Exercise therapy in fibromyalgia patients: comparison of a web-based intervention with usual care

F. Salaffi¹, M. Di Carlo¹, S. Farah¹, D. Marotto², V. Giorgi³, P. Sarzi-Puttini³

¹Rheumatology Clinic, Dipartimento di Scienze Cliniche e Molecolari, Università Politecnica delle Marche, Jesi, Ancona; ²Rheumatology Unit, P. Dettori Hospital, AST Sardegna Tempio Pausania; ³Rheumatology Unit, Internal Medicine Department, ASST Fatebenefratelli-Sacco, Milano Statale University School of Medicine, Milan, Italy.

Fausto Salaffi, MD, PhD Marco Di Carlo, MD Sonia Farah, EngD Daniela Marotto, MD Valeria Giorgi, MD Piercarlo Sarzi-Puttini, MD

Please address correspondence to: Marco Di Carlo, Clinica di Reumatologia, Università Politecnica delle Marche, Ospedale Carlo Urbani, Via Aldo Moro 25, 60035 Jesi (AN), Italy. E-mail: dica.marco@yahoo.it

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ABSTRACT

Objective. The aim of this study was to investigate the effectiveness of a web-based exercise intervention in improving the severity of symptoms in different health domains in patients with fibromyalgia (FM).

Methods. Consecutive FM patients insufficiently responding to drug treatment (defined as a score of >4 on a numerical rating scale of pain) were enrolled in a web-based intervention group (Fibro-Web) and underwent a 24-week daily home exercise programme. They were evaluated through the revised Fibromyalgia Impact Questionnaire (FIQR) and the Modified Fibromyalgia Assessment Status questionnaire (Mod FAS) at baseline, and then every two weeks until the end of the programme. The outcomes were compared with those of patients receiving usual care.

Results. The final analysis was based on 140 patients: 68 in the Fibro-Web group and 72 in the usual care group. At the end of the 24-week study period, the patients in the Fibro-Web group showed a significant improvement in overall and sub-scale scores of the FIQR (p=0.0279) and Mod FAS (p=0.0057), expressed as timeintegrated values. This improvement started in the 16th week.

Conclusion. The use of a web-based daily exercise programme in FM patients significantly improves disease severity indices.

Introduction

Fibromyalgia (FM) is a chronic condition characterised by a broad spectrum of symptoms (ranging from widespread pain to fatigue, sleep disorders, mood disturbance and sometimes cognitive impairment in areas involving memory, processing speed, decision making) (1, 2) whose heterogeneous nature highlights its complexity. It has an estimated mean global prevalence of 2.7%, and a male:female ratio of 3:1 (3).

FM is an enigmatic disease because its uncertain etiopathogenesis makes its diagnosis and treatment particularly intricate. The aim of an optimal management strategy should be to improve the patients' health-related quality of life, and so should be multidisciplinary, multi-modal and based on pharmacological and non-pharmacological treatments that are tailored to the patients' symptoms, preferences and co-morbidities (4). Commonly used medications such as anti-depressants, anti-convulsants, and analgesics are insufficient alone to provide complete disease control (5-7), and should be complemented by nonpharmacological interventions such as cognitive behavioural therapy (CBT), acupuncture, hypnotherapy and, last but not least, exercise and meditative movement (8, 9, 10-17, 18-23). The latest European League Against Rheumatism (EULAR) recommendations emphasise the role of fitness in the management of FM, and give exercise therapy a grade A recommendation with 100% agreement (4).

There have been a number of trials of various exercise interventions, with aerobic and strengthening exercises leading to the most consistent results, although these are not sufficient to recommend one over the other. It is established that regular fitness training is beneficial for FM patients, but little is known about which activities are the most useful (24-27). However, despite the benefits of physical activity (25-31), FM patients are less physically active than the general population and their reduced fitness has a major impact on their quality of life (32-41).

