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# Aquatic vs Land-Based Exercise for Fibromyalgia

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# Aquatic versus Land-Based Exercise for Fibromyalgia

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*Approved by the Division of Physical Therapy, School of Medicine, University of New Mexico in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy.*

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### Abstract

**Purpose:** The aim of this project was to present a case of an individual diagnosed with fibromyalgia (FM) and answers the following PICO question: In adult females with fibromyalgia, is aquatic-based therapy better than land-based therapy at improving symptomology and function?

**Background:** FM is a condition associated with chronic pain, tender points, fatigue, anxiety, depression, memory difficulty, gastrointestinal issues, sleep disturbances, muscle spasm, nerve pain, and sympathetic hyperactivity. Current literature shows positive effects of aerobic exercise programs on individuals with FM, but there is a lack of evidence-based review examining the effects of aquatic-based exercise programs on symptomology associated with FM.

**Case Description:** The subject was a 61-year-old female referred to outpatient physical therapy with a medical diagnosis of fibromyalgia and myofascial pain in her low back, abdominal region, bilateral lower extremities and groin.

**Outcomes:** This evidence-based review of the literature included eight studies, seven comparing land-based and aquatic-based exercise programs and one examining only aquatic-based therapy on various outcomes including pain by the visual analogue scale (VAS), Fibromyalgia Impact Questionnaire (FIQ), Six-Minute Walk Test (6MWT), Beck Depression Inventory (BDI), SF-36, cortisol levels, and several others.

**Discussion:** Both aquatic and land-based exercise interventions are beneficial for treating women with fibromyalgia. Although land-based interventions demonstrated more significant strength increases and positive impacts on stress, aquatic-based exercise showed more significant improvements in psychological well-being including reducing depression and anxiety associated with fibromyalgia. Exercise programs should be tailored to the individual patient and implemented based on the clinician's resources.

## SECTION 1: Background and Purpose of PICO Question

Ms. M is a 61-year-old female referred to outpatient physical therapy with a medical diagnosis of fibromyalgia with concomitant myofascial pain in her low back, abdominal region, bilateral lower extremities and groin. The patient was receiving several types of therapy including regular psychotherapy sessions and pain management classes, but was not participating in a regular exercise regimen.

Fibromyalgia affects between 2% and 4% of populations worldwide and is 9 times more likely to affect females.<sup>10</sup> Likelihood of development increases with age and peaks between 55 and 64 years.<sup>10</sup> It is characterized by chronic pain, fatigue, and tender points, but can present in a variety of ways and may include headaches, tenderness upon palpation, anxiety, depression, memory difficulty, gastrointestinal issues, sleep disturbances, muscle spasm, nerve pain, and sympathetic hyperactivity.<sup>10</sup> This condition was previously diagnosed based on the presence of widespread pain lasting for greater than three months, fatigue, morning stiffness, and tender points in at least 11 of 18 areas across the arms, chest, buttocks, knees, low back, neck, rib cage, thighs, and shoulders.<sup>10</sup> Currently, the American College of Rheumatology is shifting the diagnostic criteria to be based upon the Widespread Pain Index and Symptom Severity Score instead of number of tender points.<sup>10</sup> Differential diagnosis includes chronic fatigue syndrome, hypothyroidism, Lyme disease, systemic lupus erythematosus, rheumatoid arthritis.<sup>10</sup> Clinically, all films and images as well as laboratory tests for CBC, C-reactive protein, rheumatoid factor, and thyroid profile will be negative.

Although the etiology of fibromyalgia is not well understood, literature suggests several pathophysiological changes including: alterations in brain and neural structure and function, presence of inflammatory markers, changes in muscular physiology, and other genetic

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components leading to associated symptomology.<sup>10</sup> One study sought to examine the relationship between chronic stress and fibromyalgia.<sup>5</sup> Several neuroendocrine abnormalities are seen both in individuals with fibromyalgia as well as a result of chronic stress.<sup>5</sup> Authors closely evaluated the hypothalamic-pituitary-adrenal (HPA) axis regarding its role in hormone release and synthesis. Literature illustrates HPA axis hyper stimulation in instances of early exposure to severe stressors including various traumatic events in rats.<sup>5</sup> The HPA axis is the primary response system to stress.<sup>5</sup> It is responsible for the release or synthesis of corticotrophin-releasing hormone (CRH), adrenocorticotrophic hormone (ACTH), cortisol, growth hormone, and insulin-like growth factor I (IGF-I).<sup>5</sup> Authors found that individuals with fibromyalgia and individuals suffering from chronic stress demonstrated decreased levels of growth hormone and IGF-I, androgens, and serotonin while having increased levels of substance P, and cortisol.<sup>5</sup> The study was unable to determine whether endocrine changes were a result of chronic stress or of the manifestations of fibromyalgia.<sup>5</sup> Authors call for further research to be completed in this area to examine HPA axis in subjects that suffer from chronic stress and the likelihood of fibromyalgia development.<sup>5</sup>

Individuals with fibromyalgia typically have more work absences, higher health care expenditures, less social support, lower socioeconomic status and education level.<sup>2</sup> Current treatment for individuals with fibromyalgia includes a combination of pharmacological and non-pharmacological treatments, although evidence suggested that non-pharmacological treatment (exercise) is more effective at improving fibromyalgia symptomology.<sup>2</sup> Pharmacological treatments may include various analgesics or anti-depressants and typical non-pharmacological treatments range from acupuncture and massage therapy, to yoga, tai chi, or aerobic exercise in a land or water-based setting.<sup>10</sup>

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Individuals diagnosed with fibromyalgia often present with compromised muscle strength and endurance as well as cardiovascular health indicating irregular or lack of participation in regular exercise<sup>2</sup>. Exercise is vital in slowing age-related bone density loss, muscle atrophy and functional deficits, and has been proven to be effective in treating chronic pain conditions including fibromyalgia.<sup>2</sup> Literature suggests that moderate intensity exercise several times a week has a positive impact on fibromyalgia symptomology.<sup>3</sup>

The purpose of this paper is to answer the following PICO question: In adult females with fibromyalgia, is aquatic or land-based therapy more effective at improving symptomology and function?

## SECTION 2: Case Description

Ms. M was a 61-year-old female referred to outpatient physical therapy with a medical diagnosis of fibromyalgia for the past five years and was seeking treatment for myofascial pain in her low back, abdominal region, bilateral lower extremities and groin. She presented with a complicated medical history including: two previous abdominal surgeries, a significant MRSA infection, obesity, hypertension, bipolar disorder, and depression. The patient was receiving several types of therapy including regular attendance of psychotherapy sessions and pain management classes monthly. Her chief complaint was low back, abdominal, lower extremity and groin pain which she described as “unrelenting and debilitating” making it difficult for her to perform ADL’s, sleep through the night, and participate in family outings with her grandchildren.

**SECTION 3: Evidence Based Analysis**

Search Methodology: The following search methodology sought to answer the PICO question: In adult females with fibromyalgia, is aquatic or land-based therapy more effective at improving symptomology and function? The following databases were searched: PubMed, CINAHL, and PEDro. Search terms included “fibromyalgia AND land-based”, “fibromyalgia AND aquatic”, “fibromyalgia hydrotherapy”, “fibromyalgia aquatic”.

**Table 1: Systematic Literature Review Process**

<b>Search Terms</b>	<b>Number of Articles</b>	<b>Excluded/Included</b>
<b>PubMed Search</b>		
“fibromyalgia AND aquatic”	16	14 excluded due to title irrelevance. 2 selected (Munguia-Izquierdo 2008 & Assis 2006)
“fibromyalgia AND land-based”	12	10 excluded due to title irrelevance or duplication. 2 selected (Cazzola 2010 & Jentoft 2001)
“fibromyalgia hydrotherapy”	40	39 excluded due to title irrelevance or duplication. 1 selected (Vitorino 2006)
<b>PEDro Search</b>		
“fibromyalgia land-based	9	9 excluded due to title irrelevance or duplication.
“fibromyalgia aquatic	19	18 excluded due to title irrelevance. 1 selected (Sevimili 2015)
<b>CINAHL Search</b>		
“fibromyalgia aquatic”	34	32 excluded due to title irrelevance. 2 excluded due to duplication. 2 included (Kelley 2008 & Bednar 2012)

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### Articles Included for Analysis:

1. Sevimili D, et al (2015)
2. Cazzola M, et al (2010)
3. Jentoft E S, et al (2001)
4. Munguia-Izquierdo D, et al (2008)
5. Bednar M L, et al (2004)
6. Kelley C, et al (2008)
7. Vitorino D F M, et al (2006)
8. Assis M R, et al (2006)

**See Appendices A-B for Article Worksheets**

### Reference Summaries

**Reference #1:** Sevimli D, Kozanoglu E, Guzel R, Doganay A. The effects of aquatic, isometric strength-stretching and aerobic exercise on physical and psychological parameters of female patients with fibromyalgia syndrome. *J Phys Ther Sci.* 2015;27(6):1781-1786. doi:10.1589/jpts.27.1781.

**Level of Evidence:** PEDRO score: 5 Oxford Level: 2b

**Purpose:** The purpose of this study was to compare the effects of home-based isometric strength and stretching (ISSEP), gym-based aerobic exercise program (AEP), and pool-based aquatic exercises program (AAEP) on the physical and psychological parameters of patients with fibromyalgia (FM).

**Methods:** Seventy-five female patients with FM between the ages of 18 and 50 years were included in the study. Twenty-five subjects were assigned to the three different exercise groups. Exercise program: The ISSEP group performed home-based exercises lasting 15 minutes per day. The AEP and AAEP subjects performed exercises in a group 2 times per week on land and in the pool respectively. All exercise programs lasted 3 months. HR was measured 8 times during exercise programs for each subject.

**Results:** VAS: ISSEP group showed no statistically significant improvement, and had a slight increase after the 12-week study. AAEP and AEP both had significant improvements, but no difference between the groups.

Beck Depression Inventory (BDI): AAEP and AEP groups showed significant improvements (AEP>AAEP)

Fibromyalgia Impact Questionnaire (FIQ): AAEP and AEP had statistically significant improvements, but no between group differences.

Six Minute Walk Test (6MWT): AAEP and AEP had statistically significant improvements. No differences between groups.

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Multiple Chemical Sensitivity (MCS): AAEP and AEP showed more improvement than the ISSEP group. AAEP showed more improvement than the AEP group.

Pain Catastrophizing Scale (PCS): AAEP and AEP showed more improvement than the ISSEP group. No difference between AAEP and AEP groups.

