

## Original Research Article

# A pilot, controlled, randomized trial of life logy as a new complementary and alternative medicine technique in patients with fibromyalgia syndrome

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## ABSTRACT

**Background:** Fibromyalgia syndrome (FMS) is a complex disorder, with primary symptoms of pain and fatigue. No cure for FM yet exists and treatments have been largely disappointing. In most cases complementary and alternative medicine (CAM) is used adjunctively to allopathic medicine. The present study aimed to evaluate the analgesic efficacy of sessions of life logy technique as well as patients' physical and mental improvement on patients with fibromyalgia.

**Methods:** Fibromyalgia patients were recruited from a private CAM center in Beirut, Lebanon from May to June 2017. Eighty patients were included and randomly assigned (1:1) to a treatment and a control groups. Each patient received 5 life logy sessions through 5 weeks and assessed by visual analogue scale, fibromyalgia impact questionnaire and SF-36 at sixth week, third and sixth months follow-up.

**Results:** The mean visual analog score, functional impairment and quality of life and SF-32 (physical and mental) scores in treatment groups were significantly decreased for time intervals ( $p=0.003$ ,  $0.0034$  and  $0.003$ ), ( $p=0.002$ ,  $0.001$  and  $0.001$ ), ( $p=0.003$ ,  $0.005$  and  $0.002$ ) and ( $p=0.002$ ,  $0.001$  and  $0.004$ ); respectively.

**Conclusions:** This pilot study suggests that life logy technique is a promising, durable, non-invasive, outpatient and inexpensive technique with a considerable effect on reducing pain and improving life quality in fibromyalgia patients. Further studies on a larger number of patients are needed.

**Keywords:** Fibromyalgia, Complementary and alternative medicine, Life logy

## INTRODUCTION

Fibromyalgia (FM) is a syndrome that consists of persistent ( $\geq 3$  months) widespread pain (pain/tenderness above and below the waist in at least 4 or 5 regions, stiffness, fatigue, disrupted and unrefreshing sleep, cognitive difficulties (firo-fog), anxiety and/or depression, and general sensory sensitivity.<sup>1</sup> A history of other chronic pain syndromes such as headache, migraine, non-cardiac chest pain, heartburn, dysmenorrhea, and irritable bowel syndrome may be present. Other symptoms can include paraesthesias,

restless leg syndrome, morning stiffness, and sensation of tissue swelling.<sup>2</sup> The definition of FM continues to evolve reflecting the changes in understanding and shifts in diagnostic criteria.<sup>3</sup> The American College of Rheumatology (ACR) 1990 diagnostic criteria required the presence of at least 11 out of a possible 18 tender points and not better explained by any other disorder.<sup>4</sup> The 2010/2011 criteria led to misclassification when applied to regional pain syndromes, but when a modified widespread pain criterion was added in the revised 2016, misclassification was eliminated with fibromyalgia being diagnosed with widespread pain index (WPI)  $\geq 7$  and

symptom severity scale (SSS) score  $\geq 5$  or WPI of 4–6 and SSS score  $\geq 9$ .<sup>5,6</sup>

The prevalence of fibromyalgia in the US general population was estimated as 2% (3.5% in women and 0.5% in men).<sup>7</sup> However, this estimation was reached using the original 1990 ACR classification criteria that miss nearly half the patients clinically diagnosed with fibromyalgia.<sup>2,8</sup> Thus, it is especially likely to have underestimated the prevalence in men, who have fewer positive tender points. Using data from 5 countries (France, Germany, Italy, Portugal, and Spain), Branco et al estimated the prevalence of fibromyalgia in Europe at 4.7%.<sup>8</sup> Another study estimated the prevalence of fibromyalgia in Tunisia at least at 8.3%.<sup>9</sup>

Unfortunately, the etiology of this widespread pain syndrome is uncertain.<sup>10,11</sup> The biology of fibromyalgia remains a mystery. There are intriguing theories including repressed emotion, energy disturbance, adrenal fatigue, defective metabolism (excess phosphate), infection and/or vaccination hepatitis C, Epstein-Barr virus, parvovirus and Lyme disease.<sup>12</sup>

