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Overall Function and Symptom Impact of Self-Applied Myofascial Release in Adult Patients with Fibromyalgia: A Seven-Week Pilot Study

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***Abstract*—**Fibromyalgia is a chronic condition characterized by widespread musculoskeletal pain, fatigue, and reduced function. Management of symptoms include medications, physical treatments and mindfulness therapies. Myofascial Release is a modality that has been successfully applied in various musculoskeletal conditions. However, to the author's best knowledge, it is not yet recognized as a self-management therapy option in Fibromyalgia. In this study, we investigated whether Self-applied Myofascial Release (SMR) is associated with overall improved function and symptoms in Fibromyalgia. Eligible adult patients with a confirmed diagnosis of Fibromyalgia at Women's College Hospital were recruited to SMR. Sessions ran for 1 hour once a week for 7 weeks, led by the same two physiotherapists knowledgeable in this physical treatment modality. The main outcome measure was an overall impact score for function and symptoms based on the validated assessment tool for fibromyalgia, the Revised Fibromyalgia Impact Questionnaire (FIQR), measured pre- and post-intervention. Both descriptive and analytical methods were applied and reported. We analyzed results using a paired t-test to determine if there was a statistically significant difference in mean FIQR scores between initial (pre-intervention) and final (post-intervention) scores. A clinically significant difference in FIQR was defined as a reduction in score by 10 or more points. Our pilot study showed that SMR appeared to be a safe and effective intervention for our fibromyalgia participants and the overall impact on function and symptoms occurred in only 7 weeks. Further studies with larger sample sizes comparing SMR to other physical treatment modalities (such as stretching) in an randomized control trial (RCT) are recommended.

***Keywords*—**Fibromyalgia, myofascial release, fibromyalgia impact questionnaire, fibromyalgia assessment status.

I. Background

FIBROMYALGIA is a chronic condition characterized by generalized musculoskeletal pain and fatigue affecting daily functions. Between 2-4% of the population, mostly women, suffer from this condition [1]. As there is no specific test, diagnosis is based on symptoms meeting diagnostic criteria for fibromyalgia [2]. Although we do not know the exact cause of this condition, we know that multiple myofascial trigger points (areas of mechanical hypersensitivity) can reproduce the pain pattern in fibromyalgia, suggesting that these trigger points may contribute to central sensitization in Fibromyalgia Syndrome [3].

Myofascial release was first described by Andrew Still Taylor, physician-founder of osteopathic medicine in the late 1800s [4]. Although more detailed in osteopathy texts [5], we can define myofascial release as the application of varying degrees of pressure to contracted muscles and fascia to release restrictions, reduce pain and restore function [6]. Mechanistically, excessive tension in fascial trigger points leads to musculoskeletal pain and restricted function [7]. Because of fascial interconnections, the impacts can be felt in multiple areas of the body.

In general, the literature has reported implementation of myofascial release (MFR) as a passive modality. A study comparing fascial release to Swedish massage found MFR to be superior for pain reduction [8]. Similarly, a RCT comparing MFR to sham ultrasound therapy found significant improvement in pain, function, and overall severity of fibromyalgia symptoms in the MFR group [9]. Only one study assessed self-applied MFR in fibromyalgia and found it improved health-related quality of life [10].

Research Question

Does SMR have an impact on overall function and symptoms in adult (18-65 years of age) patients with fibromyalgia, and how many weeks of intervention will it take to note this impact?

II. Methods

Population of Interest and Sampling Methods

Our population of interest were adult patients with fibromyalgia, a syndrome diagnosed mostly in women, although it can also affect men. A sample of the population was recruited from two clinics (Pain Clinic, Environmental Health Clinic) at Women's College Hospital in Toronto, Canada. As severity varies from mild to severe, participants from general and specialized practice would be representative of the general adult population with fibromyalgia. However, diagnosis bias (i.e., male patients with fibromyalgia but not diagnosed due to physician bias/practice differences), may result in our sample being more or less representative of other practice communities.

