ABSTRACT

Objective: To evaluate the effect of an aquatic training program on bone mass density (BMD) in post-menopausal women with fibromyalgia (FM).

Design: Randomised controlled trial (ISRCTN53367487).

Settings: Faculty of Sport Science

Subjects: Twenty-four postmenopausal women with FM (mean age, 56, SD, 7 years) were randomised to intervention (n=12) or control group (n=12).

Interventions: The experimental group received a supervised 8-month aquatic training consisted of three 1-hour sessions per week that included aerobic and strength exercises. Outcome Measures: The BMD of the hip area and lumbar spine was assessed by dual-energy X-ray absorptiometry technique. HRQOL was assessed using EQ-5D and the Fibromyalgia Impact Questionnaire (FIQ). Data were analysed using analysis of variance adjusted for weight and age.

Results: The exercise group improved their scores for EQ-5D time trade-off utility (86%, p=.007; effect size= 0.70) and FIQ (18%, p=.005; effect size= 0.61) while the control did not. The BMD of both groups remained statistically and clinically unchanged (p> .05; effect size < 0.2).

Conclusions: The aquatic training was highly effective in improving HRQOL with no adverse effects on the BMD in women with FM. The trend of bone loss was similar to that reported in non-FM untrained women. This type of rehabilitation should be complemented with exercises with higher impact on bone mass like Whole Body Vibration.

Keywords: exercise, quality of life, rehabilitation, fibromyalgia, bone.
Introduction

Fibromyalgia (FM) is a disease characterised by chronic widespread musculoskeletal pain, stiffness, muscle fatigue, deconditioning, depression and anxiety 1. In addition, they frequently report lower levels of physical activity and fitness than the normal population 2. Both reduced physical activity and depression have been associated with decreased bone mineral density (BMD) 3, 4. In addition, there is increasing appreciation that suboptimal growth hormone secretion may occur in patients with fibromyalgia 5. In fact, women with FM showed mild to moderate early bone demineralisation compared to healthy controls, but this difference only reached significance in women older than 50 years 6-8.

Physical therapy is generally focussed on the prevention of deconditioning, and increasing the quality of life 9. Physical therapy for FM is based on exercises with low mechanical impact, such as walking, yoga, t’ai chi, low-impact aerobics, or water aerobics to reduce musculoskeletal pain 10, but the effects of these exercises on bone mass are mainly unknown. In fact, there is a lack of research analysing controlled trials of supervised exercise longer than 12 months in patients with FM.

Although swimming and running in deep water showed very low mechanical impact on the lumbar spine, running in a waist-high pool showed only a moderate reduction in impact compared to running on a treadmill 11. In healthy post-menopausal women, analysis of the effect of waist-high water exercise programmes on BMD has been scarce and controversial 12-15. This lack of knowledge about the longitudinal effects of water exercise on BMD is even more significant for persons with FM.

This study is part of a wider research (ISRCTN53367487). Some of its results have been published previously 16-18. In this study, there were additional inclusion criteria to those used in previously published articles because the main measure of this study was the bone mass, so females were excluded if they had a concomitant inflammatory rheumatic disease, known osteoporosis treated with antiresorptive drugs, vitamin D deficit, less than 1000 mg of calcium per day, and participants who smoked, drank more than three alcoholic beverages a week, or suffered pathologies affecting bone metabolism.

The purpose of this study was to evaluate the effects of 8-month waist-high water training on the quality of life and BMD in post-menopausal women.

