ORIGINAL RESEARCH

Effectiveness of Biofield Therapy for Patients Diagnosed With Fibromyalgia

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ABSTRACT

Context • Fibromyalgia (FM) is a disorder with an unknown etiology; symptoms include physical and psychological stress, widespread chronic pain, insomnia, and depression. Mind-body medicine and aerobic exercise have shown positive effects for symptom control. Several studies have reported positive effects for biofield therapy for FM, but when other studies have compared the treatment with a sham control, they have not found those beneficial effects.

Objective • The study intended to examine the effects of a biofield therapy called Okada purifying therapy on patients' FM symptoms.

Design • An open-label, self-controlled study was conducted with 2 groups of FM patients.

Setting • The study was conducted at an integrative medicine clinic in Portugal.

Participants • Twelve patients, aged 25 to 59 y, with symptoms of FM for the 3 mo before the study, participated. Participants agreed not to receive any new treatment other than the intervention throughout the study as a condition for participation.

Intervention • Participants received 50 min of biofield therapy 2 ×/wk for 3 mo, either during the first half of the 6-mo study for group A or the second half for group B. The second half of the study was designated as a sham control for group A, and the first half of the study was designated as a sham control for group B.

Outcome Measures • Measures included the Beck depression inventory (BDI), the fibromyalgia impact questionnaire (FIQ), the tender point index (TPI), and changes in the dosage of prescribed medication.

Results • A significant change was observed for scores in the FIQ ($P = .027$), BDI ($P = .027$), and TPI ($P = .027$) in the second group of patients who received the intervention in the second half of the 6-mo study. Seven of 11 participants taking prescribed medications reduced their dosage.

Conclusion • Biofield therapy may help reduce symptoms of depression, chronic widespread pain, and tenderness among patients suffering from FM. Larger studies with rigorous designs are required for further accurate evaluation. (*Altern Ther Health Med.* 2019;25(6):20-26).

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Fibromyalgia (FM) is a disorder that commonly affects more women than men, with an estimate of 4 million people or 1.75% of the US population[1] and approximately 3.6% to 3.7% of the population in Portugal[2] being affected with the disease. Common symptoms of the disease include widespread chronic pain, stiffness, and tenderness of muscles and joints; fatigue; anxiety; restless sleep; and depressive symptoms.[3] The etiology is still unknown, and medical examinations fail to detect any sort of abnormality. People who are predisposed to FM have a sensitized or hyperactive central nervous system, in which physical or psychological stress triggers an increased gain in pain and sensory processing.[4] In a metaphorical explanation, it is like stepping on the accelerator firmly, with broken breaks.

Currently, combinations of pharmacological and nonpharmacological treatments are advised for FM.[5] Commonly used pharmacological treatments are drugs such as tricyclic antidepressants, serotonin-noradrenaline reuptake inhibitors, serotonin reuptake inhibitors, γ-amino butyric acid analogues such as gabapentin and pregabalin, an antiepileptic medication also used to treat neuropathic pain, and other pain blocking medications.[5-7] Mind-body medicine[8-10] and aerobic exercise have shown positive effects for symptom control.[11-13] Furthermore, the basic strategy for the treatment of FM is to eliminate unnecessary treatment and to provide social support so that patients can improve their lifestyles and increase their participation in exercise.[14,15]

Several studies have reported positive effects for biofield therapy for FM.[16-20] Numerous studies have been conducted on different types of biofield therapy, adopting different study designs; many studies have reported positive effects after continued practice of biofield therapy.[16-18] However, when the treatment has been compared with a sham control, the studies have found no positive effects for the therapy.[19,20] Although the effects of biofield therapy remain open to question, it is still positive news for patients suffering from FM if its symptoms can be relieved simply by use of a practitioner's hands.

A biofield therapy called Okada purifying therapy (OPT) is a healing method created by Mokichi Okada during the 1930s in Japan, and the Mokichi Okada Association (MOA) International, an organization based in Japan, oversees the training and certification of OPT practitioners. OPT is based on principles developed from a unique understanding of the human body, illness, and health. It is a type of biofield therapy that assists the self-healing process through the use of subtle energy.

Practitioners of OPT determine key areas on which to focus therapy through scanning the surface of the patient's back, notably above the waist, including shoulders, neck, and head. They place their palms lightly on the surface of the patient's body to determine stiff and/or warm spots, which represent accumulated toxins.