FM patients find it difficult to adhere to conventional exercise programmes because of fatigue, muscular weakness, poor flexibility, and various psychological factors (32-39). Even aerobic training can increase symptoms such as pain and dyspnea, and negatively affect participation in physical activities (39). Other probable reasons for the lack of fitness of FM patients include physicians' limited knowledge of non-pharmacological interventions or the lack of time to suggest them, and the patients' limited access to qualified trainers or difficulties in travelling with such a potentially burdensome disease.

One possible means of overcoming these limitations is offered by internet, as is demonstrated by its increasing use in the treatment of many conditions, including chronic pain. It gives physicians an opportunity of providing patients with a complete spectrum of care and has the considerable advantages of patient self-management, convenience, respect for privacy, and being able to reach anyone wherever they may be (25, 26, 42-44).

The aim of this study was to investigate whether the use a web-based exercise programme by women with FM would lead to better levels of physical function and self-perceived effectiveness in comparison with usual care.

Methods

Population and setting

Consecutive patients were enrolled at two Italian tertiary rheumatological centres for the diagnosis and treatment of FM: the Rheumatological Clinic of the Polytechnic University of Marche, Carlo Urbani Hospital, Jesi, Ancona, and the Rheumatology Unit of the Internal Medicine Department, ASST Fatebenefratelli-Sacco, Milan State University School of Medicine.

The inclusion criteria were: age 18-75 years; fulfilment of the 2011 American College of Rheumatology (ACR) FM classification criteria (45); an insufficient response to ongoing treatment (defined as an average pain numerical rating scale (NRS) score of \geq 4); being on stable doses of FM medication for \geq 4 weeks without the introduction of any new FM drug during the study period; the possibility of accessing internet on a daily basis; and having no contraindications to exercise without supervision. Patients were also asked not to change their medication or begin other non-pharmacological treatment modalities (e.g. meditative movements, acupuncture) during the study period. The exclusion criteria were: the presence of cardiovascular diseases or uncontrolled blood pressure; moderatesevere chronic lung diseases; uncontrolled thyroid disorders; orthopedic or musculoskeletal conditions prohibiting moderate-intense exercise; comorbid inflammatory rheumatic conditions (rheumatoid arthritis, systemic lupus erythematosus, and other connective tissue diseases); planned elective surgery during the study period; and serious psychiatric problems (active suicidal ideation, schizophrenia, or other psychoses).

The study outcomes (see below) were compared with those observed in a group of patients who had received usual care, without the prescription of therapeutic physical exercise. These patients were selected from the historical databases of the two centres as having demographic characteristics and a degree of disease severity that were comparable with those of the patients of the Fibro-Web group.

The study procedures were conducted in accordance with the the principles of the Declaration of Helsinki. All the participants were informed of the research nature of this project and all signed a written informed consent form. The study was approved by the Institutional Review Board of the hospital Ethics Committee (DAV2 no. 1654).

Exercise program

The 24-week Fibro-Web exercise programme was based on specific breathing and stretching exercises learned via web and repeated daily on five days a week with the aim of improving the patients' physical activity. It was designed in collaboration with specialists at the Rehabilitation Unit of Carlo Urbani Hospital, who provided an outpatient schedule following the American College of Sports Medicine (ACSM) guidelines for developing and maintaining cardiorespiratory fitness, and the American Pain Society's guidelines on FM (44, 46). The exercise format consisted of low-impact, non-repetitive cardioaerobic training for 20 minutes, strength training for 10 minutes, flexibility training for five minutes, balance training for five minutes, and relaxation for five minutes.

Patients mainly carried out exercises in a supine positions in order to allow them to focus on perception. The exercises combined different movements of the lower and upper limbs, the head and the trunk with respiration. Throughout the programme, self-management was explicitly promoted: the participants were instructed to find their own space within the context of their daily activities. The pool sessions and land-based exercises were mainly designed to break the patients' pattern of inactivity, but also helped them to apply relaxation techniques. The daily living sessions focused on helping the participants to plan their activities in order to minimise fatigue and pain, and eventually increase their level of activity. Videos illustrating the exercise intervention are available at the web site http://www. faustosalaffi.it/site/esercizi/ (Fig. 1).