### **Bottom Line:**

Both aquatic and land-based exercise programs demonstrated significant improvements in all outcome measures when compared to a home-based program.

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**Reference #2:** Cazzola M, Atzeni F, Salaffi F, Stisi S, Cassisi G, Sarzi-Puttini P. Which kind of exercise is best in fibromyalgia therapeutic programmes? A practical review. *Clin Exp Rheumatol*. 2010;28(6 Suppl 63):S117-S124.

**Level of Evidence:** PEDro: N/A Oxford Level: 1a

**Purpose:** The purpose of this review was to determine the effects of various types of exercises on overall health and symptomology of patients with fibromyalgia (FM).

**Methods:** Authors searched four databases for relevant Randomized Control Trials (RCT).

Studies were excluded if comparing more than one exercise intervention at a time, or if not using outcome measures for mental function, physical function, and pain. Twenty-seven RCT's were included. Fifteen examined land-based aerobic exercise, 7 examined water-based aerobic activity, and 5 examined muscle strengthening exercise programs.

**Results:** Effects of exercise on physical function (PF): Nine studies found that land-based aerobic exercise programs significantly improved PF when compared to control groups (no treatment, education, or stretching). One author found significant improvements with both physical aerobic activity (PAA) and strength-training exercises (STE), but no difference between groups. Two authors found no significant difference in PF following intervention. Four studies examining water-based PAA found improvement in PF when compared to control groups. Five studies examining STE found significant improvement in PF compared to untreated controls performing flexibility exercises.

Effects of exercise on Pain: None of the studies indicated reduction in number of trigger points (TP). Land-based PAA programs showed statistically significant improvements in spontaneous pain in half of the RCT's included, while 4 studies showed no improvements. Water-based PAA is shown to be more effective in reducing subjective pain than similar intense land-based PAA interventions.

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Effects of exercise on mental function: Land-based PAA is effective in reducing symptoms associated with anxiety and depression in patients with FM. Five studies examining water-based PAA found improvement in mental function.

Exercise application methods: Most of the RCT's conducted land and water-based programs 2-3 times per week, 30-60 minutes for 12 to 32 weeks at an intensity of 50-80% of HR max (mild to moderate). Several studies found that gradually increasing amount of moderate intensity exercise was effective in improving quality of life for FM subjects.

**Bottom Line:** Both aquatic and land-based exercise programs showed significant improvements on quality of life in individuals with FM, but aquatic exercise demonstrated greater improvements in spontaneous pain and depression. This study also provides evidence to support the exacerbation of pain with high intensity exercises, indicating that the setting of exercise may not be as important as intensity.

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**Reference #3:** Jentoft ES, Kvalvik AG, Mengshoel AM. Effects of pool-based and land-based aerobic exercise on women with fibromyalgia/chronic widespread muscle pain. *Arthritis & Rheumatism: Arthritis Care & Research*. 2001;45(1):42-47.

**Level of Evidence:** Pedro Score: 4 Oxford Level: 2b

**Purpose:** The purpose of this study was to examine the efficacy of a pool-based (PE) exercise program compared to a land-based (LB) exercise program with regards to its effects on physical capacity, symptomology, and self-efficacy of adult women with fibromyalgia (FM).

**Methods:** Thirty-nine female subjects from Norway, diagnosed with FM were included in this study. Subjects were randomly allocated to either a pool-based (PE) exercise group or a land-based (LB) exercise group. Eighteen subjects were in the PE group and 16 in the LB group. Each exercise session was 60 minutes and consisted of body awareness training, ergonomics, warm-up, aerobic dance, cool down, stretching, strengthening, and relaxation training. Authors used several methods to collect data on various outcome measures.

**Results:** Effects on Symptoms and Self-Efficacy: Both groups showed statistically significant, within group, improvements. PE Group: improvements in pain (P =0.006), daytime fatigue (P=0.002), stiffness (P= 0.003), anxiety (P=0.04), depression (P=0.04), number of days of feeling food (P<0.001). LE Group: improvements in daytime fatigue (P=0.02), stiffness (P= 0.02), number of tender points (P = 0.02). Number of tender points in the LE group had risen again at the 6 month follow up, but no other changes were identified in either group at the time of follow-up. Physical Function: LE Group: improvements in grip strength (P=0.02), cardiovascular capacity (P = 0.004), walking time (P = 0.002). PE Group: improvements in self-reported physical impairment (P <0.05), cardiovascular capacity (P = 0.02), walking time (P = 0.003). The above improvements were still present at the 6-month follow-up, but there was a slight reduction in LE group cardiovascular capacity (P = 0.001) and PE group grip strength (P = 0.03).

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**Bottom Line: Clinical Relevance:** These findings indicate that both pool and land-based therapy are effective methods for improving physical capacity, self-efficacy and symptomology in patients with fibromyalgia. This research provides evidence to support pool therapy as a viable treatment option for patients with fibromyalgia.

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**Reference #4:** Munguía-Izquierdo D, Legaz-Arrese A. Assessment of the effects of aquatic therapy on global symptomatology in patients with fibromyalgia syndrome: a randomized controlled trial. *Arch Phys Med Rehabil.* 2008;89(12):2250-2257. doi:10.1016/j.apmr.2008.03.026.

**Level of Evidence:**

PEDro 7/10

Oxford Level: 1b

**Purpose:** The purpose of this study was to assess the effects of a 16-week water-based exercise program on global symptomatology of women with fibromyalgia (FM).

**Methods:** Authors sent invitations to women between the ages of 18 and 60 years from an FM association in Spain to participate in this study. Subjects were excluded if presenting with other comorbidities, participated in another type of physical or psychologic therapy, or were not diagnosed with FM according the ACR classification criteria. Subjects were randomly allocated to an exercise or a control group. Twenty-nine females in the exercise group and 24 in the control group fully completed the study and were included in the analysis. All measurements were taken by examiners blinded to assignments. *Exercise Group* trained in chest-deep warm water, 3 times per week for 16 weeks. Each session included 10 minutes of warming up (walking and mobility), 10 to 20 minutes of strengthening, 20-30 minutes of aerobic exercise (50-80% of age-predicted HR max), and 10 minutes of cool-down. HR was monitored with pulse meter. *Pain* was assessed using syringe calibrated dolorimeter for threshold of all tender points. *Health status* was assessed using the FM Impact Questionnaire (FIQ). *Psychologic well-being* was assessed with 20-item self-administered SAI. *Sleep quality* assessed with PSQI and *cognitive function* assessed PASAT. *Physical function* assessed by examining upper and lower extremity endurance.

**Results:** Subjects in the exercise group had significant improvements in PSQI scores, endurance of upper and lower extremities, and FIQ scores when compared to control group. There was no significant change in SAI scores.

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**Bottom Line:** This RCT provides evidence to support that warm water aquatic-exercise performed 3 times per week for 16 weeks improves many of the symptoms associated with FM including: sleep quality, physical function, number of tender points, and cognitive function. Although this study does not directly compare land and aquatic therapy, the authors suggest that there may be better adherence to exercise programs that are aquatic-based since the warm water is soothing and provides immediate relief to pain. Clinically, if a pool setting is available, this provides evidence to support the effectiveness of an aquatic-based exercise program to improve symptomology associated with FM.

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**Reference #5:** Bednar ML, Soroczynski AC, Groman MJ, et al. Effectiveness of land-based and aquatic-based exercises for improving the health status of individuals with fibromyalgia: a systematic review. *Journal of Aquatic Physical Therapy*. 2012;19(2):26-35.

**Level of Evidence:** PEDro: N/A Oxford Level: 1a

**Purpose:** The purpose of this review was to determine if aquatic or land-based exercise is more effective in improving overall health status as measured by the Fibromyalgia Impact Questionnaire (FIQ)

**Methods:** Authors systematically searched 8 electronic databases for RCT's published between 2000 to 2010. Two reviewers screened all titles and abstracts and eliminated articles based on exclusion criteria. Eight RCT's were included in this SR. The studies had to include either male or female subjects over the age of 18 and diagnosed with fibromyalgia for at least 2 months. Studies had to use aquatic and/or land-based exercise interventions and use the FIQ as an outcome measure. Studies were excluded if they had modalities, acupuncture, cognitive-behavior, pharmacotherapy, chiropractic, homeopathy, psychotherapy, thalassotherapy, or multidisciplinary interventions. Subjects could not have any other comorbidities that could affect the results of the study.

**Results:** Five of the 8 studies consisted solely of land-based exercise. Three of these studies found significant improvement in the FIQ following land-based intervention. One study found no significant changes between baseline and follow-up FIQ scores, and another study found that only low-intensity exercise created a positive change in the FIQ (when compared to high-intensity exercise). One of the 8 studies only included aquatic exercise and found no significant changes in the FIQ before and after intervention. The final 2 studies compared land and aquatic based exercise. One of these studies found no significant difference between groups and the other study showed greater improvement in the aquatic exercise group.

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**Bottom Line:** This review was unable to determine if land or aquatic therapy was more effective in improving FIQ scores. Low to moderate intensity land or aquatic exercise is effective in improving FIQ for females with fibromyalgia.

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**Reference #6:** Kelley C, Loy DP. Comparing the effects of aquatic and land-based exercise on the physiological stress response of women with fibromyalgia. *Therapeutic Recreation Journal*. 2008;42(2):103-118.

**Level of Evidence:**

PEDro: N/A

Oxford Level: 3b

**Purpose:** The purpose of this study is to examine the effects of aquatic and land-based exercise programs on salivary cortisol levels as a physiological indicator of stress in women with FMS.

The authors examined two questions: If aquatic and land-based programs reduce salivary cortisol levels in women with FMS and which treatment option is the most effective.

**Methods:** *Research Design:* Authors implemented a single-subject alternating treatment design (ATD) conducted across three subjects. *Selection Criteria:* Subjects were referred from a pain clinic and had to have a diagnosis of Fibromyalgia syndrome (FMS), be diagnosed for at least 2 months, be female and between the ages of 25-65, have clearance from physician for exercise, not have taken any steroidal medication for at least 1 week prior to start of study, and have no other major medical conditions. *Exercise Programs:* Land and aquatic programs were conducted over a 10-week period and compared to a control group that performed no exercise. *Aquatic program* consisted of Ai Chi exercises designed to improve balance, coordination, flexibility, and reduce pain and anxiety through diaphragmatic breathing. *Land program* consisted of treadmill session. *Data Collection:* Authors collected cortisol from saliva during and post exercise.