Materials and Methods

Participants

Participants were recruited by advertisement placed in the newletters of a local FM association in Spain and the flow chart is described in Figure 1. Researchers recruited physically untrained women with FM who have not received any osteoporosis or osteopenia treatment 19 and without history of another chronic disease known to affect bone metabolism or exercise capacity. The selection procedure began with two examinations of each woman: one examination of personal medical notes, and the other, a medical diagnosis by the responsible physicians to verify the diagnosis of FM according to the American College of
Rheumatology criteria 19. A total of 40 potentially eligible subjects responded and sought further information. The study protocol was explained, and 38 persons gave their written informed consent. The following exclusion criteria were also applied: Women were excluded if they had a concomitant inflammatory rheumatic disease, known osteoporosis treated with antiresorptive drugs, vitamin D deficit, less than 1000 mg of calcium per day, and participants who smoked, drank more than three alcoholic beverages a week, or suffered pathologies affecting bone metabolism or that could affect their attention and comprehension capacities (Alzheimer’s disease, apraxia, global aphasia, Wernick’s aphasia and other kinds of dementia and psychopathology), or for whom the aquatic training would compromise their current health status and confound the test response. In addition, participants who attended other diseases that prevent physical loading another non-pharmacological psychological or physical therapy (physical exercise with more than one exercise session of 30 min per week during a 2-week period in the last 5 years) or were on a pharmacological therapy that affects bone metabolism during follow-up were also excluded from analyses. A final sample of 24 female patients, aged 48-71 participated in the study. All
participants were randomly assigned to either an exercise training group (FME) or a control group (FMC). Finally, the 12 women in each group who fully completed the study and maintain the inclusion criteria were analysed. The outcomes were measured by bone densitometry and three questionnaires at baseline and 8 months later.

**Bone densitometry**

A technician measured the BMD (BMD; g·cm^{-2}) of the lumbar spine (L2–L4), and the left greater trochanter, femoral neck, and ward triangle via dual-energy X-ray absorptiometry technology (DXA; Excell Plus, Norland Medical Inc., Fort Atkinson, WI, USA).

**Questionnaires**

The Spanish versions of three questionnaires were administered in a face-to-face interview: a demographic survey, the EQ-5D 20, and the Fibromyalgia Impact Questionnaire (FIQ; 0=best functional health possible, 10=worst possible) 21. The first questionnaire was used to define age, gender, marital status, education level and self-perceived current occupation of the subjects. The EQ-5D assessed the generic functional health-related quality of life (HRQOL) of participants. The EQ-5D includes five dimensions, each one measuring a different dimension of HRQOL: mobility, self-care, daily activities, pain and discomfort, and anxiety or depression. Three levels for answering are included (no problems, some problems, or extreme problems/unable to), ranging from 1 to 3. The juxtaposition of the levels for these five dimensions correlate to five-digit numbers, which reflect 243 possible health status values that can be collapsed to a health functional index or a ‘utility’ using time-trade off values (EuroQolutility; 1=full functional quality of life, 0=death). The FIQ assesses the specific symptoms, disability, and handicap of FM patients.

**Delivery of intervention**

Participants assigned to FME exercised in a waist-high warm-water pool at 33°C three times per week during 8 months. Each 1-hour session included: 10 minutes of warming up, with slow walking and mobility exercises; 10 minutes of aerobic exercises at 65–75% of maximal heart rate (Hrmax) including fast walking and swaying in the water; 20 minutes of overall mobility and lower limb strength exercises; another set of 10 minutes of aerobics at 65–75% Hrmax; and 10 minutes of cooling down with low-intensity exercises. Heart rate was monitored using a pulse meter (Polar Accurex Plus, Polar Electro Oy, Kempele, Finland). During the whole 8-month period, the control group followed normal daily activities, which did not include any form of exercise related to those used in the therapy.

**Data analysis**

Descriptive characteristics of the data were used for parametric analysis using SPSS for Windows 18.0 (SPSS Inc. Chicago, IL, USA); data are described as mean (SD). An unpaired t-test compared the baseline characteristics of the groups. The effects of the intervention program compared to the control were tested by age- or weight-adjusted analysis of variance for repeated measures. The significance level was set at p<.05. Effect size was calculated to determine the magnitude of change found by the sum of the averages divided by the average of standard deviation. Cohen’s coefficient was used
to assess the change. A change from 0 to 0.2 was considered very small, a change of 0.2 to 0.6 was considered small, a change of 0.6 - 1.2 was considered moderate, a change of 1.2 - 2 was considered large and a change> 2.0 was considered very large.