Outcome measures

Follow-up data were collected using the revised version of the Fibromyalgia Impact Questionnaire (FIQR) and the modified Fibromyalgia Assessment Status questionnaire (Mod FAS). The FIQR is the updated version of the Fibromyalgia Impact Questionnaire (FIQ) (47-49), and consists of 21 questions referring to the previous week in the three main health domains of function, overall impact and symptoms, each of which is answered using an NRS. The revised version was intended to improve the original by adding new questions concerning memory, tenderness, balance, and environmental sensitivity. The final score (range 0-100, with higher values indicating greater severity) is the sum of the ratings of the three domains: the algebraic sum of the 9-item function domain (range 0-90) is divided by three, the algebraic sum of the 2-item overall impact domain (range 0-20) remains as it is, and the algebraic sum of the 10item symptom domain (range 0-100) is divided by two. The FIQR cut-off values for disease severity are $\leq 30 =$ remission, >30 but \leq 45 = mild, >46 but \leq 65 = moderate, >65 severe (50).



Fig. 1. Exercises from the "body movement and perception" method. (a-b): exercises of lateral head rotation and tilt; (c): exercises of lower limbs in a supine position; (d): exercises of upper limbs and respiration in a supine position; (e): list of available exercises.

The Mod FAS questionnaire is the updated version of the FAS (51), and includes questions addressing fatigue, the quality of sleep, and widespread pain. Like the ACR 2011 FM criteria, which include 19 pain locations in a widespread pain index (WPI) and a symptom severity scale (SS) (45), we developed alternative clinimetric instrument based on a set of symptoms and pain locations. The Mod FAS combines in a single measure the patient's assessment of fatigue and sleep disturbances (each of which is scored using an NRS), and pain evaluated on the basis of a Regional Pain Scale (RPS) referring to 19 nonarticular sites indicated on an outline drawing of a person. The final score ranges from 0 to 39.

The clinimetric evaluations was done using the instruments described above. The patients in both groups were asked to complete the questionnaires every two weeks by visiting the study website www.fibromialgiaitalia.it/site in order to ensure cost-effectiveness and a close follow-up (the server is temporarily unavailable as the results are still being analysed). Different papers demonstrated that Internet-administered selfreporting questionnaires are as valid as the paper and pencil versions (52-54). The website allowed authorised users to access the system via a personal computer and Internet browser. At the end of the study, the electronically collected raw health-related quality of life data (including the number, age and gender of participating patients, the duration of the assessments, and the test results produced by the system) were extracted from practice computers and pseudonymised.

Statistical analysis

Differences among groups in demo-

graphic and clinical characteristics were calculated with the unpaired ttest. If data were not sampled from Gaussian distributions, a non-parametric test (Mann-Whitney U-test) was used. Cumulative disease severity in both groups was estimated on the basis of the total FIQR and Mod FAS scores of each patient calculated every two weeks during the 24-week follow-up, and expressed as time-integrated values (the area under the curve [AUC]), which can be considered a good representation of global outcomes in such kind of study.

Website usage metrics were extracted by Google Analytics and on the basis of social media accounts for the period from 1 March 2017 to 19 July 2019. The selected Google Analytics variables were overall website engagement, including the utilisation rate of specific features, user access mode, and location. The data were processed using Med-Calc Statistical Software for Windows XP, v. 19.0 (Ostend, Belgium). A *p*-value of <0.05 was considered statistically significant.

Results

Patient characteristics

Eight of the 80 patients who started the Fibro-Web programme did not complete it because of a change in physiotherapy (three patients) or the worsening of painful symptoms (three patients), and two were lost to follow-up. Four patients were excluded from the analysis because of the inaccuracy of the data recorded online. The final analysis was therefore based on 68 patients in the Fibro-Web group and the 72 patients in the usual care group extracted from the database.

The Fibro-Web users (31 [45.6%] desktop users, 28 [41.2%] mobile phone users, and nine [13.2%] tablet users) spent an average of 16 minutes and 18 seconds on the individual self-exercise sections, and those who completed the programme attended 84.1% of the sessions. The majority of users (60.2%) accessed the platform from the Italian region of Marche, followed by Lombardia (20.2%) and Lazio (13.4%) (Fig. 2). The web-service was well accepted by 89.4% of the patients.