**Results:** Subject 1: Overall, treadmill and Ai Chi demonstrated positive improvements on cortisol levels, but treadmill was more effective.

Subject 2: Overall, all three interventions resulted in therapeutic improvement in cortisol levels, but treadmill was the most effective.

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Subject 3: Based on overall change in median cortisol levels, the slope trend line, and the number of sessions resulting in a decrease in cortisol, treadmill was selected as the most effective intervention.

**Bottom Line:** All three interventions showed therapeutic improvements in cortisol levels in different subjects. Treadmill training was found to be the most effective when compared to aquatic-based exercise and no exercise.

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**Reference #7:** Vitorino DF de M, Carvalho LBC de, Prado GF do. Hydrotherapy and conventional physiotherapy improve total sleep time and quality of life of fibromyalgia patients: randomized clinical trial. *Sleep Med.* 2006;7(3):293-296. doi:10.1016/j.sleep.2005.09.002.

**Level of Evidence:** PEDro 8/10 Oxford Level: 1b

**Purpose:** The purpose of this study was to compare hydrotherapy (HT) and conventional physical therapy (CP) on the quality of life (QOL), total sleep time (TST), and total nap time (TNT) in individuals with fibromyalgia (FM).

**Methods:** Fifty females between the ages of 30-60 years, diagnosed with FM per ACR were included in this study. They were randomly assigned to either CP or HT interventions (25 individuals per group). Physiotherapists were blinded to the randomizations. Authors used the SF-36 questionnaire and sleep diary to evaluate outcome measures. Subjects were instructed to complete logs for 3 weeks. Both groups completed exercises 3 times per week consisting of 5 minutes of warm-up, 6 minutes of stretching, 30 minutes of aerobic exercise, and 13 minutes of relaxation and cool-down.

**Results:** Forty-seven women completed the study. One subject dropping out of the HT groups and 2 from the CP group. They were including in the analysis. The two groups presented were similar prior to start of study. HT group demonstrated greater improvements I TST ( $p < 0.01$ ). All subjects had an increase of at least 1 hour compared to the 19 CP subjects ( $p = 0.04$ ). Both groups demonstrate decreased TNT, but more improvement was seen in HT group ( $p < 0.05$ ). Both groups showed significant improvement in SF-36 questionnaire and no difference was seen between groups.

**Bottom Line:** HT treatment was more effective in improving TST and TNT when compared to CP intervention. Both groups showed improvements in QOL.

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**Reference #8:** Assis MR, Silva LE, Alves AMB, et al. A randomized controlled trial of deep water running: clinical effectiveness of aquatic exercise to treat fibromyalgia. *Arthritis Rheum.* 2006;55(1):57-65. doi:10.1002/art.21693.

**Level of Evidence:**

PEDro 8/10

Oxford Level: 1b

**Purpose:** The purpose of this study was to evaluate the effectiveness of water and land-based aerobic exercise on symptoms associated with fibromyalgia (FM).

**Methods:** Sixty sedentary female subjects, between the ages of 18 and 60 years, who were diagnosed with FM per ACR criteria were randomly allocated to either deep water running (DWR) or land-based exercise (LBE) groups. Both groups exercised 60 minutes, 3 times per week, for 15 weeks. Each session consisted of 10 minutes of warm-up including stretching, 40 minutes of aerobic exercise and 10 minutes of relaxation and cool-down. Intensity was based on anaerobic threshold determined at baseline assessment. All sessions were conducted by 2 physical therapists that alternated each week. These therapists were not involved in the assessments. Subjects' pharmacological treatments were unaltered during this study. Land-based group performed either treadmill walking or jogging to reach target HR and then kept this pace. DWR program was instructed on proper technique for aqua jogging including upright posture, water at shoulder level, and bicycle motion with lower extremities. Target HR's for DWR program were slightly lower to account for water temperature.

**Results:** Four participants in each group dropped out during the intervention due to personal problems and work schedules. There were no significant differences between groups at baseline. Both DWR and LBE groups showed a mean decrease in VAS of 36% from baseline ( $p < 0.001$ ). No difference between groups was identified. Following 8 weeks, 50% of LBE subjects reported improvement per Patient Global Assessment of Response to Therapy (PGART) and at 15 weeks, 73% demonstrated improvements. Seventy percent from the DWR group demonstrated

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improvements at 8 and 15 weeks. No differences noted between groups ( $p = .028$ ). Both groups had improved FIQ scores at 3 different measurements ( $p < 0.001$ ) and greater improvements were seen in the DWR group at week 15 ( $p = 0.033$ ). Both groups showed improvements in Beck's Depression Inventory (BDI) with no difference between groups ( $p = 0.066$ ). Both groups demonstrated improvements in the SF -36 questionnaire with no difference between groups. LBE groups showed greater improvement in anaerobic threshold ( $p = 0.021$ ).

**Bottom Line:** Walking is a cost effective and easily accessible exercise to treat FM, but some individuals are limited in weight-bearing activities secondary to pain associated with FM or other comorbidities including osteoarthritis. This study illustrates that water-based aerobic exercise is equally as effective as land-based therapy, but may have additional advantages for populations unable to perform excessive weight-bearing activities. Aquatic exercise is a viable form of low-impact aerobic exercise for individuals with FM.

Reference Table							
#	Author(s)	Oxford Level	Pedro Score	Purpose	Outcome Measures	Results	Relevant to PICO Question?
1	Sevimili D, et al (2015)	2b	5	To compare the effects of home-based isometric strength and stretching (ISSEP), gym-based aerobic exercise program (AEP), and pool-based aquatic exercises program (AAEP) on the physical and psychological parameters of patients with fibromyalgia FM.	Visual Analog Scale (VAS), Fibromyalgia Impact Questionnaire (FIQ), Six-Minute Walk Test (6MWT), SF-36 physical and mental health scores, and the Beck Depression Inventory (BDI)	AAEP group was more effective in the treatment of FM than AEP and ISSEP groups, the results indicate that the AAEP and AEP groups were both significantly better than the ISSEP group in all outcome measures. AAEP group had the most significant improvement in the MCS, but the AEP groups had a higher improvement in the BDI. The other outcome measures showed no difference between the AAEP and AEP groups meaning that they were both equally as effective in treating FM.	Yes
2	Cazzola M, et al (2010)	1a	N/A	To determine the effects of various types of exercises (anaerobic, and aquatic and land-based aerobic) on overall health and symptomology of patients with FM.	VAS, FIQ, BDI, SF-36	Water-based aerobic and strengthening interventions were more effective in reducing pain and depression. Land-based aerobic exercise showed greater improvements in overall physical function.	Yes

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3	Jentoft E S, et al (2001)	2b	4/10	To examine the efficacy of a pool-based (PE) exercise program compared to a land-based (LE) exercise program with regards to its effects on physical capacity, symptomology, and self-efficacy of adult women with FM.	VAS, FIQ, # and severity of tender points based on pressure tolerance, Arthritis Self-Efficacy Scale, cardiovascular capacity per Astrand's indirect method, grip strength, endurance of upper extremities	Both the PE and LE groups demonstrated improvements in daytime fatigue, stiffness, and tender points. PE group also showed improvements in anxiety, depression, number of days feeling good, and overall pain. Both PE and LE groups had improvements in walking time, and cardiovascular capacity while the LE group had more improvements in grip strength and the PE groups had more improvements in self-reported physical impairment.	Yes
4	Munguia-Izquierdo D, et al (2008)	1b	7/10	To assess the effects of a 16-week water-based exercise program on global symptomology of women with FM.	<i>Pain</i> was assessed using syringe calibrated dolorimeter for threshold of all tender points. <i>Health status</i> was assessed using the FIQ. <i>Psychologic well-being</i> was assessed with 20-item self-administered SAI. <i>Sleep quality</i> assessed with PSQI and	Subjects in the exercise group had significant improvements in PSQI scores, endurance of upper and lower extremities, and FIQ scores when compared to control group. There was no significant change in SAI scores.	Yes

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					<i>cognitive function</i> assessed PASAT. <i>Physical function</i> assessed by examining upper and lower extremity endurance.		
5	Bednar M L, et al (2004)	1a	N/A	To determine if aquatic or land-based exercise is more effective in improving overall health status as measured by the FIQ.	FIQ	Three of the 8 studies included found significant improvement of FIQ following land-based intervention. One study found no significant changes, and another found that only low-intensity exercise had a positive effect. One of the 8 studies only examined aquatic exercise and found no significant changes. The remaining 2 studies compared land vs aquatic. One found no difference between groups and the other determined aquatic exercise to yield greater improvement.	Yes
6	Kelley C, et al (2008)	3b	N/A	To examine the effects of aquatic and land-based exercise programs on salivary cortisol levels as a physiological indicator	Cortisol levels in saliva taken prior to, and within 15 min post intervention.	Both groups demonstrated improvements, although the land-based group was the most effective. Water-based exercise may be appropriate when patients have	Yes

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				of stress in women with FMS. The authors examined two questions: If aquatic and land-based programs reduce salivary cortisol levels in women with FMS and which treatment option is the most effective.		difficulties adhering to land-based programs.	
7	Vitorino D F M, et al (2006)	1b	8/10	To compare hydrotherapy (HT) and conventional physical therapy (CP) on the quality of life (QOL), total sleep time (TST), and total nap time (TNT) in individuals with FM.	SF-36 and sleep diary	HT treatment was more effective in improving TST and TNT when compared to CP intervention. Both groups showed improvements in QOL.	Yes
8	Assis M R, et al (2006)	1b	8/10	To evaluate the effectiveness of water and land-based aerobic exercise on symptoms associated with FM.	Patient Global Assessment of Response to Therapy (PGART), VAS, FIQ, BDI	Both water and land based groups showed improvements in VAS, PGART, BDI, and SF-36 with no difference between groups. The water-based group showed more improvement in FIQ.	Yes

## Aquatic vs Land-based Exercise for Fibromyalgia

**Discussion:** The literature regarding aquatic and land-based exercise largely focuses on reducing symptomology associated with fibromyalgia: chronic pain, tender points, depression, anxiety, sleep disturbances, sympathetic hyperactivity, fatigue, morning stiffness, deficits in cardiovascular health, muscle strength, and endurance. Exercise in the aquatic setting not only provides a social environment for exercise, but also allows for more comfort during movement with warm water conditions and decreased weight bearing through joints. However, the available evidence does not depict a clear standard aquatic exercise program. High variability in types of exercises and ranges in duration, frequency, and intensity can be seen throughout the literature.

