

Massage Therapy Research Fund (MTRF)



Project Report - FINAL

Current Date:	Sept. 8, 2015
Project completion deadline:	April 30, 2015.
Extension granted:	June 30, 2015
Project Title:	The effects of massage therapy on the anxiety and sleep quality of individuals with fibromyalgia: A pilot study.
Amount of grant:	\$17,850
Year grant awarded:	2013
Institution:	Bishop's University
Principal Investigator (name only):	Fuschia Sirois
Co-Investigators (names only):	Anne Lebrun, Andrea Drumheller, Helene Cloutier, Nadia Savard

THE REPORT CONTENT:

Section 1 - Project overview. Please devote a maximum of one page to background, rationale and objectives, with the balance to focus on methods and outcomes. (maximum 4 pages).

Section 2 - Did the project take place as proposed? If not, briefly indicate difficulties encountered and adaptations made (maximum 1 page).

Section 3 – Information dissemination. Please provide the information dissemination plan related to the project findings. Please list all completed activities and planned activities (manuscripts, reports, conference presentations, seminars, workshops etc).

Section 4 - Project summaries. Please provide two project summaries, as follows:

- a) Lay language summary (maximum 100 words)
- b) Scientific abstract (maximum 250 words)

**Submitted the completed final report to Ania Kania-Richmond at
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Section 1 - Project overview. Please devote a maximum of one page to background, rationale and objectives, with the balance to focus on methods and outcomes. (maximum 4 pages).

BACKGROUND | Although many people with fibromyalgia (FM) turn to massage therapy (MT) as a treatment choice (Kalichman, 2010), current evidence is limited but promising regarding the effectiveness of MT for treating fibromyalgia (Tsao, 2007) and the nature of its effects (Kalichman, 2010). As a chronic pain syndrome, the key symptoms of FM include muscle pain, fatigue, and tender points (Wolfe et al., 2010). Sleeping difficulties and cognitive problems including memory issues (i.e., “fibro fog”) are common in up to 70% of patients (Katz, Heard, Mills, & Leavitt, 2004), and can detrimentally impact psychological and physical well-being (Miró et al., 2011) and lead to emotional distress and anxiety (Thieme, Turk, & Flor, 2004). As well, poor sleep and fatigue belong to the diagnostic criteria of FM (Wolfe et al., 2010), and patients with FM have poorer sleep quality than the general population due in part to the pain and anxiety that they experience (Munguia-Izquierdo & Legaz-Arrese, 2012).

A review of research on the effectiveness of MT in the treatment of FM found some support for the short-term benefits of MT for reducing pain and fatigue, and improving mood and health-related quality of life (Kalichman, 2010). However, this evidence was limited by methodological issues as many studies had no control group, and no follow-up assessment. The potential benefits of MT for the sleep dysfunction and anxiety in fibromyalgia patients has not been fully examined. For example, although Sunshine et al., (1996) found that MT was effective for improving sleep quality, the number of nights of difficult sleeping was assessed rather than taking a more comprehensive assessment. Other research has demonstrated the beneficial effects of MT over 5 weeks for improving pain, sleep quality and anxiety symptoms in FM (Field et al., 2002) and other pain syndromes (Field, Hernandez-Reif, Diego, & Fraser, 2007). If the ultimate goal of FM management is to ameliorate a spectrum of symptoms including fatigue, disrupted sleep, pain, mood and anxiety to restore functionality and improve quality of life (Arnold, 2009), then MT is a promising treatment option to help achieve this goal.

RATIONALE | A growing literature supports the interconnectedness of pain, anxiety, and sleep quality in patients with FM in particular, and the potential effectiveness of MT for improving these health-related outcomes (Field et al., 2002; Field et al., 2007). Despite the known associations between pain, anxiety, and sleep quality in FM (e.g., Miró et al., 2011), we know little about the ways in which MT may lead to such improvements. It is possible that improved sleep quality is an intermediate outcome of MT’s pain-reducing effects that explains reductions in anxiety symptoms, or conversely that reduced anxiety and especially pain-related anxiety is the intermediate outcome that explains improved sleep quality. It may also be that there is a more dynamic and synergistic relationship between sleep quality and anxiety whereby improvements in each enhance the improvements of the other as a result of MT’s effects on pain and together these outcomes improve quality of life.