The mean age of the 68 Fibro-Web patients who completed the study was 49 years, 61.8% were married, and 72.2% had a secondary and/or high/university education. The mean time from the onset of pain was 9.3 years (range 1–20 years). There was no significant difference in age, gender, marital status, educational level or the use of medications between the two groups (Table I).

Mean symptom duration was longer in the Fibro-Web group $(10.1\pm9.6 \text{ years}$ vs. $8.5\pm8.8 \text{ years})$, but this difference was not significant (p=0.072). Table II shows the mean and median total and subtotal Mod FAS and FIQR scores in the two groups at baseline and there were no statistically significant differences in the values.

Efficacy

The Fibro-Web intervention led to a significant improvement in the total



Fig. 2. The Italian locations of patients using the web platform.

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Sample demographics	All patients (n, 140)	Fibro-web group (n, 68)	Control group (n, 72)
Age, mean years ± SD	50.63 ± 8.94	49.15 ± 8.51	52.11 ± 9.19
Body mass index, mean \pm SD	26.33 ± 3.08	26.78 ± 3.16	25.89 ± 2.93
Disease duration, mean years \pm SD	9.12 ± 4.86	9.31 ± 4.72	8.94 ± 4.98
Marital status, number and (%)	87 (62.1)	42 (61.8)	45 (62.5)
Education level			
Primary school, number and (%)	44 (31.42)	19 (27.94)	25 (34.72)
Secondary school, number and (%)	65 (46.42)	34 (50.00)	31 (43.05)
High school/university, number and (%)	31 (22.14)	15 (22.05)	16 (22.22)
Females, number and (%)	124 (88.57)	60 (88.23)	64 (88.88)
SD: standard deviation			

and sub-scale scoores of the FIQR and Mod FAS after 24 weeks (Figs. 3-4). Table III shows the total FIQR and Mod FAS scores of each patient, expressed as time-integrated values (AUC), revealed a significantly greater benefit in the Fibro-Web group. The AUC values of the total FIQR scores progressively improved and, although there was some vacillation in both groups during the study period, the improvement was highly clinically relevant from the 16th week on (p=0.0006). The scores in each of the three sub-dimensions of the FIQR were similar, with the symptoms sub-scale showing the greatest improvement in the Fibro-Web group (p=0.0001). The AUC values of the Table II. Baseline Mod FAS and FIQR scores.

	Groups*							
	Control group (n=72)				Fibro-web group (n=68)			
	Mean	Median	SD	25-75 P	Mean	Median	SD	25-75 P
Mod FAS fatigue	6.71	7.00	1.83	5.00-8.00	6.36	6.00	2.24	5.00-8.00
Mod FAS WPI	5.18	5.42	3.18	3.85-6.28	4.79	5.00	1.99	3.54-6.25
Mod FAS sleep	6.09	6.00	2.33	5.00-8.00	5.43	5.00	2.73	4.00-8.00
Mod FAS total score	6.01	6.14	1.42	5.36-6.84	5.52	5.51	1.77	4.25-6.81
FIQR function	13.02	13.00	6.51	8.00-19.00	11.58	12.00	8.11	5.00-17.00
FIQR overall status	8.40	8.00	5.13	5.00-12.00	7.70	7.00	5.81	3.00-12.00
FIQR symptoms	27.98	29.00	7.67	22.00-33.00	25.84	25.00	9.43	20.00-32.00
FIQR total score	49.39	49.00	17.08	37.00-62.00	44.92	45.20	20.64	28.00-59.00

*no statistically significant differences between the treatment groups.

FAS: Fibromyalgia Assessment Status; FIQR: revised Fibromyalgia Impact Questionnaire; SD: standard deviation; P: percentiles; WPI: widespread pain index.



Fig. 3. Comparison of the trend of the FIQR values in the two groups of patients (a) and individual trajectories for the two groups (b).