Based on this research, it is evident that both aquatic and land-based exercise programs have positive impacts on many of the symptoms associated with fibromyalgia. Six studies directly compared aquatic and land based exercise, most finding no significant differences between land and aquatic-based therapies.<sup>1,3,4,6,7,9</sup> One of these six studies found that although land-based group had more improvements in walking time, and cardiovascular capacity, the aquatic-based group had more significant improvement in anxiety, depression, number of days feeling good, and overall pain.<sup>6</sup> Another study confirmed these results, demonstrating significantly higher reduction in pain for individuals in aquatic-based exercise when compared to a land-based group.<sup>4</sup> One study showed that aquatic-based therapy had more favorable effects on sleep,<sup>11</sup> while a small study of 3 women showed land-based therapy as more effective in decreasing cortisol levels.

Although aquatic-based exercise is proven to have a positive impact on fibromyalgia symptoms, the protocols for achieving these improvements are not well established. All the studies included had instructor led aquatic programs, but varied in frequency, duration, intensity,

## Aquatic vs Land-Based Exercise for Fibromyalgia

and types of exercises, making it difficult to implement. Also, most studies only included adult, female subjects with fibromyalgia making generalization beyond this population difficult. The overall quality of evidence available is low based on small sample sizes, and lack of consistency between outcome measures, and exercise protocol.<sup>3</sup>

Ms. M received physical therapy approximately one time per month to check status and to update any exercises or current home exercise program. She was not participating in regular exercise and sporadically completed her land-based exercise program. Based on the benefits of aquatic-based exercise program, referring her to pool therapy to facilitate regular physical activity and adherence to an exercise program would be an appropriate recommendation. Ms. M also suffered from concomitant depression and sympathetic hypersensitivity leading to a highly stressful life. Pool-based therapy has been shown beneficial in stress relief and reduction in depression symptoms. In combination with the possibility of a higher likelihood of maintained adherence to activity program, pool-based therapy is an ideal program for Ms. M.

Barriers to performing aquatic therapy include setting and availability of a warm water pool. Many outpatient setting do not have access to aquatic facilities, although physical therapists and other medical professionals may have the ability to refer patients out to a skilled aquatic class.

Many of the studies examined did not provide clear exercise protocol including optimal intensity, duration, and frequency of exercises.<sup>3</sup> To apply aquatic or land-based interventions in a clinical setting, more specific guidelines are required. Future research should also include larger sample sizes to strengthen results and examine the adherence to aquatic vs land-based therapy programs.

## Aquatic vs Land-Based Exercise for Fibromyalgia

**Conclusion/Bottom Line:** Based on the results of this evidence-based review of the literature, it is evident that both aquatic and land-based exercise interventions are beneficial for treating women with fibromyalgia. Although land-based interventions demonstrated more significant strength increases and positive impacts on stress, aquatic-based exercise has many advantages over land-based exercise. Aquatic-based interventions provide a unique environment for patients to be active in, and the opportunity to participate in reduced weight-bearing activities. It can be inferred that for patient populations having difficulty adhering to exercise programs due to the monotony or pain of a typical land-based exercise program, aquatic exercise is more appealing and beneficial. Aquatic therapy also showed more significant improvements in psychological well-being including reducing depression and anxiety associated with fibromyalgia. Exercise programs should be tailored to the individual patient and implemented based on the clinician's resources. Although there is not enough evidence available yet to make a strong conclusion regarding whether aquatic or land-based exercise is more effective, this evidence-based review depicts the importance of activity and its link to decreasing symptomology associated with fibromyalgia. Further research should be conducted to determine ideal exercise protocols in both settings.

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**Appendix A: Evidence Appraisal Worksheets**

## Intervention – Evidence Appraisal Worksheet

**Citation:** Sevimli D, Kozanoglu E, Guzel R, Doganay A. The effects of aquatic, isometric strength-stretching and aerobic exercise on physical and psychological parameters of female patients with fibromyalgia syndrome. *J Phys Ther Sci.* 2015;27(6):1781-1786. doi:10.1589/jpts.27.1781.

<b>Is the purpose and background information sufficient?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Study Purpose</b>                      Stated clearly?                      Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis.                      A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>The purpose was clearly stated at the end of the introduction: “This study compared the effects of home-based isometric strength and stretching, gym-based aerobic and pool-based aquatic exercises programs on the physical and psychological parameters of patients with FMS.”</p>
<p><b>Literature</b>                      Relevant background presented?                      A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic.                      Describe the justification of the need for this study</p>	<p>The authors provide relevant background information regarding studies done to examine diagnostic criteria for fibromyalgia (FM), the effect of low intensity exercise on FM, and pool therapy compared to several control groups including non-exercising groups, relaxation groups, and spa therapy groups. The authors imply that there is a gap in literature comparing pool-based therapy and home-based exercise programs and their effect on physical and psychological well-being in patients with FM.</p>

<b>Does the research design have internal validity?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>➤ <b>Discuss possible threats to internal validity in the research design. Include:</b></p> <ul style="list-style-type: none"> <li>➤ <b>Assignment</b></li> <li>➤ <b>Attrition</b></li> <li>➤ <b>History</b></li> <li>➤ <b>Instrumentation</b></li> <li>➤ <b>Maturation</b></li> <li>➤ <b>Testing</b></li> <li>➤ <b>Compensatory Equalization of treatments</b></li> <li>➤ <b>Compensatory rivalry</b></li> <li>➤ <b>Statistical Regression</b></li> </ul>	<p>Assignment: Subjects were matched by age and FM symptoms and then randomly assigned to one of three groups. The authors did not discuss the differences present between each group prior to the start of the experiment or whether any differences were significant or not. If groups present with too much variety, it is difficult to compare results accurately.</p> <p>Attrition: 25 subjects were placed in each group. None dropped out or were lost.</p> <p>Instrumentation: No instrumentation was used for this study, but some measurements require correct precision with following protocol. If tests are conducted in different ways, this could skew results.</p> <p>Maturation: This study had a control group (ISSEP). Subject performance on outcome measure may have been influenced by emotions, physical, psychological or spiritual changes over the course of the study resulting in inconclusive results.</p>

	<p>Compensatory Equalization of Treatments: Authors did not mention if investigators were blinded. This could lead to unequal treatment of the three groups and skew results.</p> <p>Compensatory Rivalry: It is unclear if the subjects were blinded. This could lead to changes in subject behavior and affect their motivation to participate in the exercise program, skewing results.</p> <p>Statistical Regression: Authors did not mention if they eliminated outliers. Outliers alter test scores and skew data.</p>
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<b>Are the results of this therapeutic trial valid?</b>	
<i><b>Appraisal Criterion</b></i>	<i><b>Reader's Comments</b></i>
<p><b>1. Did the investigators randomly assign subjects to treatment groups?</b></p> <p style="margin-left: 20px;"><b>a. If no, describe what was done</b></p> <p style="margin-left: 20px;"><b>b. What are the potential consequences of this assignment process for the study's results?</b></p>	<p>Subjects were randomly assigned to groups after being matched by age and FM symptomology.</p>
<p><b>2. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</b></p> <p style="margin-left: 20px;"><b>a. If they were not similar – what differences existed?</b></p>	<p>Authors did not mention if there were statistically significant differences between groups at the start of the study. No demographics were reported. If the groups were not similar, this would cause inaccurate comparison of groups since values for various outcome measures may be higher or lower when measured at baseline.</p>
<p><b>3. Did the subjects know to which treatment group they were assigned?</b></p> <p style="margin-left: 20px;"><b>a. If yes, what are the potential consequences of the subjects' knowledge for this study's results?</b></p>	<p>Subjects were aware of what exercise group they were in, but it is unclear if they were aware of the other exercise groups. If subjects were aware of the three exercise groups, this could affect their motivation to participate in the programs and alter their performance.</p>
<p><b>4. Did the investigators know who was being assigned to which group prior to the allocation?</b></p> <p style="margin-left: 20px;"><b>a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</b></p>	<p>Authors made no mention of this. If the investigators were not blind, they introduce bias into selecting groups and give one group an advantage over the other two.</p>
<p><b>5. Were the groups managed equally, apart from the actual experimental treatment?</b></p> <p style="margin-left: 20px;"><b>a. If not, what are the potential consequences of this knowledge for the study's results?</b></p>	<p>Groups were not managed equally. The home-based isometric strength and stretching exercise program (ISSEP) were given an HEP to complete daily for 15 per day. No mention was made of a medical professional following up with them periodically. The gymnastic-based aerobic exercise program (AEP), and pool-based aquatic aerobic exercise program (AAEP) exercised 2 times per week for 40 min, 45 min, and 50 min in months 1,2, and 3 respectively. Since the groups were not managed equally, some of the groups have an advantage for improve scores on outcome measures.</p>
<p><b>6. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</b></p>	<p>Yes, the follow-up time was sufficient and the authors could answer their question.</p>