OBJECTIVES | This pilot study aims to 1) examine the effects of an 8-week course of Swedish massage on the general and pain-related anxiety symptoms and sleep quality of individuals with FM, 2) explore the ways in which these effects may be related by testing intermediate outcomes and synergistic outcomes models, and 3) investigate the more general effects of MT on these outcomes for improving health-related quality of life and psychological well-being.

RESEARCH DESIGN AND METHODOLOGY | We conducted a two-arm (treatment + wait list control) partial cross-over, mixed between and within subjects design to study of the effects of 8-weeks of Swedish massage on the physical (sleep quality) and psychological (anxiety, quality of life) well-being of FM patients. Baseline and weekly measures of fibromyalgia quality of life, state and pain-related anxiety, mood, and sleep quality were administered to assess potential post-massage benefits. A post-treatment survey assessed any potential changes due to treatment, and an interview will further assess participants' perceptions of MT treatment for their fibromyalgia symptoms. An 8 week follow-up survey assessed any lasting treatment benefits.

Participants and Procedure: Fifty-three participants were recruited from the L'Estrie community through ads placed in local newspapers, via flyers distributed throughout the region, and through the Association de la fibromyalgie de l'Estrie (FM L'Estrie), the regional fibromyalgia association. All materials for this study were made available in English and French. Potential participants were screened to determine their suitability for the study. Those who met the inclusion and exclusion criteria were scheduled for the baseline assessment, after which they were assigned to either the wait list control or the treatment group. Only people who had been formally diagnosed with fibromyalgia by a physician were qualified to participate.

Massage Therapy Protocol: The MT sessions were conducted in the therapists' private therapy rooms off campus. Each session lasted 60 minutes and intensity of the massage was varied according to the client's pain levels. One participant found the massages to be too painful by week 2 and temporarily dropped out from the study. However, on advice of her physiotherapist she rejoined the study and found that the sessions became more manageable as time went on.

Measures: In addition to demographic questions, a measure of current health problems, coping efficacy, and questions about the use of other CAM modalities, the baseline, weekly and post-test surveys included the following outcome measures.

Sleep quality: The Pittsburgh sleep quality index (PSQI; Buysse, Reynolds III, Monk, Berman, & Kupfer, 1989) is a well-validated multi-dimensional measure of sleep quality with good diagnostic sensitivity and specificity.

Anxiety: General state anxiety was assessed with the State-trait anxiety scale, state form (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), a well-validated, widely used, and sensitive measure of transitory anxiety. Pain-related anxiety was assessed with the short version of the Pain Anxiety Symptoms Scale (PASS-20; McCracken & Dhingra, 2002), a reliable and well-validated measure of fear and anxiety responses specific to pain.

Fibromyalgia-related Quality of Life (FMQoL): FMQoL will be assessed with the Revised Fibromyalgia Impact Questionnaire (RFIQ; Bennett et al., 2009), a well-validated brief measure of fibromyalgia patients' health-related quality of life that can be completed in 2 minutes. It includes questions regarding pain, fatigue, physical functioning, and overall fibromyalgia symptoms that provided an assessment of FM symptom severity. A single item global health rating of overall health from the SF-36 was also included.

Mood: An assessment of general psychological well-being via the positive and negative affect schedule (PANAS; Watson, Clark, & Tellegen, 1988) provided an alternative means to measure changes in quality of life as a result of the MT. The PANAS is a reliable and valid measure of current mood states.

OUTCOMES | Although the initial plan was to recruit 40 participants we were able to recruit a total of 53 participants with the help of small top-up grants from internal sources at Bishop's

University. This sample excludes 3 participants who dropped out of the study permanently due to health and personal reasons unrelated to the massage treatments they received.

