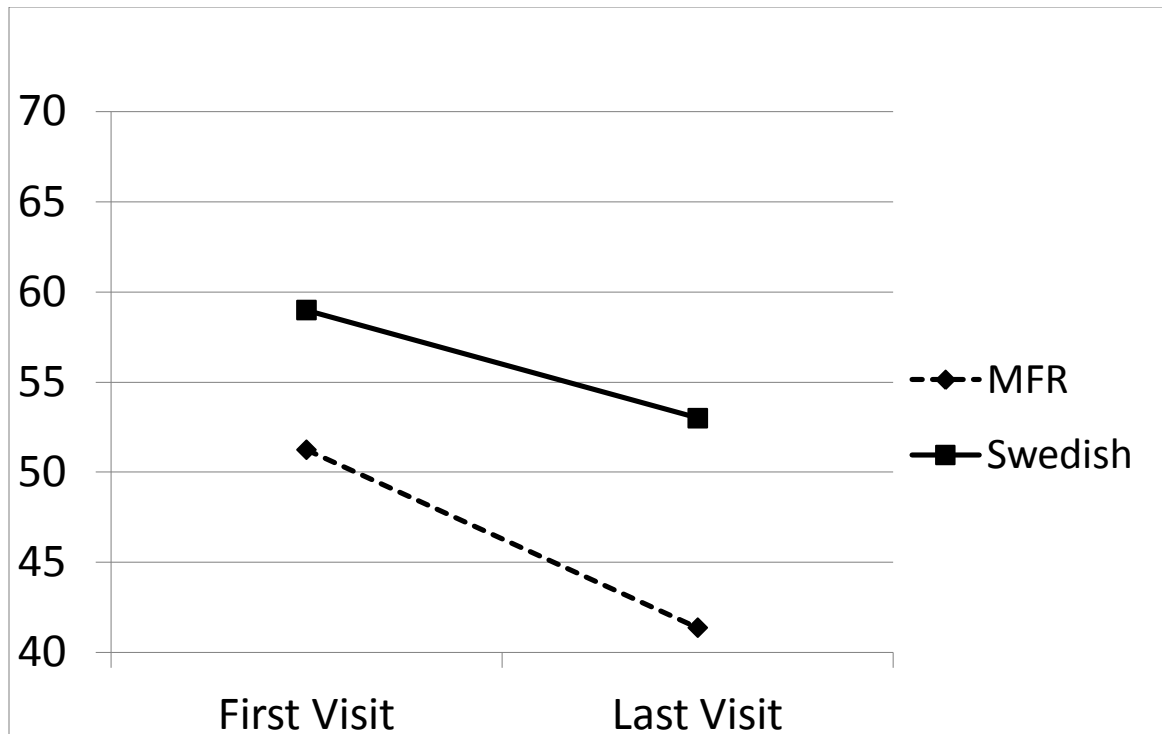


Figure 1. Mean FIQ-R from both groups from first and last visit.