<p>a. <b>If not, what are the potential consequences of this knowledge for the study's results?</b></p>	
<p>7. <b>Did all the subjects originally enrolled complete the study?</b></p> <p>a. <b>If not how many subjects were lost?</b></p> <p>b. <b>What, if anything, did the authors do about this attrition?</b></p> <p>c. <b>What are the implications of the attrition and the way it was handled with respect to the study's findings?</b></p>	<p>Yes, 25 subjects in each group started and completed the study.</p>
<p>8. <b>Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</b></p> <p>a. <b>If not, what did the authors do with the data from these subjects?</b></p> <p>b. <b>If the data were excluded, what are the potential consequences for this study's results?</b></p>	<p>Yes, all patients analyzed in the groups to which they were randomized.</p>
<p><b>Are the valid results of this RCT important?</b></p>	
<p><b><i>Appraisal Criterion</i></b></p>	<p><b><i>Reader's Comments</i></b></p>
<p>9. <b>What were the statistical findings of this study?</b></p> <p>a. <b>When appropriate use the calculation forms below to determine these values</b></p> <p>b. <b>Include: tests of differences? With p-values and CI</b></p> <p>c. <b>Include effect size with p-values and CI</b></p> <p>d. <b>Include ARR/ABI and RRR/RBI with p-values and CI</b></p> <p>e. <b>Include NNT and CI</b></p> <p>10. <b>What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</b></p>	<p>VAS: ISSEP group showed no statistically significant improvement, and had a slight increase after the 12-week study. AAEP and AEP both had significant improvements, but no difference between the groups.</p> <p>BDI: AAEP and AEP groups showed significant improvements (AEP&gt;AAEP)</p> <p>FIQ: AAEP and AEP had statistically significant improvements, but no between group differences.</p> <p>6MWT: AAEP and AEP had statistically significant improvements. No differences between groups.</p> <p>MCS: AAEP and AEP showed more improvement than the ISSEP group. AAEP showed more improvement than the AEP group.</p> <p>PCS: AAEP and AEP showed more improvement than the ISSEP group. No difference between AAEP and AEP groups.</p> <p>These results indicate that pool therapy is as effective as land therapy for addressing physical and psychological symptoms of FM. It is unclear if one method is better than the</p>

	other and should be based on individual patient.
<p>11. Do these findings exceed a minimally important difference?                  a. If not, will you still use this evidence?</p>	These findings demonstrate clear improvement in several outcome measures important to individuals with fibromyalgia.
<p><b>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</b></p>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
12. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	This intervention does not give strong evidence to support pool therapy over land therapy. It suggests that either program is more effective than just a HEP.
13. Are the study subjects similar to your patient/ client? a. If not, how different? Can you use this intervention in spite of the differences?	The subjects were adult females which is representative of my current client population with FM.
14. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	There is very little risk with either a pool or land based exercise program, making either option relevant and achievable.
15. Does the intervention fit within your patient/client's stated values or expectations? a. If not, what will you do now?	Pool therapy is available at some outpatient clinics and should be more highly considered in areas that do not have the option.
16. Are there any threats to external validity in this study?	The authors did not include much information regarding the demographics of the subjects used. Since it is unclear if this population is diversified, it may be difficult to extrapolate data to use with the general population.

<p><b>What is the bottom line?</b></p>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
PEDRO Score (see scoring at end of form)	5
Summarize your findings and relate this back to clinical significance	This study indicates that both pool and land-based therapies are effective in reducing pain, number of tender points, and depression, while improving quality of life, endurance, and physical and mental aspects in patients with FM. Although there was not much difference between these groups, both pool and land-based therapy showed more improvement than home-based programs in which subjects had very little improvement in any outcomes. Pool therapy is just as effective as land therapy, yet not many clinics provide the opportunity for patients to utilize this resource. Pool therapy should be more readily available to patients with FM as an alternative.

### Pedro Scoring System:

#### Internal Validity Score (scored out of 8)

Criteria	Rating
1. Subjects were <b>randomly allocated</b> to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received.)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
2.	
3. <b>Allocation was concealed.</b>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
4. The groups were <b>similar at baseline</b> regarding the most important prognostic indicators.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
5. There was <b>blinding of all subjects.</b>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
6. There was <b>blinding of all therapists</b> who administered the therapy.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
7. There was <b>blinding of all assessors</b> who measured at least one key outcome.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
8. Measures of at least one key outcome were obtained from <b>more than 85% of the subjects</b> initially allocated to groups.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by <b>"intention to treat"</b> .	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
<b>Statistical reporting score (scored out of 2)</b>	
10. The results of <b>between-group statistical comparisons</b> are reported for at least one key outcome	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
11. The study provides both <b>point measures</b> and <b>measures of variability</b> for at least one key outcome.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
12. <b>Eligibility criteria</b> were specified (not included in score).	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:

Adapted from : Jewell, D. Guide to Evidence Based Physical Therapy Practice.  
Jones  
and Bartlett Publishers, Sudbury, MA 2008

## Systematic Review – Evidence Appraisal Worksheet

**Citation:** Cazzola M, Atzeni F, Salaffi F, Stisi S, Cassisi G, Sarzi-Puttini P. Which kind of exercise is best in fibromyalgia therapeutic programmes? A practical review. *Clin Exp Rheumatol*. 2010;28(6 Suppl 63):S117-S124.

**Level of Evidence (Oxford scale): 1a**

<b>Does the design follow the Cochrane method?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Step 1 – formulating the question</b></p> <ul style="list-style-type: none"> <li>• <b>Do the authors identify the focus of the review</b></li> <li>• <b>A clearly defined question should specify the types of:</b> <ul style="list-style-type: none"> <li>• <b>people (participants),</b></li> <li>• <b>interventions or exposures,</b></li> <li>• <b>outcomes that are of interest</b></li> <li>• <b>studies that are relevant to answering the question</b></li> </ul> </li> </ul>	<p>The purpose of this review was to determine the effects of various types of exercises on overall health and symptomology of patients with fibromyalgia (FM).</p> <p><i>Participants:</i> The authors do not specify how many subjects were included in this review, but they do include tables denoting how many subjects were in each RCT and how many drop-outs occurred. They do not specify the inclusion criteria of the subjects.</p> <p><i>Interventions:</i> Physical aerobic exercise (PAE), muscle strengthening exercise (MSE), physical aerobic activity (PAA)</p> <p><i>Outcome Measures:</i> Pain (VAS), mental/physical well-being (FIQ, BDI), cardiovascular health (VO2 max)</p> <p><i>Relevant Studies:</i> Twenty-seven RCT's published between 1985 and 2010 that used outcome measures associated with FM (pain and physical/mental well-being).</p>
<p><b>Step 2 – locating studies</b></p> <ul style="list-style-type: none"> <li>• <b>Should identify ALL relevant literature</b></li> <li>• <b>Did they include multiple databases?</b></li> <li>• <b>Was the search strategy defined and include:</b> <ul style="list-style-type: none"> <li>○ <b>Bibliographic databases used as well as hand searching</b></li> <li>○ <b>Terms (key words and index terms)</b></li> <li>○ <b>Citation searching: reference lists</b></li> <li>○ <b>Contact with 'experts' to identify 'grey' literature (body of materials that cannot be found easily through conventional channels such as publishers)</b></li> <li>○ <b>Sources for 'grey literature'</b></li> </ul> </li> </ul>	<p>Authors searched 4 databases (Medline, EMBASE, Cochrane Central Register of Controlled Trials, and Cochrane Database of SR's) for relevant sources. They included the MeSH terms used. They do not mention if they contacted 'excerpts' regarding 'grey' literature.</p>
<p><b>Part 3: Critical Appraisal/Criteria for Inclusion</b></p> <ul style="list-style-type: none"> <li>• <b>Were criteria for selection specified?</b> <ul style="list-style-type: none"> <li>• <b>Did more than one author assess the relevance of each report</b></li> </ul> </li> </ul>	<p>The authors do not specify the process in which each study was evaluated, but do include that they identified 437 publications with their initial search and then eliminated studies that were not RCT's. They also excluded studies using more than one type of exercise intervention at a time. The RCT's needed to include</p>

<ul style="list-style-type: none"> <li>• <b>Were decisions concerning relevance described; completed by non-experts, or both?</b></li> <li>• <b>Did the people assessing the relevance of studies know the names of the authors, institutions, journal of publication and results when they apply the inclusion criteria? Or is it blind?</b></li> </ul>	<p>outcome measures regarding mental function, physical functions, and pain (subjective questionnaires, tender points, myalgic scores, VAS). The authors do not specify if they were blinded during the article selection process or if there was a third-party to reconcile any discrepancies between the authors.</p>
<p><b>Part 3 – Critically appraise for bias:</b></p> <ul style="list-style-type: none"> <li>• <b>Selection –</b> <ul style="list-style-type: none"> <li>• <b>Were the groups in the study selected differently?</b></li> <li>• <b>Random? Concealed?</b></li> </ul> </li> <li>• <b>Performance-</b> <ul style="list-style-type: none"> <li>• <b>Did the groups in the study receive different treatment?</b></li> <li>• <b>Was there blinding?</b></li> </ul> </li> <li>• <b>Attrition –</b> <ul style="list-style-type: none"> <li>• <b>Were the groups similar at the end of the study?</b></li> <li>• <b>Account for drop outs?</b></li> </ul> </li> <li>• <b>Detection –</b> <ul style="list-style-type: none"> <li>• <b>Did the study selectively report the results?</b></li> <li>• <b>Is there missing data?</b></li> </ul> </li> </ul>	<p>The authors do not specify the selection process of subjects within each RCT. Fifteen studies examined land-based PAE, 7 examined water-based PAE, 5 examines MSE. No mention of blinding within each RCT. Attrition was included in tables outlining the number of subjects in each RCT and the number of dropouts. No mention of how this affected group similarities at the end of the study. The authors do not speak to the RCT’s data or if they selectively reported results.</p>
<p><b>Part 4 – Collection of the data</b></p> <ul style="list-style-type: none"> <li>• <b>Was a collection data form used and is it included?</b></li> <li>• <b>Are the studies coded and is the data coding easy to follow?</b></li> <li>• <b>Were studies identified that were excluded &amp; did they give reasons why (i.e., which criteria they failed).</b></li> </ul>	<p>Authors did not specify if a collection data form was used and none were included. No mention of study coding. Authors detail inclusion criteria for RCTs (detailed in “part 3: critical appraisal”).</p>

<b>Are the results of this SR valid?</b>	
<i>Appraisal Criterion</i>	<i>Reader’s Comments</i>
<p><b>17. Is this a SR of randomized trials? Did they limit this to high quality studies at the top of the hierarchies</b></p> <ol style="list-style-type: none"> <li><b>If not, what types of studies were included?</b></li> <li><b>What are the potential consequences of including these studies for this review’s results?</b></li> </ol>	<p>This review only utilized RCT’s, but did not mention the quality of studies or include PEDro scores. The quality of evidence is important to this review clinical relevance. If the study quality is low, it is difficult to make definitive conclusions regarding their PICO question.</p>
<p><b>18. Did this study follow the Cochrane methods selection process and did it identify all relevant trials?</b></p> <ol style="list-style-type: none"> <li><b>If not, what are the consequences for this review’s results?</b></li> </ol>	<p>This study follows Cochrane methods selection process.</p>

<p><b>19. Do the methods describe the processes and tools used to assess the quality of individual studies?</b>  <b>a. If not, what are the consequences for this review's results?</b></p>	<p>No mention of how the authors assessed quality of individual studies. This affects the reliability of their conclusions in that the RCT's may be of low quality, compromising the strength of their results.</p>
<p><b>20. What was the quality of the individual studies included? Were the results consistent from study to study? Did the investigators provide details about the research validity or quality of the studies included in review?</b></p>	<p>Not included.</p>
<p><b>21. Did the investigators address publication bias</b></p>	<p>Not mentioned. No study limitations were included.</p>