Our analyses for this report focuses on using multi-level modelling to better detect any of the hypothesized changes in mood, sleep, pain, anxiety, and well-being. Set up of the data files for this very sophisticated analyses is very time consuming. Although we were able to prepare some of the data for this analyses in order to present it at IN-CAM last year, the newer data has not yet been added as it will require a complete reorganization of the data files. Accordingly the results reported here are those from a subsample ($N= 37$) for which the analyses files were complete, and focus on the treatment arm of the study for the control and treatment groups, rather than on comparisons between treatment and control groups. The analyses also focus on one of the outcome measures, the FIQR, as well as a global measure of adjustment, coping efficacy.

Thirty-seven individuals screened for self-reported diagnosis of fibromyalgia (95% female, M age = 53.64 ± 10.7 years) and randomly assigned to an 8-week wait-list control ($N = 16$) or treatment group ($N = 21$), completed the baseline, weekly and post-treatment measures of fibromyalgia-related well-being and symptoms.

Multi-level modeling analyses of the effects of weekly massage therapy treatment on a subset of the variables of interest revealed significant improvements over time in coping with fibromyalgia and fibromyalgia -related well-being (FIQR scores), including attenuation of the intensity, difficulty, and impact of fibromyalgia symptoms. See Figures 1 and 2 below for detailed results.

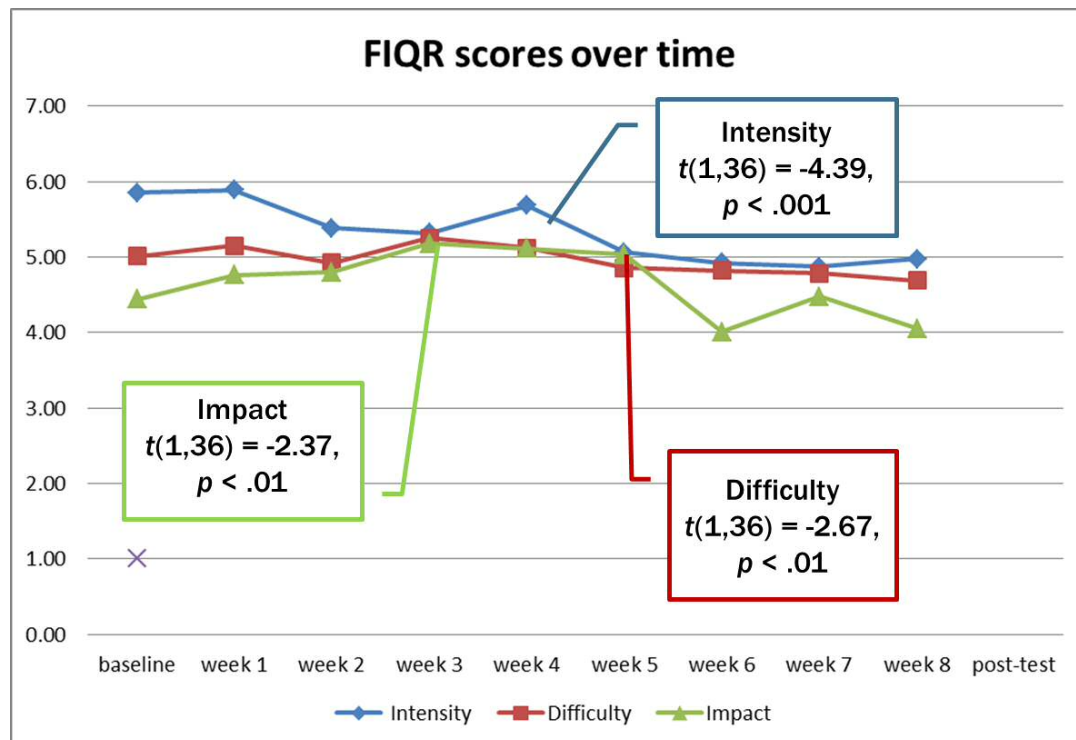


Figure 1: Preliminary results from the multi-level modelling analyses showing decreases in fibromyalgia symptom impact, intensity, and difficulty (FIQR subscale scores; scores range

from 1 to 7) over the 8 week course of massage therapy. Visual inspection of the graph suggests that most decreases occurred after week 3 of treatment.