**Results**

Table 1 shows a close matching between groups in age, age at menopause, FIQ scores, number of tender points and drugs related to FM treatments.

<table>
<thead>
<tr>
<th>Group</th>
<th>Exercise (n=12)</th>
<th>Control (n=12)</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td>57 (8)</td>
<td>56 (6)</td>
<td>.855</td>
</tr>
<tr>
<td>Age at menopause (year)</td>
<td>45 (4)</td>
<td>46 (3)</td>
<td>.785</td>
</tr>
<tr>
<td>Duration of FM symptoms (year)</td>
<td>24 (10)</td>
<td>19 (8)</td>
<td>.188</td>
</tr>
<tr>
<td>Number of tender points (1-18)</td>
<td>17.0 (1.3)</td>
<td>17.0 (1.6)</td>
<td>.999</td>
</tr>
<tr>
<td>Fibromyalgia Impact Questionnaire score</td>
<td>6.1 (2.0)</td>
<td>5.7 (1.2)</td>
<td>.600</td>
</tr>
<tr>
<td>Body Mass Index (kg/m²)</td>
<td>26.7 (4.3)</td>
<td>26.8 (3.3)</td>
<td>.916</td>
</tr>
</tbody>
</table>

† P of t-test; Values are expressed as mean (SD).

Table 2 presents the outcomes in HRQOL and BMD. The exercise group significantly improved their generic HRQOL measured using the generic EQ-5D questionnaire (86%) and the FM-specific HRQOL assessed by FIQ (18%) while the control group remained unchanged.

The BMD of all four sites assessed remained unchanged in both groups and no effect of programme was detected on BMD. A non-statistically significant decrease in percentage BMD was observed in the femoral neck (0.46%) and lumbar spine (0.58%) in participants.

**Discussion**

This study demonstrated that aquatic training in a waist-high pool exercise could improve HRQOL without adverse effects on bone mass in women with FM (17/18 tender points and 24 years living with FM symptoms) in a long-term supervised exercise program.

Related to HRQOL, several pool exercise programs have been reported women with FM. One of these studies was conducted by Jentoft et al 23 who found that the FIQ scores for women with FM improved more after a water-based exercise program (21%) than after a comparable land-based program (14%) that included three sessions per week over a period of 20 weeks. The study by Altan et al 24 showed a similar gain after only 12 weeks of water-based exercise. Mixed pool and land training programs including three to five sessions per week also reported 17–21% improvement in FIQ scores after 8–20 weeks of training 25-27 while mixed programs including two sessions per week showed an improvement of 9–11% 25, 26. Most of the gains obtained were maintained over a period of 1 year with a physically active lifestyle 25, 26, 28. However, Redondo et al. 27
Table 2. Effects of 8 month of an aquatic exercise programme in a therapeutic pool on the health related quality of life and bone mass density in women with fibromyalgia (exercise group, n=12; control group, n=12)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Group</th>
<th>Pre-training</th>
<th>Treatment effect</th>
<th>$p^*$</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health-related Quality of Life</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EQ-5D</td>
<td>Exercise</td>
<td>0.31 (0.32)</td>
<td>0.27 (0.09 to 0.44)</td>
<td>.011</td>
<td>0.70</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.36 (0.31)</td>
<td>-0.03 (-0.21 to 0.16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FIQ</td>
<td>Exercise</td>
<td>6.1 (1.9)</td>
<td>-1.1 (-1.7 to -0.4)</td>
<td>.010</td>
<td>-0.61</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>5.7 (1.2)</td>
<td>0.1 (-0.5 to 0.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone Mass Density (g·cm$^{-2}$)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumbar spine</td>
<td>Exercise</td>
<td>0.913 (0.146)</td>
<td>-0.004 (-0.034 to 0.026)</td>
<td>.853</td>
<td>-0.02</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.952 (0.190)</td>
<td>-0.007 (-0.050 to 0.037)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femoral neck</td>
<td>Exercise</td>
<td>0.795 (0.129)</td>
<td>-0.003 (-0.025 to 0.018)</td>
<td>.952</td>
<td>-0.02</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.773 (0.096)</td>
<td>-0.004 (-0.019 to 0.011)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trochanter</td>
<td>Exercise</td>
<td>0.636 (0.124)</td>
<td>0.017 (-0.009 to 0.042)</td>
<td>.308</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.631 (0.106)</td>
<td>0.003 (-0.010 to 0.017)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ward triangle</td>
<td>Exercise</td>
<td>0.602 (0.132)</td>
<td>0.011 (-0.027 to 0.049)</td>
<td>.617</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.586 (0.093)</td>
<td>-0.016 (-0.138 to 0.106)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EQ-5D: EuroQol 5-D utility (Worst: -1 to best: 1); FIQ: Fibromyalgia Impact Questionnaire score (Worst: 10 to best:0); Pre-training values are expressed as mean (SD) and $p^*$-values for repeated measures