The overall perception and experience of pain is dependent on a balance of peripheral nociceptive inputs central descending facilitation and inhibition of nociceptive sensory processing, cortical processing and the consequent emotional, psychological, autonomic, hormonal and behavioral response.<sup>13,14</sup> The understanding of FM has moved away from a predominantly peripheral musculoskeletal pathology towards a centralized pain state. Central pain mechanism is supported by changes in brain morphology and evidence of altered function of brain neurotransmission including increased cerebrospinal fluid substance P, glutamate and nerve growth factor, and decreased serotonin, norepinephrine, dopamine and GABA.<sup>15,16</sup> There is plenty going-on fibromyalgia that is not explained by central sensitization (like fatigue and mental fog). The peripheral mechanisms are likely to contribute to both the initiation and maintenance of the centralized pain state. These might include subtle inflammatory activity and changes to the inflammatory cytokine network and glial cell activity.<sup>17</sup> Other possible factors include sleep disturbance, psychosocial and behavioral issues and genetic factors as familial aggregation has been noted in FM.<sup>18-20</sup> The MTHFR gene is located on 1p36.3 with MTHFR A1298C mutations are tied to higher levels of fibromyalgia, IBS, fatigue, chronic pain, schizophrenia, and mood-related problems. A heterozygous MTHFR mutation (from one parent) or a homozygous mutation (from both parents) are possible, though individuals with homozygous mutations tend to have more severe symptoms and health problems.<sup>21</sup>

Conditions that may be confused with FM include autoimmune diseases (systemic lupus erythematosus, ankylosing spondylitis, and rheumatoid arthritis), myelopathy, myofascial pain syndrome, psychosomatic

disorders, vitamin D deficiency, hypothyroidism, Lyme disease, positional cervical cord compression, and myalgic encephalomyelitis, psychosocial factors and central sensitivity syndromes.<sup>13,22-24</sup>

No cure for FM yet exists and treatments (both pharmacotherapy and others) have been largely disappointing.<sup>25</sup> In most cases complementary and alternative medicine (CAM) is used adjunctively to allopathic medicine, but patients may completely stop allopathic treatment in favor of CAM.<sup>26,27</sup> The different types of CAM patients reported using included chiropractic treatment, arthropathy, herbal therapies, electrical stimulators, diet supplements with minerals or megavitamins, acupuncture, spiritual healing and exercises (warm water aerobics, stretching and walking).<sup>28-31</sup>

Life logy is a new CAM technique introduced by a Lebanese researcher 20 years ago with cumulating experience in dealing with many diseases. The technique is depending on manual disengaging the neural strangulations from their roots in the spine (accredited from Palmer Authorized Center British Board, PALM-BB21 and Lebanese patent wright No.4290). Life logy is a manually-based technique working on certain points with no any chemicals or instruments.

### *Aim of study*

The purpose of this study was to evaluate the analgesic efficacy of sessions of life logy technique on patients with fibromyalgia. This technique, in addition to the standard multidisciplinary approach, could have a therapeutic and durable effect on pain. A second goal is to evaluate the quality of life as well as the patients' physical and mental improvement after the sessions. We hypothesize that: 1) participants receiving life logy will have greater improvement in fibromyalgia symptoms severity (musculoskeletal pain, fatigue, physical and psychosocial functioning) and 2) participants who receive maintenance life logy sessions will have durable benefits as determined over a third and sixth months follow-up period.

## **METHODS**

### *Study design*

This is a pilot, randomized, controlled, single blinded trial of 5 weeks duration to test the efficacy of life logy as a CAM technique for the control of pain and impact of disease in patients with FM. It was implemented in a single, CAM private center and designed with two treatment arms and a pre, post treatment follow-up.

### *Participants and eligibility criteria*

Fibromyalgia patients were recruited from a well-known, governmentally certified, private CAM center in Beirut,

Lebanon from May to June 2017. Inclusion criteria included: A. diagnosis of FM by a rheumatologist or neurologist according to ACR 2010 criteria, B. more than 1 year from diagnosis, C. lack or partial response to previous pharmacological and/or non-pharmacological treatment.<sup>5</sup> The exclusion criteria were: A. prior experience of other similar types of CAM treatment in the past 6 months, B. cancer, cardiovascular disease, pulmonary disease, metabolic disease, renal disease, liver disease, or other serious medical conditions limiting ability to participate, C. any other diagnosed medical condition known to contribute to fibromyalgia symptomatology that is not under adequate control for the study period such as thyroid disease, inflammatory arthritis, systemic lupus erythematosus, rheumatoid arthritis, myositis, vasculitis and/or Sjogren's syndrome, D. pregnancy, and E. concurrent participation in another clinical trial. All participants are encouraged to maintain their usual physical activities. Patients maintained current treatment on a regular basis without modification during the duration of the study.