Practitioners of Okada believe that the universe is permeated with certain energy that allows all living things to exist. The practitioner purports to absorb this universal energy and radiate it from his or her palm toward the key areas on the recipient's body. The distance between the practitioner's palm and the recipient's body is usually 1 to 2 feet (30 to 61 cm). The administration of OPT typically lasts from 30 to 60 minutes for 1 session. From the perspective of Okada, OPT invigorates the patient's self-healing ability, allowing him or her to remove accumulated toxins and facilitating physical, mental, and spiritual health.[21]

The current research team conducted a study to examine the effectiveness of OPT for patients diagnosed with FM. The study aimed to test the hypothesis that the treatment would elicit significant improvements in physical and psychological symptoms and that the amount of medication taken by FM patients would decrease as the result of continued practice of OPT, compared with a control.

METHODS

Participants

An open-label, self-controlled design was employed. The study was conducted at MOA Porto Therapeutic Institute, an integrative medicine clinic in Porto, Portugal. Nineteen patients between the ages of 25 and 60 years who had been diagnosed with FM were recruited for participation in the study. Participants were either requested to participate in the study by medical doctors as they visited the clinic, or were recruited at other clinics operated by friends of the authors; however, only 12 patients met the inclusion criteria.

To be included, potential participants had to (1) have received a diagnosis of FM based on the American College of Rheumatology's (ACR's) criteria 1990,[22] (2) have had symptoms of FM for the 3 months before being recruited for the study, (3) be willing to refrain from starting any other new treatment during the period of the study, and (4) be 20 years of age or older.

The study plan for this research was approved by the institutional review board (IRB) of the MOA Health Science Foundation (IRB receipt code, TS1003). Informed consent was obtained from all of the participants before taking part in the study.

Procedures

The study examined the effectiveness of a 3-month longitudinal OPT intervention compared with a 3-month period with no intervention, for patients diagnosed with FM. Participants received OPT from an OPT practitioner, and the participants were notified of the intervention schedule in person.

Participants were assigned to 1 of 2 groups, group A or group B. Participants in group A received the OPT intervention during the first 3 months of the 6-month study, and participants in group B received the OPT intervention during the second half. The second half of the study was designated as a sham control for group A, and the first half of the study was designated as a sham control for group B.

All of the patients received a routine medical assessment 5 times during the study, approximately every month. Each patient's health status—such as physical function, work difficulty, pain, fatigue, morning tiredness, stiffness, anxiety, and depression—was measured using the fibromyalgia impact questionnaire (FIQ) and the Beck depression inventory (BDI). The tender point index (TPI) was used to assess the severity of the FM symptoms. These assessments were conducted at the MOA Porto Therapeutic Institute at 5 time points during the 6-month period. Participants were required to complete the FIQ, the BDI, and the TPI at each time point, and the scores were assessed by a physician to track the severity of the symptoms.

Intervention

The intervention consisted of receiving OPT twice per week, for 50 minutes each time. The treatments were administered by a certified OPT practitioner at the integrative

medicine clinic where the patients were recruited. Before administration of OPT, the practitioner determined key areas to focus the therapy based on investigating the stiffness and the surface temperature of the patient's head, shoulders, and back. The patients either sat quietly in front of the practitioner, or laid on the bed sideways, as the practitioner focused their palm toward the key areas, without physically touching the patient.

Outcome Measures

Fibromyalgia Impact Questionnaire. The measure is a 20-item, self-administered questionnaire developed by Burckhardt et al[23] to evaluate the severity of symptoms of FM. The first 11 items are a subscale that measures physical functioning and impairment, rated on a 4-point Likert scale. The range of scores is 0 to 3, with 0 indicating always able to function and 3 indicating never able to function. The 2 items that follow are questions that ask the person to rate the number of days they felt well, from 0 to 7 days, and the number of days that they were unable to work due to symptoms, from 0 to 7 days. The remaining items are used to rate work difficulty, pain, fatigue, morning tiredness, stiffness, anxiety, and depression on a scale of 0 to 10, with 0 indicating no impairment and 10 indicating maximum impairment. The overall score of the FIQ ranges from 0 to 100, with higher scores indicating a greater effect from the disease.[23] The validity and reliability of the instrument has been reported in previous studies.[24]