ANOVA adjusted by weight.

reported an important and rapid loss of the gains obtained after intense (5 days per week) but short-term (8 weeks) physical therapy. In the current study, FM patients, older than in the previously reported studies, similarly improved their FIQ scores (18%) by exercising in three pool sessions per week over a period of 8 month. On the whole, the frequency and length of exercise training appeared to be a determinant of the HRQOL gains. A higher magnitude of change was obtained in programmes with three or more sessions per week, and maintenance of the gain was obtained in the longer protocols. In addition, it is likely that most of the FIQ score gains are achieved during the first 12–20 weeks of training.

The EQ-5D utility is a non-specific disease score useful to compare the cost-utility of different treatments in several diseases 29 so the report of this utility could help to make decision in health care management. To date, the EQ-5D has not been commonly used to assess the HRQOL of FM patients in longitudinal studies 30, although EQ-5D has been useful in assessing FM patients in cross-sectional studies 31. The current study reported an impressive 86% improvement in the HRQOL as measured with the utility feature of the EQ-5D but a similar improvement was found in a comparable aquatic
program after 3 months. Therefore, the short-term aquatic program enhanced impressively the HRQOL and the long-term retained them.

Regarding bone adaptation, although hydrotherapy and exercise in a heated pool is frequently recommended to FM patients in order to prevent pain related to the mechanical impact of exercise, to the best of our knowledge, the current study is the first attempt to study the longitudinal impact on the bone mass of aquatic training in waist-high pool in women with FM.

In the current study, women with FM, exercise plus control group, showed a similar trend of annual bone loss in the femoral neck (0.46%) and lumbar spine (0.58%) that this previously reported in non-FM women in the absence of hormone therapy. In previous cross-sectional studies, pre- and post-menopausal women with FM presented similar BMD to matched healthy women, though FM patients tended to have lower BMD in the femoral neck and mid-distal forearm. This increased bone loss tendency could partially be attributable to the lower 25-OH vitamin D concentrations detected in FM that are likely due to less sunlight exposure in the less physically active FM patients. In addition, FM patients usually showed an increased risk of bone fractures because they are more likely to be smokers, fallers, steroid users, less physically active, have a personal history of physical traumas, and have a family history of osteoporosis. Other highly prevalent characteristics of FM patients, such as depression, chronic pain and fatigue, have been associated with inadequate nutrition and osteoporosis. Generally, the mild differences in bone health between FM patients and healthy matched subjects have been attributed to poorer lifestyle in FM patients (lower physical activity and poorer diet).