### **Patients**

A total of 80 patients were included in the study. Patients were randomly assigned (1:1) to two groups; a treatment group who received life logy sessions (40 patients) and a control (wait-list) group (40 patients; did not change anything in their everyday activities); using a randomization scheme generated through the <http://www.randomization.com> website.<sup>32</sup>

### **Interventions**

Each patient received 5 life logy standard sessions of 25-30 minutes each/week for 5 weeks; each life logy session is formed of 3 minutes of gentle pressing on the paravertebral muscles for relaxation and adapting the patient for the therapist hands; followed by careful specialized manipulation of cervical vertebrae to relief any possible nerve root compression, then specialized pressing upwards in the intervertebral spaces of dorsal 8 to 12 vertebrae, lumber 1/2, and lumber 5/sacral 1 to relief any possible nerve root compression; then specialized single pressure by the thumb is done for 3 seconds followed by 2 more pressures and a final long one for 7 seconds aiming to interrupt pain-signalling pathway and relief the pain (repeated for 3 minutes). Also, pressing on points 7 cm from the midline on patient's back with U-shaped pattern is performed aiming to reduce sympathetic and improve the parasympathetic autonomic nervous function. Then, downward pressing is performed 7 cm to the right of umbilicus to improve liver function from life logy point of view. Patients complaining of nasal sinusitis, irritable bowel syndrome, headache or eye dryness received extra sessions for such particular complaints. For ethical reasons, following completion of the study, participants in the control group had the option to receive life logy treatment.

### **Data collection protocol**

General practitioners identified potential participants who were then interviewed at the same clinic by an independent researcher (blinded assessor) until the required sample size was achieved. This researcher assessed suitability according to the inclusion/exclusion criteria through the criteria of the American College of Rheumatology 2010 and provided potential participants with a general overview of the study. Before baseline assessment, the participants signed the Informed Consent Form. Next, demographic and anthropometric data were collected, as well as information on the use of medications (type and quantity) for fibromyalgia and any other previous non-pharmacological intervention (if any). Finally, the participants were assessed for the primary and secondary outcomes. The assessments were performed at baseline and at the end of treatment at the sixth week, as well as at three months and 6 months follow-up. Patients received 2 more sessions at third and sixth month follow-up visits. Patients were instructed not to provide information about their treatment to the blinded assessor.

### **Assessment of clinical outcomes**

It is essential in fibromyalgia treatment studies to measure a wide spectrum of variables due to the complex nature of fibromyalgia and the importance of seeking subsets of responses. Study primary endpoint was changes in pain, assessed by global visual analogue scale (GVAS) and in impact of disease, assessed by the fibromyalgia impact questionnaire (FIQ).<sup>33,34</sup> Secondary endpoint evaluated by changes in the severity of the disease was assessed by the SF-36.<sup>35</sup> The Patient's GVAS is a visual analogue scale that measures the level of fibromyalgia severity on a 10-point scale with 10 reflecting the most extreme severity and 0 reflecting no severity. The FIQ is a self-administered questionnaire that tests the ability to perform large muscle tasks, difficulty with work, pain, fatigue, morning tiredness, stiffness, anxiety and depression; it contains ten items with a range of scores from 0 to 100, with higher score indicating a negative impact. Health related quality of life assessments are made using the medical outcome study short form 36 health survey (SF-36); which is a self-administered, 36-item questionnaire that assesses the concepts of physical functioning, role limitations due to physical problems, social function, bodily pain, general mental health, role limitations due to emotional problems, vitality, and general health perceptions. Summary scores include physical mental function, and combined total function. Scores range from 0 to 100, with higher scores indicating better health status.

### **Statistical analysis**

A sample size of 80 participants was deemed sufficient to detect a significant treatment group difference on pain

VAS, accounting for a dropout rate of 20% (power 80% and alpha level of 0.05).