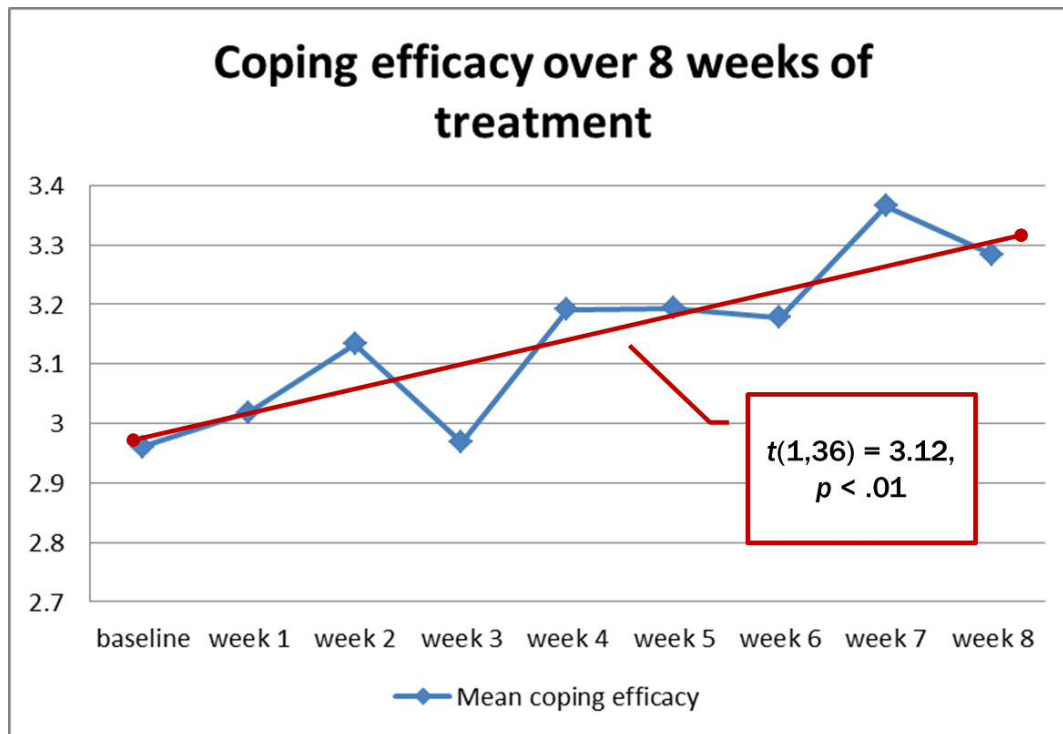


Figure 1: Preliminary results from the multi-level modelling analyses showing increases in coping efficacy scores for fibromyalgia over the 8 week course of massage therapy (scores range from 1 to 5). The sloped red line has been added to show the average rate of increase in coping efficacy.

As coping efficacy captures an overall sense of being able to better manage fibromyalgia symptoms, the findings suggest that the massage therapy treatments empowered the participants to feel more capable of managing their symptoms, regardless of whether they improved or not. This psychological measure of adjustment and improvement is important as it may translate into patients taking a more active role in the management of their condition rather than feeling like a victim to the constant pain.

Nonetheless, the improvements in the FIQR scores suggests that more objective improvements in symptoms were experienced by the participants, as the fibromyalgia symptoms were less troubling overall across the 8 weeks of the massage therapy treatments.

The next step in the analyses will be to conduct a more stringent tests not only with the entire sample, but also by comparing the control to the treatment group in both within and between subjects analyses across a more comprehensive set of outcomes including pain and sleep quality.

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Occasionally, due to vacation schedules for the massage therapists or the participants, we had to assign participants in a non-random manner to either the treatment or control group. However, we have continued to match participants within the treatment and control groups as best as possible.