Beck Depression Inventory. The measure is one of the most widely used instruments for assessing the severity of depression among patients diagnosed with it and also for detecting depression in normal populations, developed by Beck et al.[25] The instrument is a 21-item questionnaire, with each item rated on a 4-point Likert scale. Zero indicates low, whereas 3 indicates a high level of depressive symptoms and attitudes, for each of the 21 questions. The ratings given to each of the 21 items are added to obtain a total score, with anything 17 or above indicating clinical depression. Symptoms and attitudes—such as low mood, pessimism, sense of failure, lack of satisfaction, feelings of guilt, or a sense of punishment—are assessed through the use of this questionnaire. Validity and reliability of the instrument has been reported in past studies.[26]

Tender Point Index. The TPI is used to observe the change in severity of physical symptoms of FM across different time points for the current study. The ACR developed criteria for diagnosing FM in 1990, which depended primarily on physical examination of tender points. The presence of 11 of 18 tender points in the presence of widespread pain served as the criteria for the diagnosis of FM, and practitioners followed that system until 2010. The ACR 2010 criteria was later established, which abandoned the tender point count, and introduced a diagnostic criteria based on the number of painful body regions and the presence and severity of fatigue, unrefreshed sleep, cognitive difficulty, and the extent of somatic symptoms.[22] The TPI is a scoring system for grading the severity of tender points from the ACR 1990 criteria. The severity is evaluated on a scale from 0 to 4 for each of the 18 tender points: 0, no pain; 1 (mild), complaint of pain without grimace, flinch, or withdrawal; 2 (moderate), pain plus grimace or flinch; 3 (severe), pain plus marked flinch or withdrawal; and 4 (unbearable), patient is untouchable and withdraws without palpation.[27]

Statistical Analysis

Data were analyzed using the Japanese SPSS version 11 (SPSS Inc, Tokyo, Japan). The Friedman test was employed as the statistical method of analysis for the purpose of observing statistically significant differences in repeated measurements for groups A and B. The method of analysis was chosen due to the limited sample size and the inability to meet the required assumptions to conduct a parametric test. A Wilcoxon signed-rank test was conducted to observe whether statistically significant differences existed among different periods within groups. $P < .05$ was designated as the cutoff point to determine statistical significance. The data are presented as medians.

RESULTS

Demographics

The participants were aged between 25 and 59 years, with a median age of 51 years. Of the 12 participants, 11 were female (92%), and 1 was male (8%). All participants except 1 were taking medications for treating symptoms of FM in the course of the study.

Fibromyalgia Impact Questionnaire

For group B, a statistically significant difference on the FIQ was observed between the group's start of OPT, with a median score of 83, and postintervention after 3 months of OPT, with a median score of 52 ($P = .028$), as shown in Figure 1. The severity of the symptoms of FM decreased significantly among participants in group B after the intervention, whereas no changes were observed during the group's control period. No statistically significant changes were observed for group A for either period.