The sample was described by summary statistics (mean and standard deviation, median, frequencies and percentages). Differences between groups at baseline were tested with Student's t or Mann-Whitney U tests, depending on the distribution of continuous variables, and Chi square for qualitative variables. Normality was tested with the Kolmogorov-Smirnov test. Within-group differences in outcome measures by time were assessed using repeated measures ANOVA. A difference was considered statistically significant when the p value was

≤0.05. Statistical package SYSTAT 12 (SYSTAT Software Inc, USA) was used to perform all the statistical analyses in this study.

**RESULTS**

A total of 80 patients were included in the study. Patients were randomly assigned (1:1) into two groups; a treatment group (40 patients) and a control (wait-list) group (40 patients). The sample was predominantly females (n=60, 75%) with male to female ratio 3:1. The age ranged from 22 years to 68 years with a mean age was 39 years (Table 1).

**Table 1: Characteristics of patients of the trial.**

	Group A	Group B	P value
Age (yrs)	38.6±12.2	40±13.1	
<b>Gender (n=80)</b>			
Male	8	12	
Female	32	28	
Duration of FMS diagnosis in years	5±3.2	4.6±2.9	0.264
Pharmacological treatment (antidepressant, pregabalin, muscle relaxants and analgesics)	32	33	0.691
Non-pharmacological treatment	12	10	0.095

Data was expressed as mean±standard deviation (SD).

**Table 2: Primary and secondary outcomes at baseline.**

	Treatment group (n=40)	Control group (n=40)	P value
VAS (mm)	7.4±1.2	7.1±1.5	0.734
FIQ	70.2±5.8	72.3±7.2	0.143
SF-36 physical component	35.7±4.2	36.9±6.2	0.164
SF-36 mental component	39.1±2.3	38.5±12.0	0.626
SF-36 (physical functioning)	37.2±6.4	39.0±5.7	0.827
SF-36 (role physical)	30.0±2.7	33.6±8.3	0.067
SF-36 (bodily pain)	39.2±6.4	42.1±2.1	0.017
SF-36 (general health)	50.5±8.4	53.1±3.3	0.326
SF-36 (vitality)	39.2±2.3	40.5±8.6	0.077
SF-36 (social functioning)	60.5±6.1	47.9±8.7	0.146
SF-36 (role emotional)	70.7±9.5	67.5±3.3	0.096
SF-36 (mental health)	62.5.9±8.4	58.3±4.7	0.174

Data was expressed as mean±standard deviation (SD).

**Table 3: Primary and secondary outcomes at 6th week, 3rd month and 6th month.**

	VAS	P value	FIQ	P value	SF- 36 physical/ p value	SF-36 mental/p value
6 <sup>th</sup> week group A	4.7±3.7	0.003*	50.4±1.7	0.002*	62±5.4 (0.003*)	69.2±2.4 (0.002*)
3 <sup>rd</sup> month group A	5.1±5.6	0.004*	47.7±4.8	0.001*	60.6±2.5 (0.005*)	68.1±7.2 (0.001*)
6 <sup>th</sup> month group A	4.6±7.1	0.003*	47.1±3.9	0.001*	58.9±7.8 (0.002*)	65.6±5.7 (0.004*)
6 <sup>th</sup> week group B	7.2±3.5	0.832	71.6±2.5	0.065	35.3±4.7 (0.324)	38.7±5.7 (0.474)
3 <sup>rd</sup> month group B	7±6.1	0.631	72.7±6.8	0.164	34.6±9.4 (0.164)	40.8±2.1 (0.032)
6 <sup>th</sup> month group B	7.3±7.3	0.656	71.0±4.6	0.254	37.4±7.3 (0.053)	39.9±3.3 (0.062)

Data expressed as mean±standard deviation (SD), \*P value is significant.

No statistically significant differences regarding age, duration of disease, VAS and treatments received were found between the two groups at baseline (Table 2).

At the sixth week, third and sixth months, the mean VAS scores in group A were significantly decreased;

(respectively  $p=0.003$ ,  $0.004$  and  $0.003$ ). However, the VAS score in group B remained unchanged (Table 3).

While the FIQ score decreased in the sixth week, third and sixth months in the treatment group, yet no changes were reported in the control group. There was a statistically significant improvement in the control group at the end of treatment sessions and follow up periods ( $p=0.002$ ,  $0.001$  and  $0.001$ ; respectively).