Inclusion criteria to participate in our study were: 1) adult 18-65 years; 2) confirmed diagnosis by physician documented by diagnostic criteria for fibromyalgia [11]. Exclusion criteria were: 1) children and elderly; 2) pregnancy - due to unknown effects; 3) POTS (postural orthostatic tachycardia syndrome) - due to risk for fall injury; 4) recent/unhealed fracture within 6

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months of study start date. It should be noted that these exclusions were precautionary measures and do not necessarily reflect an inherent risk of MFR therapy.

Diagnostic criteria for fibromyalgia require either: 1) chronic (more than 3 months) widespread pain index (WPI) of at least 7 and symptom severity score (SSS) of at least 5 or 2) chronic WPI of 3-6 and SSS score of at least 9. The self-reported criteria correctly identify 88% of fibromyalgia cases based on the American College of Rheumatology (ACR) classification [11] and its use has been validated in research studies [12], [13].

Potential bias includes self-selection by more motivated participants who may have more severe symptoms than the average patient with fibromyalgia. To mitigate this bias, we compared everyone's initial FIQR [14] scores to their final FIQR scores, as well as the mean scores for all study participants from pre- to post- intervention.

Intervention

Participants recruited into our study met eligibility criteria. This included confirmed diagnosis of fibromyalgia based on validated diagnostic criteria, which should have reduced misclassification bias. There were no exclusions for severity of condition, existence of co-morbidities, or use of other treatment modalities.

In our SMR pilot study, participants were guided to place a therapy ball (different sizes and firmness available) on a trigger point area; then to slowly sink body weight onto the ball as tolerated and maintain pressure for several minutes until the trigger point area relaxed or 'released.' Pressure was controlled/ adjusted by participant, as was the length of time needed to release muscle and fascial tension. Options included standing, sitting or supine positions to accommodate varying abilities and reduce confounding bias based on severity of condition.

Outcomes

The study outcomes were measured using a self-administered questionnaire called FIQR [14]. This tool is a composite score of overall functional impact of Fibromyalgia symptoms. In the score, there are three domains, each with a rating scale between 0 to 10 reflecting 'never' to 'always' in the preceding 7 days: 1) function domain (consists of nine questions, such as difficulties in climbing a flight of stairs); 2) overall impact domain (consists of two questions about general impact, such as fibromyalgia symptoms preventing patient from accomplishing goals for the week) and; 3) symptoms domain (consists of 10 questions, such as intensity of pain or fatigue).

In previous studies, the average FIQR score for fibromyalgia patients was shown to be 56.6 ± 19.6 with a median score of 58. FIQR has been verified for construct validity (good correlation with SF-36) and internal consistency, indicating that the domain questions measure the same construct [14]. The composite score gives 30% weight to function domain, 20% to overall domain, and 50% to symptoms domain, with a maximum score of 100. Although other self-assessment tools exist (such as FAS - Fibromyalgia Assessment Status and NRS - Numerical Rating Scale for Fibromyalgia), we chose FIQR as the primary tool because it reliably distinguishes the impact of Fibromyalgia from other similar conditions such as Rheumatoid Arthritis and Major Depressive Disorder [14], [15]. It can also be completed by patients in several minutes and is relatively easy to score.

Potential biases include measurement bias, which we have reduced by clearly defining: the intervention (SMR) and the outcome (mean change in FIQR score from pre to post intervention). As FIQR is a self-assessment tool rather than an objective measurement, it can be prone to measurement bias.

To reduce recall bias, FIQR was be obtained within a week of start/end dates of the intervention, thus reflecting pre and post overall status. To reduce reporting bias (influenced by the presence of a research team or setting), participants were asked to complete the self-administered FIQR at home and to bring these to the first session and/or mail them to our clinic (no personal identifying information).

III. Results

Five female participants were recruited into the study. Three of the five were employed or self-employed. One participant was unable to continue after the third session for personal reasons, thus only four participants completed the sessions until the end of the seventh session. All the participants were either married or in a domestic partnership and the average age was 46.4 years. All four participants completed at least 6 of the 7 sessions.