Ay and Yurtkuran reported that water-based exercise can increase heel bone mass, where have a high mechanical strain with the pool-floor. An increase of bone mass in hip area could be also expected because water is about eight hundred times denser than air and the resistance to movement increases with velocity in water, quadrupling the water-drag when the speed doubles. But previous studies reported that aquatic training prevented bone loss, but it failed to increase BMD in spine and hip area although the program included jumps in water and high velocities of movement. The lack of BMD increase in the hip area after aquatic exercise in the scientific literature could be partially attributed to lower bone-loading due to the buoyancy of water, which helps to support the immersed part of the body against the downward pull of gravity. In fact, the weight bearing of a standing person immersed in hip-high water is approximately 50% of the total body weight on dry land at hip level. Persons with greater amounts of adipose tissue in the body, as the patients of the current study (body mass index >26.7 kg·m–2), show a further small reduction in weight bearing in water. In the current study, exercise in water did not increase BMD; however, no adverse effects of pool exercise training on bone mass were observed, such as bone demineralisation.

Limitations

Although the small sample size could make it difficult to find significant statistical differences in BMD, the magnitude of differences within and
between groups were smaller (effect size < 0.2) than those that are clinically relevant using the precision and reproducibility of DXA technology for the lumbar spine (±0.05 g·cm⁻²) or total hip region (±0.04 g·cm⁻²). Therefore, the lack of clinically relevant effect of aquatic training on bone mass could be attributed mainly to the nature of the training. The generalisation of outcomes had to be constrained to previously untrained and non-smokers women with FM free of hormonal therapy for bone loss prevention.

**Implications**

This study informs health professionals and FM patients about the effectiveness of aquatic exercise training in improving HRQOL and the necessity of bone loss prevention in women with FM. Professionals can expect an improvement of 15–20% of FIQ scores after exercise programs mainly achieved during the first 20 weeks of training.

Although some previous cross-sectional studies recommended special care regarding bone health in FM patients, other did not. Our longitudinal data do not justify additional measures for bone loss prevention different to those associated with chronic patients with unhealthy lifestyle features such as low physical activity or inadequate nutrition. In addition, fitness deconditioning in FM patients such as lower knee muscle strength and decreased balance with closed eyes has been associated with an increased risk of falls. Exercise in water can improve muscle strength and balance without adverse effects on pain and bone mass, but training programs with higher mechanical impact on bone are required to exert bone remodelling. High strains require a low number of repetitions per day to induce maximal bone formation, but low strains could also generate new bone formation. As applied load or strain magnitude decreased, the number of cycles per day required for activation of bone formation increased. Therefore, a need for more research related to the effects of aquatic training on bone mass including moderate strain in exercises to avoid pain is encouraged. In this sense, 3 ways to explore are suggested: a) an increase in the number of exercises with low strain in a single session or in more sessions per week; b) a mixed aquatic and land training to obtain higher strains; c) a mixed aquatic and Whole-body vibration training because whole-body vibration training is a good method to increase bone mass and in patients with fibromyalgia it is well tolerated.

**Conclusions**

The physical therapy in water was highly effective in improving HRQOL, with no adverse effects on the BMD in women with FM. The bone loss trend was similar to that reported in non-FM women. We suggest that this type of rehabilitation should be complemented with exercises with higher mechanical impact on bone mass using more sessions per week or higher strains. Further and larger studies adding or combining exercises with higher mechanical impact on bone but avoiding pain are suggested.

**Acknowledgments**

The study was supported by the European Social Funds and Regional Government of Extremadura (Spain) (2PR02B017 and Health Department). We are very grateful to all the participants in this study.
Author Disclosure Statement

The authors did not have financial benefits.

This work was not presented in any other publication.

The authors declare that they have no competing interests.

References


49. Gusi N, Raimundo A, Leal A. Low-frequency vibratory exercise reduces the risk of bone fracture more than walking: a randomized controlled trial. BMC Musculoskelet Disord. 2006; 7: 92.