Aside from this minor adjustment, the study was conducted as planned.

Section 3 – Information dissemination. Please provide the information dissemination plan related to the project findings. Please list all completed activities and planned activities (manuscripts, reports, conference presentations, seminars, workshops etc).

Our information dissemination plan involved communicating results from this research within and outside of the academic communities, both locally and more broadly at the national and international levels. To this end we have successfully presented our preliminary findings in the form of two talks at a professional CAM conference, the biennial IN-CAM Research Symposium 2014 (see list below), with a target audience of both massage therapy practitioners and researchers. We also gave a talk for Research Week at Bishop’s University which was open to the public.

As data collection was only completed late Spring, we are still in the process of analyzing the data to compile a final report which will be made available to local stakeholders from the L’Estrée Fibromyalgia Association.

Once the rather complex analyses are complete we plan to submit at least 2 -3 papers based on the findings to scholarly CAM journals such as the Journal of Complementary and Alternative Medicine, to Rheumatology and pain journals such as Pain, and to health psychology journals such as Psychology and Health.

Public Lecture

Sirois, F. M. (2014, March). *The effects of massage therapy on the executive functions, physical and psychological well-being of individuals with fibromyalgia: Preliminary findings from a pilot study.* Invited talk for the 9th annual Research Week, Bishop’s University, Sherbrooke, QC.

Conference Papers

Sirois, F. M., Drumheller, A., & **Lebrun, A.** (2014, November). *Harnessing the power of the few: Multilevel modeling for assessing complementary and alternative medicine (CAM) treatment effects in pilot studies.* Paper presented at the 8th Annual IN-CAM Symposium, Calgary, AB.

Sirois, F. M., **Lebrun, A.,** Drumheller, A., Cloutier, H., **Pepin, E.,** **Barlow, M.,** & Savard, N. (2014, November). *“When you have less pain you have more energy”: Preliminary findings from a pilot study on the effects of massage therapy on the well-being of individuals with fibromyalgia.* Paper presented at the 8th Annual IN-CAM Symposium, Calgary, AB.

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Lay Summary

In addition to pain, people with fibromyalgia experience sleep disturbances, anxiety, and poor quality of life. This study examined the effects of 8 weeks of massage therapy on the sleep quality and anxiety and symptoms of fibromyalgia patients, and its associated benefits for psychological well-being. The preliminary results suggest that massage therapy is beneficial for improving the impact of symptoms on daily functioning for fibromyalgia patients and for empowering patients to be better able to cope with the troubling symptoms of this painful condition.

Scientific Abstract

Although many people with fibromyalgia turn to massage therapy (MT) to help manage symptoms, current evidence is limited but promising regarding the effectiveness of MT for fibromyalgia, and the nature and extent of its effects. The aim of this pilot study was to quantitatively examine the effects of an 8-week course of Swedish massage on the general and pain-related quality of life of individuals with fibromyalgia, as well as examine the implications of MT for overall psychological well-being. The effects of MT for treating fibromyalgia symptoms were investigated in a pilot study with a two-arm (treatment + wait list control) cross-over, mixed methods, repeated measures design. Fifty-three people screened for fibromyalgia completed the study. Preliminary results are reported for 37 individuals with fibromyalgia (95% female, M age = 53.64±10.7 years) who were randomly assigned to an 8-week wait-list control ($N = 16$) or treatment group ($N = 21$). All participants completed baseline, weekly and post-treatment measures of fibromyalgia -related well-being and symptoms. Analyses focused on the treatment arm of the study for the control and treatment groups. Multi-level modeling analyses of the effects of weekly MT treatment revealed significant improvements over the 8 week course of MT treatment in coping with fibromyalgia and fibromyalgia-related well-being, including attenuation of the intensity, difficulty, and impact of fibromyalgia symptoms. These preliminary findings provide suggestive evidence that MT is associated with self-reported changes in functioning and well-being in people with fibromyalgia.