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Low Risk, Non-Invasive Means to Achieve Wellness in Fibromyalgia

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Abstract

Fibromyalgia affects up to 15 million Americans and 3.6% the world population. It produces intense body pain, is much more common in women than men (9:1) and often associated with excessive sitting. The latter produces harmful, oxidative stress. Fibromyalgia responds to physical activity but patient compliance is low. Accordingly, we administered ***passive physical activity*** with a horizontal, motorized platform that rapidly and repetitively moved the body back and forth in a head to foot direction. This process increased endothelial nitric oxide, a molecule with antioxidant properties which is increased by aerobic exercise. Effectiveness was measured with the Fibromyalgia Impact Questionnaire (FIQ). Daily 45 minutes treatments over a 4-week period reduced FIQ scores comparable to current pharmacotherapies. Since the motion platform weighs 179 kg (394 lb.) and can applied solely in supine posture, patients needed to visit a clinical facility to receive daily treatments. As time went by, dropouts prevented long-term assessments of effectiveness. Here, we describe a portable, low-cost, computerized, self-operated, patented, with an app "passive simulated jogging device" that weighs 4.8 kg (10.5 lb.) for seated or supine home treatments to allow long-term trials. This side-effects-free device is about 20 times less expensive than leading drugs for fibromyalgia.

Introduction

Fibromyalgia affects up to 15 million Americans and 3.6% the world population. it is more prevalent in females than males (9:1 ratio), occurs between ages 20 to 50, and incidence increases with age. Its major symptom is chronic widespread pain with multiple tender points. Fatigue, morning stiffness, and poor sleep quality are associated symptoms. The cause and etiology are unknown but evidence indicates that increased oxidative stress, chronic inflammation and

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decreased blood flow play a role. Pain appears to be centrally mediated with inappropriate heightened pain processing. The root cause for fibromyalgia is an enigma.

Material and Methods

Subjects ages 18 to 64 with complaints of fibromyalgia were recruited from local newspaper/ magazine advertisements and contact with local fibromyalgia organizations in the Philadelphia, Pennsylvania area.[1] All patients who agreed to participate signed informed consent forms and underwent an examination at the Pain Center, University of Pennsylvania. All patients underwent a documented tender point exam conducted by a trained examiner to establish if they met the American College of Rheumatology (ACR) 1990 criteria for fibromyalgia.

550 patients who thought that they had fibromyalgia contacted the Pain Center for potential enrollment. Of these, 87 were examined and 65 agreed to participate in the trial. After baseline data were collected, all enrolled patients were randomized to one of three groups: 1) Motion platform (Whole Body Periodic Acceleration or WBPA) daily for four weeks, 2) craniosacral therapy three times a week for four weeks or 3) ITT delayed treatment, where treatment would be offered after 12 weeks of observation. Randomization was accomplished using sealed numbered envelopes containing the assignment generated by a random number generator processed by an uninvolved research coordinator. Only primary outcome results for WBPA will be reported since no significant changes occurred in other two groups.

Baseline data were collected for at least 3 days prior to the initiation of therapy. At each visit, a brief questionnaire was administered about the patient's general and specific conditions, and weekly data collected for the primary outcome. Delayed treatment patients were called by telephone weekly to collect the same data. An a priori primary outcome was specified as the change over time in the Fibromyalgia Impact Questionnaire (FIQ) total score at week 4. Only the primary outcome measure, the Fibromyalgia Impact Questionnaire (FIQ), is reported in this current presentation.

The Fibromyalgia Impact Questionnaire (FIQ)[2] was selected as the primary outcome measure of the study. It is a disease-specific measure that assesses subjects' perception of their physical function, pain, fatigue, stiffness, depression, anxiety, and overall well-being. The 10 item FIQ, ranging from 0 (best) to 100 (worst), has been widely accepted to describe the severity of fibromyalgia in study participants and to evaluate the effect of treatments.

Patients who received the motion platform (WBPA) were treated in sessions lasting 45 minutes, 5 days a week for the 4 weeks, totaling 20 treatments. Fifty-seven patients were enrolled in the study, with 19 in each of the three groups. There were no statistically significant differences in the baseline values for any of the symptom questionnaires. Over the course of the study, patients dropped out from each group. For the primary endpoint, seven subjects dropped out from each of the active treatment groups and 10 dropped out from the ITT control group. The most common stated reason was due to the time commitment to receive therapy.