Three Fibromyalgia self-assessment questionnaires were completed at initial (before start of intervention), mid (before start of fourth session), and final (after the end of the seventh session). The three questionnaires were: FAS, FIQR (Fibromyalgia Impact Questionnaire Revised), and NRS (Numerical Rating Scale) for Fibromyalgia. See graphs in Figs. 1-3 for the trend in scores.

A paired t-test was performed, comparing the pre- and post-intervention mean scores of the three self-rated questionnaires. Although all the self-assessment questionnaires showed a clinically significant improvement in function and symptom scores (see Figs. 1-3), there was no statistically significant difference in the pre- and post- mean scores due to the small number of participants. The difference between pre- and post- means, SD, t-values and probabilities were as follows: FAS mean score reduction 2.05, SD 2.13, $t = 1.92$, $p < 0.15$ (Fig. 1); FIQR mean score reduction 15.43, SD 13.88, $t = 2.2$, $p < 0.11$ (Fig. 2); NRS mean score reduction 10, SD 13.58, $t = 1.47$, $p < 0.23$ (Fig. 3).

Analysis

We determined, based on other studies as well as our own pilot study, that a 10 point mean difference in the FIQR score with a variance of 5 points in the FIQR scale (maximum of 100 points, in which the mean scores in Fibromyalgia are around 60/100) is a clinically significant (meaningful treatment) difference or effect. Three of the four participants in our pilot study achieved at least a 10-point reduction in the FIQR score. We noted that the average initial FIQR score in our study was higher (75/100) than the reported average in the literature.

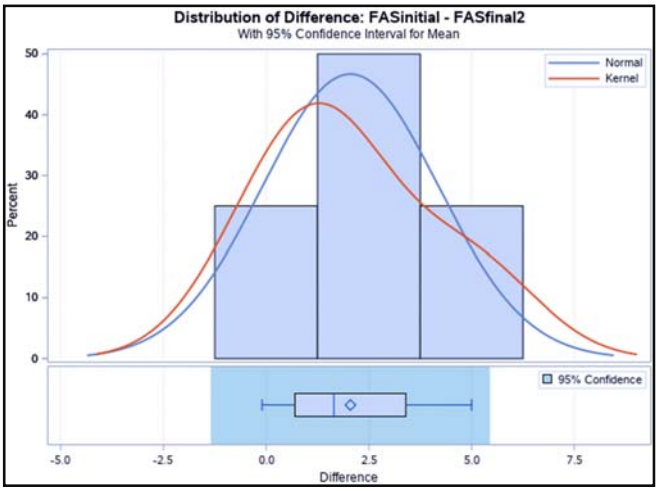

Fig. 1 (a) Distribution of the mean difference between the pre- and post-FAS in our pilot study

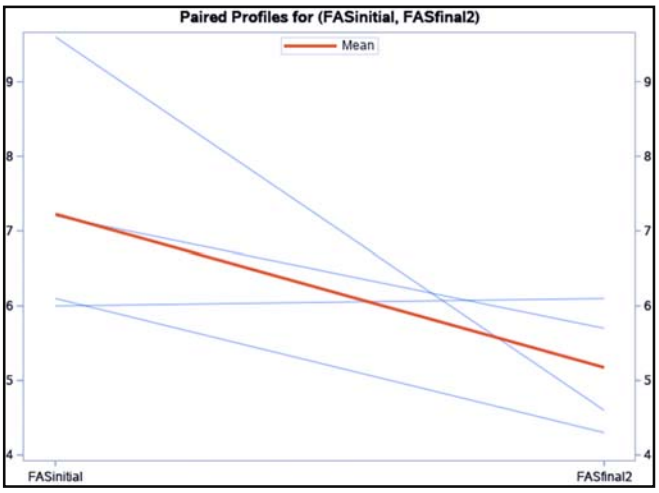

Fig. 1 (b) Plot illustrating a mean score reduction of 2.05 (SD 2.13, t = 1.92, p < 0.15) in the FAS after implementing Self- MFR for 6 weeks