SF-36 physical component scores showed marked improvement at sixth week, third and sixth months in comparison to the control group ( $p=0.003$ ,  $0.005$  and  $0.002$ ; respectively), while the SF-36 mental component demonstrated a significant improvement for the same periods evaluated with  $p=0.002$ ,  $0.001$  and  $0.004$ ; respectively.

## DISCUSSION

Fibromyalgia costs the US healthcare system over \$25 billion annually. Current pharmacological therapies may cause serious adverse effects, are expensive and fail to effectively improve pain and function. Finding new and effective non-pharmacological treatments for fibromyalgia patients is urgently needed.<sup>36,37</sup>

There is no known cure or universally accepted treatment for fibromyalgia and treatment is typically aimed at symptom management. Developments in the understanding of the pathophysiology of the disorder have led to improvements in treatment, which include prescription medication, behavioral intervention, exercise and CAM.<sup>26</sup> Life logy is a new CAM manually-based technique directed to reduce some of fibromyalgia symptoms as well as some other diseases.

The aim of the current trial was to evaluate the analgesic efficacy of sessions of life logy as a new CAM technique on patients with fibromyalgia with an ultimate goal of providing a cost-effective, complementary and integrative approach to symptom management for individuals with fibromyalgia with limited therapeutic options.

In the present study we did not find a statistically significant difference between the study two groups at baseline in terms of age, duration of disease, VAS and treatments received. At the end of treatment sessions (sixth week) and follow-up at third and sixth months, there was a significant improvement in VAS scores in patients who received life logy sessions; (respectively  $p=0.003$ ,  $0.004$  and  $0.003$ ) while, the VAS scores in control patients remained unchanged. Also, FIQ score significantly decreased at same intervals in the treatment group ( $p=0.002$ ,  $0.001$  and  $0.001$ ; respectively). Lastly, both SF-36 physical and mental components scores showed a significant improvement at the same time intervals in comparison to the control group (physical component  $p=0.003$ ,  $0.005$  and  $0.002$ ; respectively,

mental component  $p=0.002$ ,  $0.001$  and  $0.004$ ; respectively).

Not all mechanisms of action of life logy technique are well understood, however its main action is possibly through disengaging the neural strangulations from their roots in the spine. The cervical spinal cord is a neurological bottleneck through which every nerve impulse from or to the body must pass. Symptoms caused by trouble at this level of the spinal cord are notoriously variable and can cause trouble essentially anywhere. Erratic low-grade irritation of the cervical spinal cord could actually be the direct, specific, and mechanical cause of fibromyalgia (possibly not the only cause, but a major one). It was reported that minor spinal cord pinching was present in 70% of patients with fibromyalgia and chronic widespread pain and treating such minor pinching seems to show some promise for treating fibromyalgia. Unfortunately, conventional MRI images taken with the neck in a neutral position will miss a lot. It is a dramatic and sensational hypothesis, but it is not outrageous.<sup>38,39</sup> Myelopathy is mysterious and erratic and often involves widespread pain and that intermittent compression of nerves causes different kinds of symptoms in the peripheral nervous system than constant pressure, so it is not much of a reach to suppose the central nervous system also responds differently: an atypical, subtle myelopathy, caused by pinching that is invisible to all but the most thorough MRI examination. Lastly, irritation of the cervical spinal cord may have unusual properties, different from other parts of the spinal cord and may cause strong arousal of the autonomic nervous system; the same effect as severe chronic stress.<sup>38</sup>

Also, although studies have been conflicting, there is evidence for autonomic dysfunction in FM and sympathetic dysfunction has been consistently described.<sup>40</sup> Life logy technique includes a U-shaped patient's back special handling aiming to reduce sympathetic and improve the parasympathetic autonomic nervous function. The intermittent pressure applied may possibly interrupt the pain pathway.

This pilot study provided support for the positive role of Life logy as a new CAM technique in fibromyalgia. With 25 standard sessions and two follow-up sessions at the third and sixth months from starting treatment, there were significant improvements in VAS, FIQ and both SF-36 physical and mental components. So, it was concluded that life logy is a promising, effective, low cost new CAM technique to reduce some of fibromyalgia symptoms; mainly musculoskeletal pain; with few follow-up sessions. However, further studies on a larger number of patients are required.

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