Fig. 4. Comparison of the trend of the Mod FAS values in the two groups of patients (a) and individual trajectories for the two groups (b).

Mod FAS total scores were also significantly better in the Fibro-Web group (p=0.0002), with the greatest improvements being shown in relation to the quality of sleep (p=0.0015) and fatigue (p=0.0064). As in the case of the FIQR, the significant improvements were observed from week 16.

Discussion

This study, confirming the effectiveness of physical activity in reducing the severity of FM, shows that this type of therapeutic strategy can be easily implemented at home using a web-based approach.

Promoting physical activity should be considered a priority in the manage-

Table III. Summary of FIQR and Mod FAS total scores expressed as the time-integrated values (area under the curve) calculated for each patient during the 24 weeks of the study period.

FIQR total score	Mean AUC	95% CI	SD	Median AUC	95% CI		
Control group	1178.88	1117.94-1239.81	251.73	1180.50	1111.89-1232.53		
Fibro-web group	1070.81	995.26-1146.36	312.12	1081.10	959.00-1133.21		
two-tailed probability $p=0.0279$							
Mod FAS total score	Mean AUC	95% CI	SD	Median AUC	95% CI		
Control group	143.39	138.13-148.65	21.72	140.80	137.83-151.12		
Fibro-web group	132.21	126.21-138.21	24.79	134.61	129.30-138.18		
two-tailed probability	p=0.0057						

FIQR: revised Fibromyalgia Impact Questionnaire; FAS: Fibromyalgia Assessment Status; AUC: area under the curve; CI: confidence interval; SD: standard deviation.

ment of FM because there is strong evidences supporting its efficacy in relieving symptoms. Therapeutic exercise leads to weight loss, prevents dysfunctions, releases tension, enriches sensory awareness, and enhances or maintains strength, aerobic resistance, coordinated mobility, flexibility, and physical and cognitive abilities (5, 6, 55-61). Weight loss improves posture and well-being, and reduces obesityinduced inflammation and peripheral nociceptive inputs (24, 62). It has been shown that FM patients have decreased thoraco-abdominal mobility, impaired respiratory muscle mechanics and poor cardiorespiratory fitness (32, 35).

One possible explanation for the improvement in cognitive function is the correlation between aerobic exercise and an increase in the volume of brain areas such as the temporal lobe and prefrontal cortex due to the release of neurotropic brain-derived neurotrophic factor (BDNF) and insulin-like growth factor-1 (IGF-1) (22).

Women with FM are significantly less physical fit than age-matched healthy subjects, and their level of physical fitness is similar to that of healthy older people (33-36); furthermore, published data have shown that they have less cardiorespiratory fitness, agility, flexibility and strength; higher muscle stiffness scores; decreased postural control and balance; and are more likely to experience symptoms of bradykinesia than healthy controls (37, 38).

The al-Andalus study revealed that the physical fitness of FM patients is deeply altered even when they are relatively young (58), and Aparicio *et al.* have suggested that physical fitness should be considered an additional element in the diagnosis and prognosis of FM, where additional means of assessing its severity (59, 60). However, the prescription of non-pharmacological treatment is limited in routine clinical practice (61), and most FM patients with FM do not receive a full spectrum of care (4).

Our study demonstrates the effectiveness of a home-delivered, web-based intervention in promoting adherence to an exercise programme and relieving the symptoms of FM patients. It also has the advantage of being less expensive and time consuming than travelling to a gym or being trained by physiotherapist, requires minimal medical supervision, allows self-managed access to information (25), protects privacy, and makes it possible to do the exercises anywhere, at any time, and for as long as desired.

In line with previous findings, our Fibro-Web exercise programme led to a significant and clinically relevant improvement in FM symptoms and showed that it can be flexible, efficacious and portable means of increasing and sustaining physical activity levels in sedentary patients with FM. However, it does have the limitations that the participating patients must be technologically literate, and there is as yet no information concerning its long-term effects. Furthermore, there is a need for a cost-effectiveness analysis in order to determine its added value in everyday clinical practice.

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