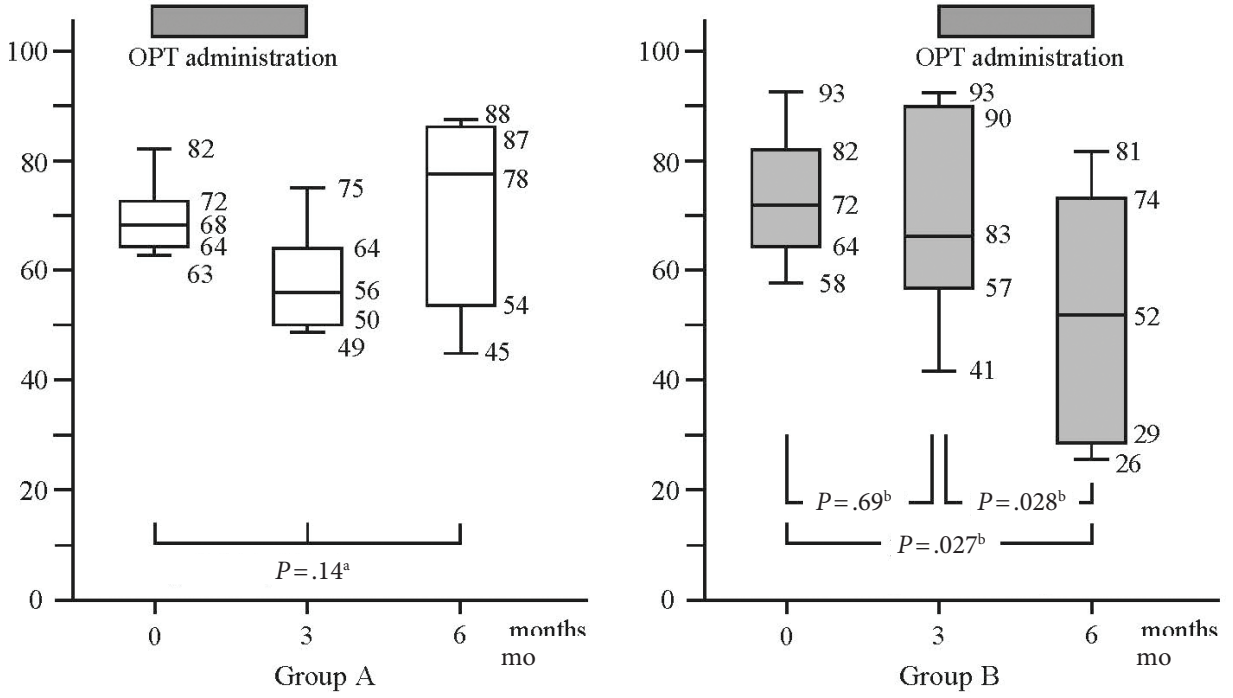
Beck Depression Inventory

In group B, a statistically significant difference on the BDI was observed between the group's start of OPT, with a median score of 23, and postintervention after 3 months of OPT, with a median score of 12 ($P = .027$), as shown in Figure 2. The depression of participants in group B improved significantly after 3 months of OPT, whereas no statistically significant changes were observed for group A for either period or and for group B during its control period.

Tender Point Index

As shown in Figure 3, a statistically significant difference on the TPI was observed for group A between the group's start of OPT, with a median score of 34, and postintervention after 3 months of OPT, with a median score of 12 ($P = .027$). No

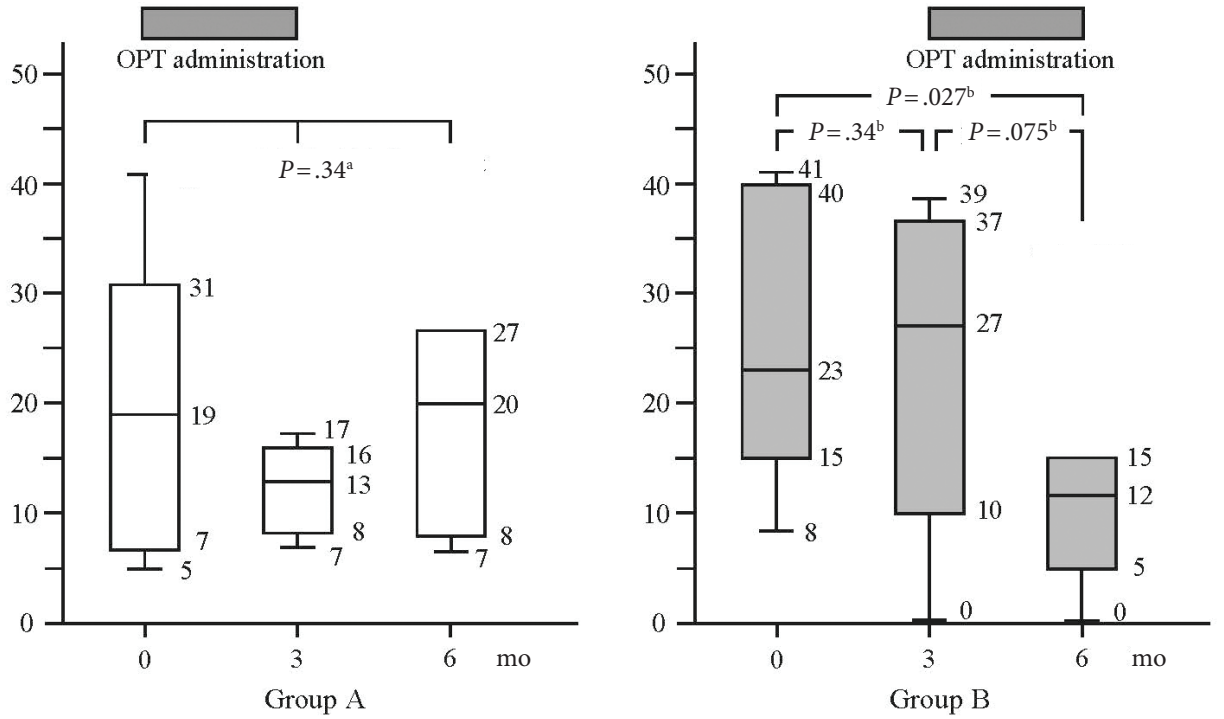
Figure 1. Changes in Scores on the FIQ



[a]Calculated by the Friedman test.
[b]Calculated by the Wilcoxon signed-rank test.