Results

Primary outcome. The mean pre-treatment value for FIQ in the ITT group was 57.3, motion platform (WBPA) 61.5, and craniosacral therapy 53.9. There were no significant differences among baseline values of FIQ. The change in FIQ between baseline and week 4 was significant only for WPBA -10.7 ($p < 0.02$). In United States, the most recommended drug therapy for symptomatic relief of fibromyalgia is Lyrica®, also known as pregabalin. Selected short term clinical trials

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using change of FIQ scores for effectiveness revealed 1) Mease[3] (2007) baseline FIQ 64.3 and 13 weeks FIQ change -14.9; 2) Arnold[4] (2008) baseline FIQ 60.0 and 14 weeks FIQ change -12.2; 3) Ohta[5] (2012) baseline FIQ 52.7; 15 weeks FIQ change -10.6. The present trial of four weeks with a baseline of 61.5 reduced FIQ -10.7 which compares favorably to pregabalin.

For long-term outcome results, it was not possible to evaluate WPBA because clinic travel five days a week became too onerous with missing appointments more frequent and data collection less reliable. This does not pose a limitation to drug studies which generally require weekly, monthly or semi-annual evaluations for long-term studies while patients self-medicate at home.

Recent studies suggest that increased oxidative stress accompanies fibromyalgia.[6] Antioxidant properties of WBPA are similar to moderate aerobic exercise owing to increased availability of endothelial derived nitric oxide with its antioxidant properties.[7;8] Oxidative stress does not cause fibromyalgia, whose etiology remains elusive, but is strongly associated with it. Patients with fibromyalgia sit for longer durations than healthy controls, a hazard to health that increases oxidative stress. Such physical inactivity is an independent risk for fibromyalgia, shortened lifespan, heart disease, high blood pressure, and other chronic diseases and conditions such as Type 2 diabetes, obesity, cancer, and dementia.[6;9;10]

Wellness products are needed in the workplace and home to treat physical inactivity with technology that allows sitting and single-tasking. Such products should not require intense mental concentration or physical exertion thereby allowing most activities of daily living. They should have high benefits to cost ratio and be demonstrable of effectiveness. With respect to fibromyalgia, such technology should reduce FIQ with scores comparable to pharmacotherapies.

A major regulatory breakthrough occurred in 2016 when FDA decided not to regulate low-risk, non-invasive wellness devices thereby facilitating early, less costly marketing introduction. FDA recommended the following major intended uses, viz., in conjunction with a healthy lifestyle, Product X should help prevent and aid in living well with heart disease, diabetes Type 2, and high blood pressure. In addition, FDA allowed the following general wellness claims: to improve a.) physical fitness, b.) relaxation, c.) mental acuity, d.) general mobility and e.) specific body function or structure such as swelling of ankles or legs, stiffness, diminished flexibility. The immediate preceding points are directly applicable to symptoms of fibromyalgia. It should be cautioned that FDA requires that devices claiming to *specifically treat diseases* such as fibromyalgia still require FDA approval for marketing.

Because of the disadvantages and high-cost (~$10,000) of the motion platform (WBPA), an innovative, patented “Passive Simulated Jogging Device” is introduced in this paper that provides symptomatic relief of fibromyalgia. It is portable, of low cost and can be self-operated in the home and /or workplace as a stand-alone device or with a smartphone app that has controls and logging features. This device incorporates computer controlled, motorized movements of foot pedals placed within a chassis to repetitively tap against a semi-rigid surface as a simulation for jogging or running on the ground. It weighs about 10.5 lbs. or 4.8 kg and can be placed on the floor for administration while sitting or can be secured to the footplate of a bed. The foot pedals rapidly and repetitively lift the forefeet upward about 1” followed by downward tapping against a semi-rigid surface (Figure).

Pregabalin (Lyrica®) is the leading medication in the United States for fibromyalgia administered in a dose of 300 to 450 mg per day. One capsule contains 75 mg pregabalin; each capsule in United States costs about $6.67. Optimal dosing constitutes four to six capsules per day = $27 to $40 per day. This equates to a monthly cost = $800 to $1,200 and yearly cost = $9,600 to

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$14,400. The one-year cost of the passive simulated jogging device with warrantee and app = $600 or about 20 times less expensive than pregabalin.