**Are the valid results of this SR important?**

<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>22. Were the results homogenous from study to study?  <b>a. If not, what are the consequences for this review's results?</b></p>	<p>Yes, the results for the RCT's were homogenous and drew similar conclusions.</p>
<p><b>23. If the paper is a meta-analysis did they report the statistical results? Did they include a forest plot? What other statistics do they include? Are there CIs?</b></p>	<p>N/A</p>
<p><b>24. From the findings, is it apparent what the cumulative weight of the evidence is?</b></p>	<p>No</p>

**Can you apply this valid, important evidence from this SR in caring for your patient/client? What is the external validity?**

<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>25. Is your patient different from those in this SR?</b></p>	<p>Specifications of subject demographics were not included. The authors only confirm that each RCT used subjects diagnosed with fibromyalgia were included.</p>
<p><b>26. Is the treatment feasible in your setting? Do you have the facilities, skill set, time, 3<sup>rd</sup> party coverage to provide this treatment?</b></p>	<p>Land, aquatic, stretching and strengthening programs are all possible in my current setting.</p>
<p><b>27. Does the intervention fit within your patient/client's stated values or expectations?</b>  <b>a. If not, what will you do now?</b></p>	<p>These interventions were geared toward improving physical and mental well-being. This aligns with my patient's goals and values.</p>

**What is the bottom line?**

<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Summarize your findings and relate this back to clinical significance</b></p>	<p>This review found no definitive differences between various types of exercise including water, land, aerobic or strengthening programs regarding physical fitness. Water-based aerobic programs and strengthening exercises seemed to be more effective in reduction pain and depression in subjects. The review found that pain was exacerbated with high intensity workload and that low to moderate intensity exercise is more effective for</p>

## Aquatic vs Land-Based Exercise for Fibromyalgia

	<p>physical and mental function. Authors also conclude that lifestyle changes to include more moderate intensity exercise, regardless of type, is the most effective strategy to improve quality of life in patients with fibromyalgia.</p> <p>Clinically, this indicates that intensity is more important than type of exercise. Beginning low to moderate intensity exercise is effective in improving physical and mental well-being for patients with fibromyalgia.</p>
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**Adapted from : Jewell, D. Guide to Evidence Based Physical Therapy Practice. Jones and Bartlett Publishers, Sudbury, MA 2008**

## Intervention – Evidence Appraisal Worksheet

**Citation:** Jentoft ES, Kvalvik AG, Mengshoel AM. Effects of pool-based and land-based aerobic exercise on women with fibromyalgia/chronic widespread muscle pain. *Arthritis & Rheumatism: Arthritis Care & Research*. 2001;45(1):42-47.

<b>Is the purpose and background information sufficient?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Study Purpose</b>                      Stated clearly?                      Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis.                      A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>Purpose is clearly stated: "The aim of the present study was to examine whether there were any differences in symptoms, self-efficacy, self-reported physical impairment, and physical capacity in a group of FM patients performing structured pool-based and land-based aerobic exercise programs."</p> <p>This study is relevant to an outpatient PT population in that it provides treatment ideas for patients with fibromyalgia (FM).</p>
<p><b>Literature</b>                      Relevant background presented?                      A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic.                      Describe the justification of the need for this study</p>	<p><del>Background is present. The authors provide</del> descriptions of how FM is diagnosed based on presence of 11/18 tender points, widespread musculoskeletal pain for at least 3 months, and subjective symptoms such as sleep difficulties, stiffness, gastrointestinal problems, anxiety, depression, and fatigue. The authors included information from various studies regarding diagnosis of FM, pharmaceutical treatment, and aerobic exercise programs on physical capacity. The authors justify the need for this study based on the lack of evidence examining if aquatic exercise has similar outcomes when compared to land-based exercise.</p>

<b>Does the research design have internal validity?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>➤ <b>Discuss possible threats to internal validity in the research design. Include:</b></p> <ul style="list-style-type: none"> <li>➤ <b>Assignment</b></li> <li>➤ <b>Attrition</b></li> <li>➤ <b>History</b></li> <li>➤ <b>Instrumentation</b></li> <li>➤ <b>Maturation</b></li> <li>➤ <b>Testing</b></li> <li>➤ <b>Compensatory Equalization of treatments</b></li> <li>➤ <b>Compensatory rivalry</b></li> <li>➤ <b>Statistical Regression</b></li> </ul>	<p>Assignment: PE group had 18 subjects while LE group had 16 subjects. The authors also mention that the groups had several differences described above, although not considered statistically significant.</p> <p>Attrition: Nine subjects dropped out or were excluded prior to the start of exercise programs.</p> <p>Instrumentation: several instruments and tests were used that require proper calibration and trained personnel familiar with specific protocol to perform correctly and accurately.</p> <p>Testing: Testing protocol for outcome measures was not detailed by authors. Possibility of learning curve if subjects were allowed multiple attempts prior to recorded measure.</p>

	<p>Compensatory Rivalry: Not mentioned weather subjects were blinded to other groups involved in the study. This can alter subject performance based on personal bias of treatment type.</p> <p>Statistical Regression: Authors did not discuss if outliers were eliminated. This could skew results.</p>
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<b>Are the results of this therapeutic trial valid?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>28. Did the investigators randomly assign subjects to treatment groups?</b></p> <p>a. If no, describe what was done</p> <p>b. What are the potential consequences of this assignment process for the study's results?</p>	<p>Subjects were randomly allocated to pool exercise (PE) group and land exercise (LE) group.</p>
<p><b>29. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</b></p> <p>a. If they were not similar – what differences existed?</p>	<p>Authors reported that there were differences between groups although not statistically significant. Characteristics of each group were reported; however, no demographics were reported. Subjects were all female, but differences included: number of subjects in each group (PE = 18, LE = 16), average age (PE = 42.9, LE = 39.4), number of tender points (PE = 13, LE = 9)</p>
<p><b>30. Did the subjects know to which treatment group they were assign?</b></p> <p>a. If yes, what are the potential consequences of the subjects' knowledge for this study's results</p>	<p>It is unclear if the subjects were aware of the study's design and if they were aware of the opposite group. Subjects did know what exercise group they were in since they only participated in either pool or land-based exercises. Potential consequences could include bias from subjects that would change their performance in the exercise programs, skewing the results of the study.</p>
<p><b>31. Did the investigators know who was being assigned to which group prior to the allocation?</b></p> <p>a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</p>	<p>The investigators did not know who was being assigned to which group prior to allocation. The physiotherapists conducting the examinations/reexaminations and exercise programs were blinded for the patients' group affiliation.</p>
<p><b>32. Were the groups managed equally, apart from the actual experimental treatment?</b></p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p><b>Exercise Program:</b> Both groups were managed equally. Both exercise programs were 20 weeks with a 6 month follow up following the conclusion of the study. Both groups were also evaluated by the same two physiotherapists. LE group used a standardized exercise program based on the Norwegian Aerobic Fitness Model. PE group used a modified version of the same model. Both programs were focused on improving cardiovascular capacity, lasting 60 min, and consisted of body awareness training, ergonomics, warm-up exercise, aerobic dance, cooling down exercises, stretching, strengthening, and relaxation training.</p> <p><b>Effects on symptoms and self-efficacy:</b> Both groups filled out the Fibromyalgia Impact Questionnaire (FIQ), Visual analog scales (VAS),</p>

	<p>tender points were located with ACR classification criteria, and the Arthritis Self-Efficacy Scale.</p> <p><b>Effects on Physical Function:</b> Both groups performed the same tests to measure cardiovascular capacity (max O2 uptake on bicycle ergometer), grip strength (hand-held manometer), endurance of shoulder muscles (non-dominant UE holding paper against wall with a pencil at 90 degrees), and walking time (100m timed walk)</p>
<p>33. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>Exercise programs were 20 weeks and there was an additional 6-month follow-up. This was enough time to gather results and measurements to answer the question posed by the research.</p>
<p>34. Did all the subjects originally enrolled complete the study?</p> <p>a. If not how many subjects were lost?</p> <p>b. What, if anything, did the authors do about this attrition?</p> <p>c. What are the implications of the attrition and the way it was handled with respect to the study's findings?</p>	<p>38 females participated in the study. 9 subjects were lost. The authors did not mention making any adjustments for the attrition. Since this study already had a small sample size, once 9 subjects were lost, this left on 18 subjects in the PE group and 16 subjects in the LE group. The authors state that these small groups sizes may have contributed to the differences seen between groups making it more difficult to directly compare results between groups.</p>
<p>35. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>All subjects were analyzed in the groups to which they were randomized. There was no mention of excluded data from either group.</p>
<p><b>Are the valid results of this RCT important?</b></p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>36. What were the statistical findings of this study?</p> <p>a. When appropriate use the calculation forms below to determine these values</p> <p>b. Include: tests of differences? With p-values and CI</p> <p>c. Include effect size with p-values and CI</p> <p>d. Include ARR/ABI and RRR/RBI with p-values and CI</p> <p>e. Include NNT and CI</p> <p>37. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p><b>Effects on Symptoms and Self-Efficacy:</b> Both groups showed statistically significant, within group, improvements. <u>PE Group:</u> improvements in pain (P =0.006), daytime fatigue (P=0.002), stiffness (P= 0.003), anxiety (P=0.04), depression (P=0.04), number of days of feeling food (P&lt;0.001). <u>LE Group:</u> improvements in daytime fatigue (P=0.02), stiffness (P= 0.02), number of tender points (P = 0.02). Number of tender points in the LE group had risen again at the 6 month follow up, but no other changes were identified in either group at the time of follow-up.</p> <p><b>Physical Function:</b></p>