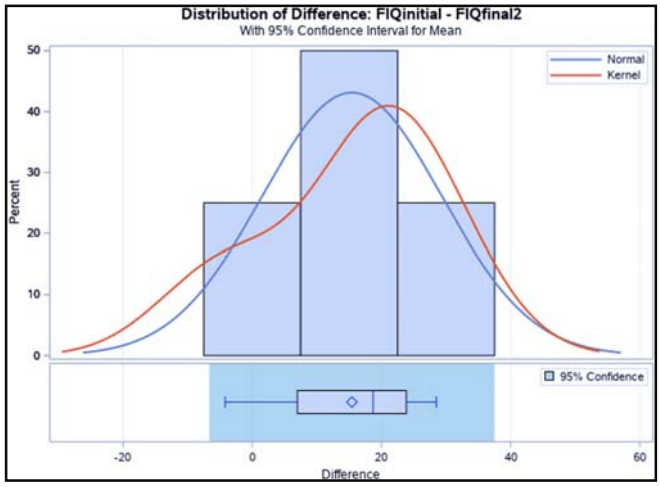

Fig. 2 (a) Distribution of the mean difference between the pre- and post-FIQR

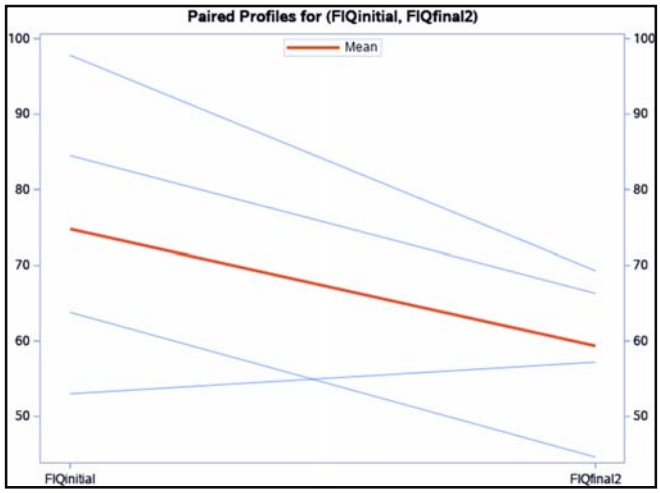

Fig. 2 (b) Plot illustrating a mean score reduction of 15.43 (SD 13.88, t = 2.2, p < 0.11) in the FIQR after implementing Self- MFR for 6 weeks

To avoid bias in data analysis, we clearly defined the primary endpoint (the mean difference in FIQR scores between initial and final scores). In order to avoid bias in data interpretation, statistical tests were interpreted based on pre-defined statistical and clinical significance values. As we were comparing the means of scores (continuous measures) between two-time intervals, we used the 2-sided Student's T-test as our statistical method. Our sample size calculation, based on an alpha of 0.05 and a power of 80%, with a variance or SD of 5 and a clinically significant size effect of 10-point difference, we would have needed 16 people. Unfortunately, we only recruited five participants, with four participants completing the intervention.

Limitations

The potential threats to validity in this study are the subjective nature of self-assessment tools. As there are no objective function-symptoms tests to measure outcomes, we relied on accurate self-reporting, but interpretation of severity varies from person to person. Some individuals will rate their difficulties either lower or higher, depending on their own perceptions and related to mood. Another limitation in our study may have been logistics (i.e., time availability, travel distance to attend sessions, weather issues, pandemic restrictions). In future studies, this limitation may be overcome by making sessions available remotely, through live webcast and/or videorecording.

In addition, our study did not compare SMR to another intervention, such as stretching, flexibility, resistance, or other commonly employed therapeutic exercises in the management of Fibromyalgia [16]-[20].