Conclusion

Physical inactivity causing oxidative stress in fibromyalgia can be alleviated with a non-invasive motion platform which provides comparable symptomatic effectiveness to drugs as reflected by reduced FIQ scores. The high-cost and heavy weight of the motion platform prevents long-term home assessment in fibromyalgia. A low-risk, low-cost, non-invasive wellness device is described with the same therapeutic properties as the motion platform that is applicable to long-term home use in fibromyalgia.

Caption for Figure

This depicts a woman working at her desk with feet on the pedals of the "passive simulated jogging device."

Acknowledgment

I thank Dr. John T Farrar for granting permission to publish the FIQ scores in his study of fibromyalgia.

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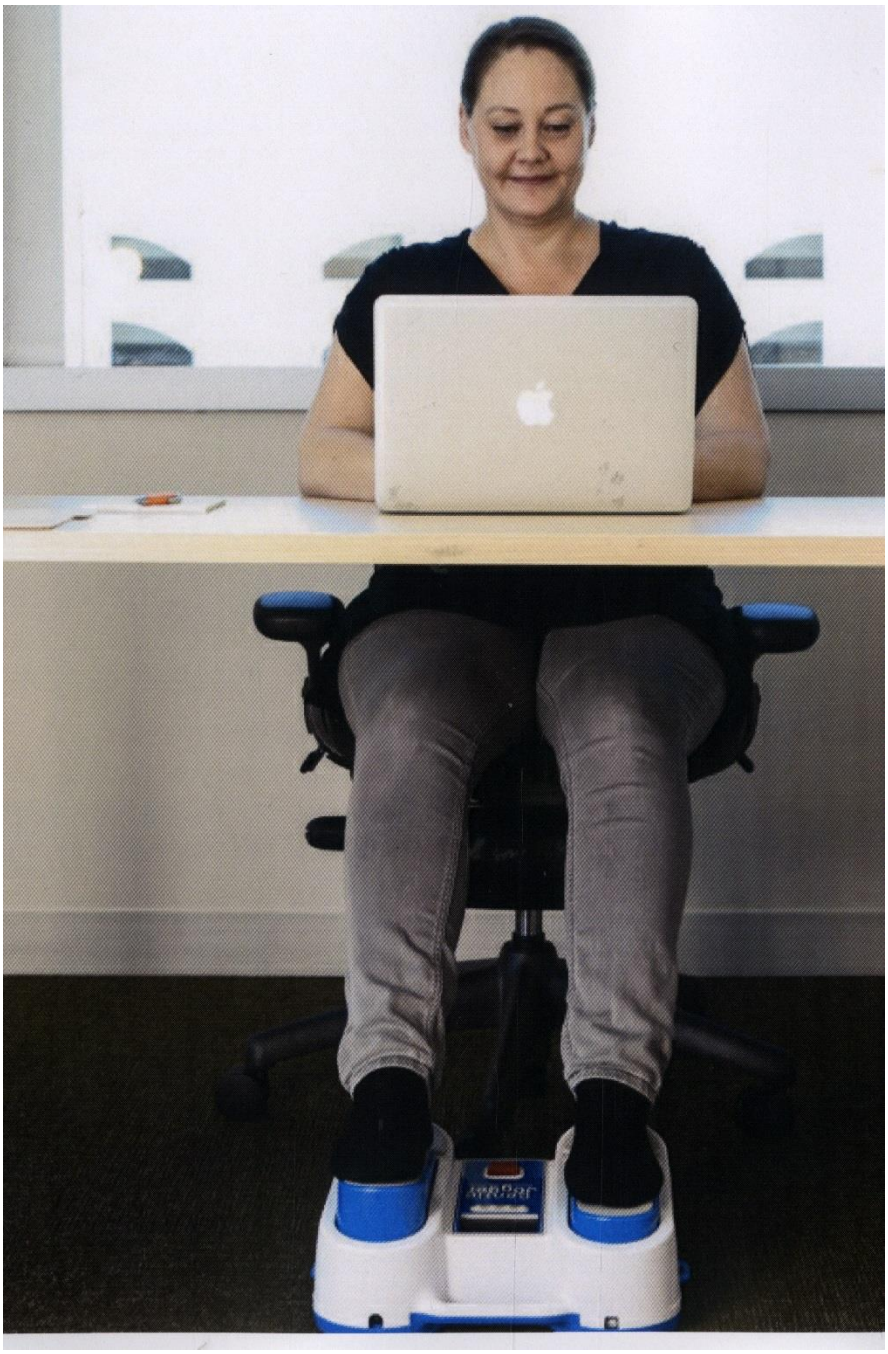

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