	<p>LE Group: improvements in grip strength (P=0.02), cardiovascular capacity (P = 0.004), walking time (P = 0.002).                  PE Group: improvements in self-reported physical impairment (P &lt;0.05), cardiovascular capacity (P = 0.02), walking time (P = 0.003).                  The above improvements were still present at the 6-month follow-up, but there was a slight reduction in LE group cardiovascular capacity (P = 0.001) and PE group grip strength (P = 0.03).  <b>Clinical Relevance:</b>                  These findings indicate that both pool and land based therapy are effective methods for not only improving physical strength and endurance, but pain and fatigue. This research provides evidence to support pool therapy as a viable treatment option for patients with fibromyalgia.</p>
<p>38. Do these findings exceed a minimally important difference?                  a. If not, will you still use this evidence?</p>	<p>The findings indicate a significant improvement in physical capacity and self-efficacy. These improvements are clinically important and relevant.</p>
<p><b>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</b></p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>39. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?</p>	<p>Not many outpatient clinics can provide their patients with pool therapy, but for those that can, this could be an effective program.</p>
<p>40. Are the study subjects similar to your patient/ client?                  a. If not, how different? Can you use this intervention in spite of the differences?</p>	<p>I have treated several women diagnosed with fibromyalgia that are close to this age group. The study is a good representation of the patients I have encountered.</p>
<p>41. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?</p>	<p>Yes, there is very little risk to participating in pool or land-based exercise programs and the benefits are vast.</p>
<p>42. Does the intervention fit within your patient/client's stated values or expectations?                  a. If not, what will you do now?</p>	<p>The intervention addressed a wide variety of outcome measures that are all relevant to my patient population and their values.</p>
<p>43. Are there any threats to external validity in this study?</p>	<p>The subjects used in this study were all adult women and all from Norway. Although more adult women are affected by fibromyalgia</p>

	than adult males, this study is difficult to generalize to populations outside of Norway.
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<b>What is the bottom line?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<b>PEDRO Score (see scoring at end of form)</b>	<b>4</b>
<b>Summarize your findings and relate this back to clinical significance</b>	This study found that both land-based and pool-based exercise programs create significant improvements in physical capacity, symptomology, and self-efficacy in patients with fibromyalgia. A greater improvement in grip strength was seen in the land-based exercise group, but pool-based exercise group had a more favorable effect on self-reported depression. This is clinically significant in that this study justifies that pool-based therapy is just as effective as land-based therapy to improve physical capacity, symptomology, and self-efficacy in women with fibromyalgia. Pool-based therapy should be considered a viable treatment option for this population.

### Pedro Scoring System:

#### Internal Validity Score (scored out of 8)

Criteria	Rating
13. Subjects were <b>randomly allocated</b> to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received.)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
14.	
<b>15. Allocation was concealed.</b>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
16. The groups were <b>similar at baseline</b> regarding the most important prognostic indicators.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
17. There was <b>blinding of all subjects.</b>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
18. There was <b>blinding of all therapists</b> who administered the therapy.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
19. There was <b>blinding of all assessors</b> who measured at least one key outcome.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
20. Measures of at least one key outcome were obtained from <b>more than 85% of the subjects</b> initially allocated to groups.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
21. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by <b>"intention to treat"</b> .	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
<b>Statistical reporting score (scored out of 2)</b>	
22. The results of <b>between-group statistical comparisons</b> are reported for at least one key outcome	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
23. The study provides both <b>point measures</b> and <b>measures of variability</b> for at least one key outcome.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
24. <b>Eligibility criteria</b> were specified (not included in score).	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:

Adapted from : Jewell, D. Guide to Evidence Based Physical Therapy Practice.  
Jones  
and Bartlett Publishers, Sudbury, MA 2008

## Systematic Review – Evidence Appraisal Worksheet

**Citation:** Bednar ML, Soroczynski AC, Groman MJ, et al. Effectiveness of land-based and aquatic-based exercises for improving the health status of individuals with fibromyalgia: a systematic review. *Journal of Aquatic Physical Therapy*. 2012;19(2):26-35.

**Level of Evidence (Oxford scale):** 1a

<b>Does the design follow the Cochrane method?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Step 1 – formulating the question</b></p> <ul style="list-style-type: none"> <li>• <b>Do the authors identify the focus of the review</b></li> <li>• <b>A clearly defined question should specify the types of:</b> <ul style="list-style-type: none"> <li>• <b>people (participants),</b></li> <li>• <b>interventions or exposures,</b></li> <li>• <b>outcomes that are of interest</b></li> <li>• <b>studies that are relevant to answering the question</b></li> </ul> </li> </ul>	<p>The purpose of this review was to determine if aquatic or land-based exercise is more effective in improving overall health status as measured by the Fibromyalgia Impact Questionnaire (FIQ)</p> <p><i>Subjects</i> included could be either male or female and 18 years of age or older. Only RCT's were included in this review. The FIQ was the only <i>outcome of interest</i> and all RCT's had to use this as an outcome measure. Studies had to have land and/or aquatic interventions. Interventions that caused a study to be <i>excluded</i> were: modalities, acupuncture, cognitive-behavior, pharmacotherapy, chiropractic, homeopathy, psychotherapy, thalassotherapy, multidisciplinary, comorbidities.</p>
<p><b>Step 2 – locating studies</b></p> <ul style="list-style-type: none"> <li>• <b>Should identify ALL relevant literature</b></li> <li>• <b>Did they include multiple databases?</b></li> <li>• <b>Was the search strategy defined and include:</b> <ul style="list-style-type: none"> <li>○ <b>Bibliographic databases used as well as hand searching</b></li> <li>○ <b>Terms (key words and index terms)</b></li> <li>○ <b>Citation searching: reference lists</b></li> <li>○ <b>Contact with 'experts' to identify 'grey' literature (body of materials that cannot be found easily through conventional channels such as publishers)</b></li> <li>○ <b>Sources for 'grey literature'</b></li> </ul> </li> </ul>	<p>The authors looked at RCT's within a 10-year time span, but also included several systematic reviews examining similar topics.</p> <p>The authors electronically searched 8 databases and hand searched for additional resources.</p> <p>Key terms were listed in Figure 1.</p> <p>The authors made no mention of 'grey' literature.</p>
<p><b>Part 3: Critical Appraisal/Criteria for Inclusion</b></p> <ul style="list-style-type: none"> <li>• <b>Were criteria for selection specified?</b> <ul style="list-style-type: none"> <li>• <b>Did more than one author assess the relevance of each report</b></li> <li>• <b>Were decisions concerning relevance described; completed by non-experts, or both?</b></li> <li>• <b>Did the people assessing the relevance of studies know the names of the authors, institutions, journal of publication and results</b></li> </ul> </li> </ul>	<p>Two reviewers assessed the list of citations and screened titles for relevance. Any discrepancies were decided by an arbitrator. There was no mention whether the reviewers were blinded to the journal, or authors of the studies they were screening.</p>

<b>when they apply the inclusion criteria? Or is it blind?</b>	
<b>Part 3 – Critically appraise for bias:</b> <ul style="list-style-type: none"> <li>• <b>Selection –</b> <ul style="list-style-type: none"> <li>• <b>Were the groups in the study selected differently?</b></li> <li>• <b>Random? Concealed?</b></li> </ul> </li> <li>• <b>Performance-</b> <ul style="list-style-type: none"> <li>• <b>Did the groups in the study receive different treatment?</b></li> <li>• <b>Was there blinding?</b></li> </ul> </li> <li>• <b>Attrition –</b> <ul style="list-style-type: none"> <li>• <b>Were the groups similar at the end of the study?</b></li> <li>• <b>Account for drop outs?</b></li> </ul> </li> <li>• <b>Detection –</b> <ul style="list-style-type: none"> <li>• <b>Did the study selectively report the results?</b></li> <li>• <b>Is there missing data?</b></li> </ul> </li> </ul>	<i>Selection:</i> A total of 442 subjects completed interventions in the 8 studies examined (sample size ranging from 21 to 136). <i>Attrition:</i> Authors were not concerned with attrition since the rate of drop out was low and consistent between study and control groups. No mention of how the individual studies assigned subjects to groups. <i>Performance:</i> Five of the 8 studies examined only land-based exercises. One study looked at aquatic exercise only and the remaining 2 studies compared land and aquatic-based exercises. Only 2 of the studies used random allocation or concealing of the comparison groups. Five studies did not use intent-to-treat. None of the studies blinded the subjects or therapists. <i>Detection:</i> The authors do no mention if the 8 studies left out results.
<b>Part 4 – Collection of the data</b> <ul style="list-style-type: none"> <li>• <b>Was a collection data form used and is it included?</b></li> <li>• <b>Are the studies coded and is the data coding easy to follow?</b></li> <li>• <b>Were studies identified that were excluded &amp; did they give reasons why (i.e., which criteria they failed).</b></li> </ul>	A data extraction form was included. The coding was not included.

<b>Are the results of this SR valid?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<b>44. Is this a SR of randomized trials? Did they limit this to high quality studies at the top of the hierarchies?</b> <ul style="list-style-type: none"> <li>a. <b>If not, what types of studies were included?</b></li> <li>b. <b>What are the potential consequences of including these studies for this review's results?</b></li> </ul>	The authors mention that 2 reviewers rated each of the 8 RCT's based on the PEDro scale and that any discrepancies were resolved by an arbitrator. They did not, however, include the scores of the RCT's that they evaluated. All RCT's averaged a PEDro score of 6/10 (range 5-8).
<b>45. Did this study follow the Cochrane methods selection process and did it identify all relevant trials?</b> <ul style="list-style-type: none"> <li>a. <b>If not, what are the consequences for this review's results?</b></li> </ul>	The authors followed the Cochrane methods selection process and identified all relevant trials.
<b>46. Do the methods describe the processes and tools used to assess the quality of individual studies?</b> <ul style="list-style-type: none"> <li>a. <b>If not, what are the consequences for this review's results?</b></li> </ul>	See #1 The authors also include that the 2 reviewers practiced rating RCT's using the PEDro scale and following 3 reviews were deemed competent in the area.
<b>47. What was the quality of the individual studies included? Were the results consistent from study to study? Did the investigators</b>	No, the quality of the individual studies was not included. The authors did not include much information regarding the research validity or quality of the RCT's.