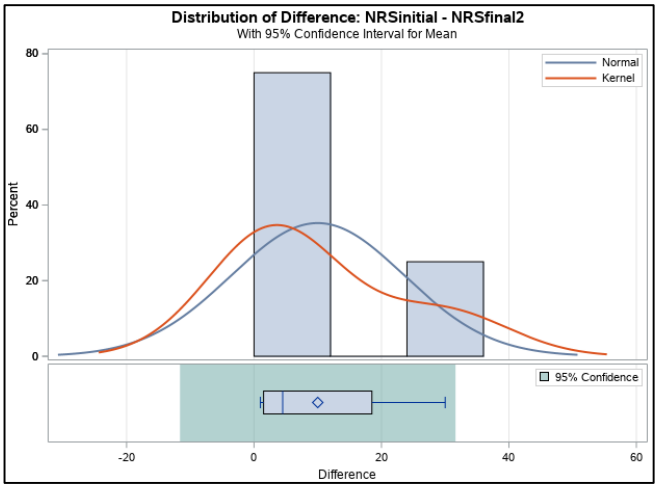

Fig. 3 (a) Distribution of the mean difference between the pre- and post- Numerical Rating Scale (NRS) for Fibromyalgia

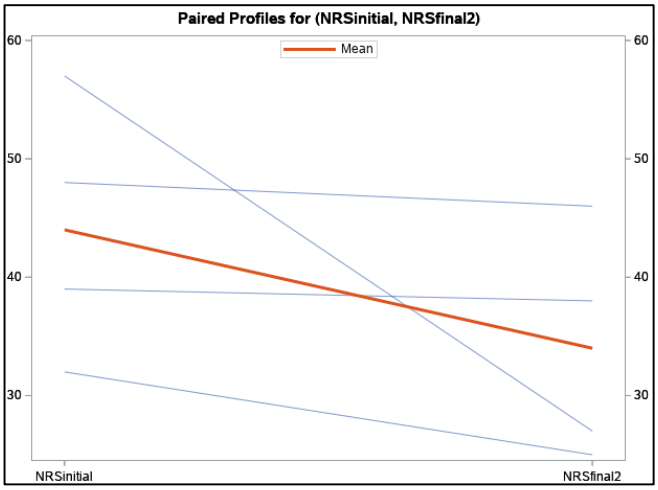

Fig. 3 (b) Plot illustrating a mean score reduction of 10 (SD 13.58, t = 1.47, p < 0.23) in the NRS after implementing Self- MFR for 6 weeks

Feasibility

Our pilot (proof of concept) study using this technique showed that SMR was safe (no adverse events), relatively easy to learn, and feasible to do independently (all participants had invested in their own therapy balls by the third session to use at home, even though an assortment of therapy balls were available at the sessions). We also realized from this pilot study that we did not require the original 12 weekly sessions to see benefit, as we noticed improvements in scores by the 6th week. It should be noted that, should in-person sessions not be feasible in future studies due to continued COVID restrictions, we propose video-taped sessions.

Significance

Fibromyalgia is a chronic, often disabling condition and many sufferers rely on multiple medications, with associated risks and side effects. Chronicity of the condition impacts both health care system costs as well as patients' finances. Given health resource limitations, we need safe and effective self-management strategies, such as SMR.

In osteopathic medicine, it is believed that MFR can address dysfunctional restrictions [21]. MFR may be able to reduce pain signals and restore function in this central sensitivity syndrome [21], [22]. As 90% of the 18 predetermined tender points in Fibromyalgia are myofascial trigger points [22], the implications for impact of this treatment modality are worthy of further study.

SMR can be learned relatively quickly and applied anywhere. It can be done while sitting, standing or supine on a mat. The level of pressure is controlled/adjusted by the user. It reduces pain and restores function in many musculoskeletal conditions. Should SMR prove to be effective in a future Randomized Controlled Trial (RCT), it will be a powerful addition to the therapeutic armamentarium in Fibromyalgia.

IV. Conclusions

Our pilot study showed that SMR was safe and clinically effective in reducing the self-reported functional impact scores of Fibromyalgia of our participants. Given the limitation of the number of participants, we recommend a larger Randomized Control Trial be initiated. Given the previous limitations of travel distance of participants to the on-site location of study, and the current social distancing recommendations, we suggest that this intervention be implemented virtually.

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