Abbreviations: FIQ, fibromyalgia impact questionnaire; OPT, Okada purifying therapy.

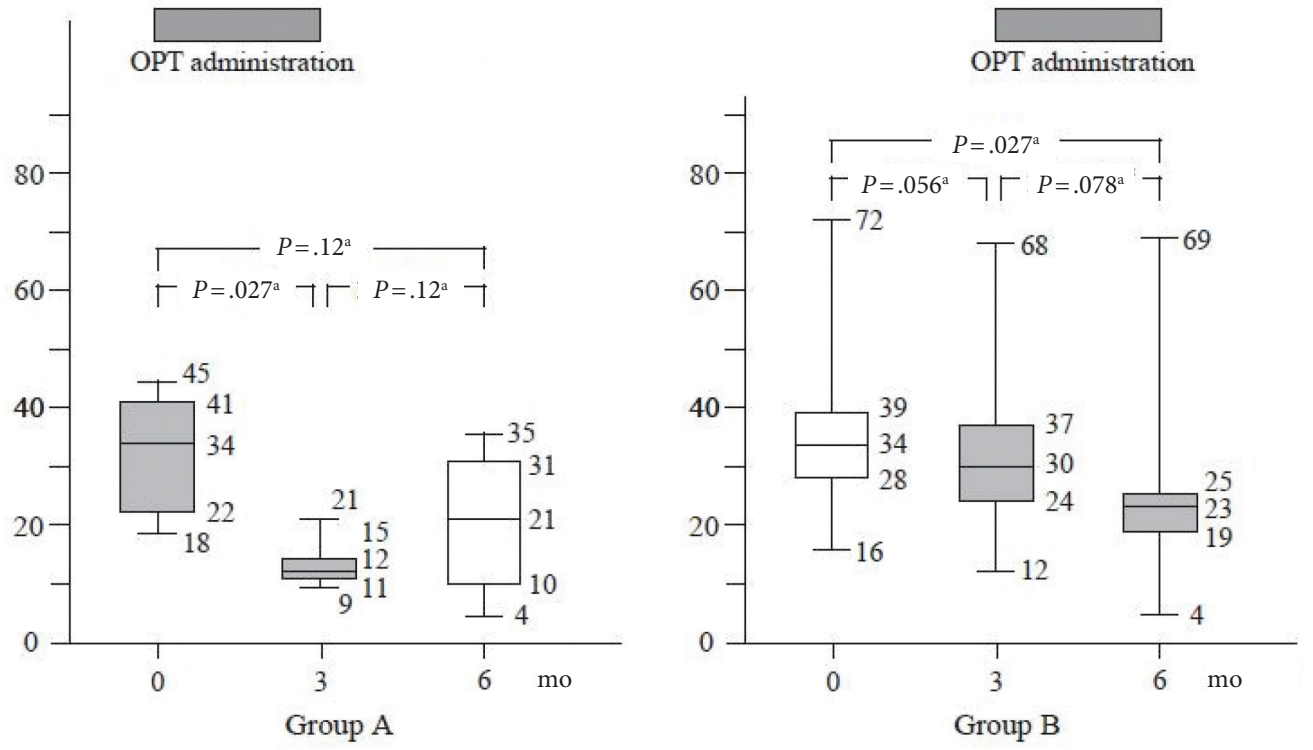
Figure 2. Changes in Scores on the BDI



[a]Calculated by the Friedman test.
[b]Calculated by the Wilcoxon signed-rank test.

Abbreviations: BDI, Beck depression inventory; OPT, Okada purifying therapy.

Figure 3. Changes in Scores on the TPI



[a]Calculated by the Wilcoxon signed-rank test.

Abbreviations: TPI, tender point index; OPT, Okada purifying therapy.

statistically significant change was observed for the group's control period. For group B, the median TPI score of 34 at baseline for the study slightly decreased to 30 during its control period ($P = .056$). However, a statistically significant change was observed for group B after 3 months of OPT, during which the median score declined to a median score of 23 ($P = .027$).

Medication Dosage

All 6 patients in group A were taking prescribed medication to alleviate pain and decrease depressive symptoms; 4 patients (67%) were able to reduce the amount of prescribed medication by the end of the study. In group B, 5 of 6 patients were taking prescribed medication; 3 patients (60%) were able to reduce the amount of prescribed medication. The adjustments for medication were based on clinical evaluations of participants in both groups. Throughout the study, no reports of adverse effects occurred from receiving OPT.

DISCUSSION

Many FM patients suffer from excessive sensitization to pain, triggered by physical and psychological stress, thereby leading to strong pain, insomnia, and depressive symptoms. Due to the absence of an established treatment, FM patients' efforts to alleviate symptoms using various modalities are understandable. Patients are encouraged to consider the effectiveness of the treatment and to bear in mind any risks from combining pharmacological treatments with complementary therapies.

Previous studies have reported improvements in symptoms through the practice of biofield therapy[16-18]; however, the effectiveness of biofield therapy has been hard to establish under rigorous study designs.[19] This issue demonstrates the possible benefits and limitations of biofield therapy. The improvements in symptoms seen in some studies may have been produced by a byproduct of the therapy. In other words, an individual being available and offering support to a patient and doing something that is presumed to be good for the patient may have boosted the placebo effect. When the placebo effect is removed, the remaining effects of biofield therapy may be negligible. Conversely, no risk or harm has been reported from combining biofield therapy with other types of treatment.

The limits and benefits discussed above apply generally to all biofield therapies. However, in certain instances a highly skilled practitioner may be able to produce dramatic effects. The research team in the current study has witnessed such moments. Several studies have shown effects for biofield therapy, with significant changes in the readings on electroencephalograms and electrocardiograms[28-30]; however, presently no measurement tools are available to detect directly the existence of the therapy's subtle energies.

Therefore, no means exist to measure objectively a person's level of ability in administering the biofield therapy. Moreover, even if the practitioner is considered a highly skilled master of the therapy, it does not necessarily mean that he or she is capable of producing the same effects for different people.

Further research is required to examine how much improvement in symptoms can be expected after the regular practice of biofield therapy. The current study was a pilot study, and the number of participants was limited, but the study showed significant improvements in the measurements on the TPI for patients in both group A and group B after 3 months of OPT. Group A's symptoms tended to exacerbate after they stopped receiving OPT. Patients in group B did not show improvements in symptoms when they were not receiving OPT; however, during the 3 months of OPT, the measurements for both the FIQ and the BDI improved significantly. Furthermore, 60% or more of the patients in both groups were able to reduce the amount of their prescription medications.

Results from the current study suggest that OPT may be suited as a healing technique for patients with FM, for similar cases in which symptoms increase due to stress, and also for diseases for which a standard protocol for treatment does not exist.

Limitations

Due to the small sample size in the current study, the decline in the scores for the BDI, FIQ, and TPI may have been induced by chance alone, and the generalizability of the study's results are limited. The measurement tools used to assess the effectiveness of OPT were self-administered questionnaires, which lack objectivity and provide risks of social-desirability bias. A common characteristic of FM is the inability to detect an abnormality through physical examinations; however, Sanada et al[32] reported a reduction in inflammatory biomarkers, especially interleukin 8 and 6 after interventions of exercise and dietary programs.

Confounding effects may have occurred that could be attributed to the therapists coincidentally providing emotional comfort and other elements of counseling, which are not directly parts of biofield therapy. Last, the effects of a long-term practice of biofield therapy are unknown. These aspects need to be considered in the designs of future studies.

CONCLUSIONS

Biofield therapy may help reduce symptoms of depression, chronic widespread pain, and tenderness among patients suffering from FM. Larger studies with rigorous designs are required for further accurate evaluation.

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F. Sarmento and E. Cordeiro are both physicians employed at the MOA Porto Therapeutic Institute, in partner with the MOA International; however, both physicians receive no salary and/or research funding directly from MOA International. Kiyoshi Suzuki is the president, and Hideaki Tanaka is a researcher at the MOA Health Science Foundation. MOA International and MOA Health Science Foundation are not-for-profit organizations, and Kiyoshi Suzuki does not receive any salary or research funding from these organizations.

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