## Aquatic vs Land-Based Exercise for Fibromyalgia

provide details about the research validity or quality of the studies included in review?	
<b>48. Did the investigators address publication bias</b>	Yes, the authors discuss how there is publication bias in that they were only able to analyze articles published in English.
<b>Are the valid results of this SR important?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
49. Were the results homogenous from study to study? a. If not, what are the consequences for this review's results?	6 of 8 RCT's showed statistically significant within-group changes in the treatment group between baseline and follow-up measurements. One study found that aquatic therapy had a more significant impact than land therapy. One study found no change between baseline and follow-up measurements in the control or treatment groups.
50. If the paper is a meta-analysis did they report the statistical results? Did they include a forest plot? What other statistics do they include? Are there CIs?	N/A
51. From the findings, is it apparent what the cumulative weight of the evidence is?	The cumulative weight of the evidence is not apparent.
<b>Can you apply this valid, important evidence from this SR in caring for your patient/client? What is the external validity?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
52. Is your patient different from those in this SR?	My patient fits into the subjects used in this SR.
53. Is the treatment feasible in your setting? Do you have the facilities, skill set, time, 3 <sup>rd</sup> party coverage to provide this treatment?	Land-based therapy is feasible in all outpatient settings. Aquatic-based therapy may be more difficult to implement depending on available facilities. Both types of intervention are covered by insurance companies.
54. Does the intervention fit within your patient/client's stated values or expectations? b. If not, what will you do now?	My patient's goals align with both interventions. They are aimed at improving quality of life in both physical and psychological aspects.
<b>What is the bottom line?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
Summarize your findings and relate this back to clinical significance	This SR examined 8 RCT's in which subjects participated in either aquatic or land-based exercise programs. Interventions ranged from 5 to 24 weeks and subject improvements were based on baseline and follow up scores on the FIC. Six of the 8 RCTs determined that statistically significant improvements occurred in both land and aquatic-based programs. One

## Aquatic vs Land-Based Exercise for Fibromyalgia

	<p>study found a greater statistically significant improvement in aquatic therapy when compared to land therapy and another study found improvements in only low-intensity land-based therapy.</p> <p>This review was unable to determine if land or aquatic therapy was more effective in improving FIQ scores. This may be due to the small sample sizes and short time frames of the RCT's. The authors also mention that there is little consistency between the studies exercise protocol. This lack of detail regarding exercise prescription and intensity indicates need for future research with larger trials that directly compare land to aquatic-based exercise programs.</p> <p>The clinical significance of this article suggests that low to moderate intensity exercise in either land or aquatic-based programs are effective in improving FIQ for females with fibromyalgia.</p>
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**Adapted from : Jewell, D. Guide to Evidence Based Physical Therapy Practice. Jones and Bartlett Publishers, Sudbury, MA 2008**

## Intervention – Evidence Appraisal Worksheet

**Citation:** Kelley C, Loy DP. Comparing the effects of aquatic and land-based exercise on the physiological stress response of women with fibromyalgia. *Therapeutic Recreation Journal*. 2008;42(2):103-118.

<b>Is the purpose and background information sufficient?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Study Purpose</b>                      Stated clearly?                      Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis.                      A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>The purpose is clearly stated at the end of the background.                      The purpose of this study is to examine the effects of an Ai Chi (aquatic program) and a land-based exercise program on salivary cortisol levels as a physiological indicator of stress in women with FMS.                      The authors want to examine two questions: If aquatic and land-based programs reduce salivary cortisol levels in women with FMS and which treatment option is most effective.</p>
<p><b>Literature</b>                      Relevant background presented?                      A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic.                      Describe the justification of the need for this study</p>	<p>The authors provide a thorough background including diagnostic criteria for FMS and what population it is most prevalent in. They include references regarding the findings that individuals with FMS often have elevated sympathetic responses and are constantly over-stimulated. Elevated levels of cortisone lead to chronic stress and a state of adrenal exhaustion. The authors also provide information regarding literature findings that land-based exercise program is shown to have a positive impact on FMS symptoms, but that patient compliance is lower when compared to aquatic therapies. Both treatment options have been found to be effective in improve physical and psychological distress, but there is a gap in literature examining the effects of aquatic and land-based therapy on cortisol levels and stress response.</p>

<b>Does the research design have internal validity?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>➤ <b>Discuss possible threats to internal validity in the research design. Include:</b>                      ➤ <b>Assignment</b>                      ➤ <b>Attrition</b>                      ➤ <b>History</b>                      ➤ <b>Instrumentation</b>                      ➤ <b>Maturation</b>                      ➤ <b>Testing</b>                      ➤ <b>Compensatory Equalization of treatments</b>                      ➤ <b>Compensatory rivalry</b>                      ➤ <b>Statistical Regression</b></p>	<p>Assignment: This study implemented a single-subject alternating treatment design (ATD) conducted across 3 participants. This allows for comparison of effects within individual cases. No groups were formed. All participants completed the same intervention at the same time and results were compared to their own baseline.                      Attrition: Four participants were initially included and one dropped out after 3 weeks. This has a higher effect on the external validity, since this did not affect groups size or homogeneity.                      History: The authors did not discuss if the subjects had directions for outside activities. One of the subjects had adult-aged children, and one subject had no children. Various circumstances and social factors</p>

	<p>could affect the subjects' stress level and cause inaccurate results.</p> <p><b>Instrumentation:</b> This study used salivary cortisol results as its main objective measure since it is easy for subjects to complete at home. To assure accuracy, the authors had the subjects complete the process several times in front of them until the process was done 100% correct. They also observed the subjects collect saliva 3 times throughout the study to determine procedural reliability revealing 92% accuracy. The same procedure was taken for both aquatic and land-based programs by using a checklist during 3 exercise sessions. Procedural reliability was 98% for both programs.</p> <p><b>Maturation:</b> FMS is not a condition that heals over time although subjects may have outside factors contributing to improvement of symptoms outside that of the exercise programs. This would affect the results of the study.</p> <p><b>Testing:</b> Since salivary cortisol levels and journal entries regarding the subjects' personal feelings of improvement were the only measures taken, it is unlikely that subjects had learning curves that effected results.</p> <p><b>Compensatory Equalization of Treatment:</b> All subjects completed the same exercises at the same time. Exercise regimens were the same every time.</p> <p><b>Compensatory Rivalry:</b> No groups were created although subjects may have been competitive with one another during sessions, altering results. This was managed in that subjects were instructed to exercise at low to moderate HR max for their age (40-69%). HR was monitored via digital HR monitor.</p> <p><b>Statistical Regression:</b> N/A in this study since comparisons were solely intra subject.</p>
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<b>Are the results of this therapeutic trial valid?</b>	
<i><b>Appraisal Criterion</b></i>	<i><b>Reader's Comments</b></i>
<p><b>55. Did the investigators randomly assign subjects to treatment groups?</b></p> <p style="margin-left: 20px;"><b>a. If no, describe what was done</b></p> <p style="margin-left: 20px;"><b>b. What are the potential consequences of this assignment process for the study's results?</b></p>	<p>No groups were assigned. The study used a single-subject alternating treatment design conducted across 3 subjects. The subject's results were only compared to themselves. This type of study makes external validity low since there is such a small sample size and it is difficult to generalize and extrapolate one subject's data to a large population.</p>
<p><b>56. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</b></p> <p style="margin-left: 20px;"><b>a. If they were not similar – what differences existed?</b></p>	<p>N/A since there were no groups formed.</p> <p>Subject 1: white female, 41 y/o married with 4 children. Receiving long-term disability benefits due to FMS. Diagnosed with FMS for 12 years. Prior to study, received treatments including medication, massage therapy, and exercise, but was unsatisfied with results.</p>

## Aquatic vs Land-Based Exercise for Fibromyalgia

	<p>Subject 2: white 58 y/o divorced female with 4 adult children. Receiving long-term disability for FMS. Diagnosed with FMS 15 years ago, and reported participating in aquatic therapy and taking medication prior to this study.</p> <p>Subject 3: white 46 y/o single female with no children. Works as a part-time writer and collects disability for FMS. Diagnosed with FMS 15 years ago, and has taken medication, participated in a walking program and massage therapy prior to study.</p>
<p><b>57. Did the subjects know to which treatment group they were assigned?</b></p> <p>a. If yes, what are the potential consequences of the subjects' knowledge for this study's results</p>	<p>The subjects were made aware of the studies design and the importance of salivary collection since they would be responsible for collections at home. There were no treatment groups. Low external validity.</p> <p>Exercise days were randomized. Land-based and pool-based days were randomized to account for sequencing effects.</p>
<p><b>58. Did the investigators know who was being assigned to which group prior to the allocation?</b></p> <p>a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</p>	<p>No groups were created leading to low external validity.</p>
<p><b>59. Were the groups managed equally, apart from the actual experimental treatment?</b></p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>All subjects were managed equally. They each received the same treatments and instruction.</p>
<p><b>60. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</b></p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>Authors state that for all subjects there was overlap in data when comparing exercise programs indicating that more time was needed to effectively determine the overall best treatment and collect long-term data.</p>
<p><b>61. Did all the subjects originally enrolled complete the study?</b></p> <p>a. If not how many subjects were lost?</p> <p>b. What, if anything, did the authors do about this attrition?</p> <p>c. What are the implications of the attrition and the way it was handled with respect to the study's findings?</p>	<p>One subject dropped out at 3 weeks. Her data was not included. This further lowers the external validity of the study, making it more difficult to generalize to a larger population.</p>
<p><b>62. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</b></p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>N/A. Each subjects' data was analyzed against their own baseline.</p>
<b>Are the valid results of this RCT important?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>

<p><b>63. What were the statistical findings of this study?</b></p> <ol style="list-style-type: none"> <li>a. When appropriate use the calculation forms below to determine these values</li> <li>b. Include: tests of differences? With p-values and CI</li> <li>c. Include effect size with p-values and CI</li> <li>d. Include ARR/ABI and RRR/RBI with p-values and CI</li> <li>e. Include NNT and CI</li> </ol> <p><b>64. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</b></p>	<p><b>Subject 1:</b>  <u>Comparison Phase</u>  Treadmill (land-based program) resulted in higher frequency of positive cortisol changes on 7 of 7 occasions. Treadmill and no-exercise interventions demonstrated positive reduction in cortisol, while Ai Chi (aquatic) resulted in an increase in cortisol. Percent Level stability for each of the three interventions was only 14%, indicating that the length of the comparison phase was too short to determine any long-term trends in the data. Overlap between treadmill and Ai Chi was high (71.4%) and low (28.5%) when compared to no exercise group. This supports superiority of the treadmill over the no exercise intervention. When comparing Ai Chi and no exercise, Ai Chi is superior. Overall, treadmill and Ai Chi demonstrated positive improvements on cortisol levels, but treadmill was more effective.</p> <p><b>Subject 2:</b>  <u>Comparison Phase</u>  Treadmill had the highest frequency of improved cortisol levels per session than Ai Chi or no exercise. All three interventions showed positive impact on trend of cortisol levels. High percentage of overlap between treadmill and no exercise (71.4%) and low overlap between treadmill and Ai Chi (57.1%) indicates that the length of the comparison phase was too short to effectively determine best overall treatment. Ai Chi had more positive impact on cortisol levels than the no exercise intervention. Overall, all three interventions resulted in therapeutic improvement in cortisol levels, but treadmill was the most effective.</p> <p><b>Subject 3:</b>  <u>Comparison Phase</u>  Treadmill had higher frequency of improvements in cortisol levels when compared to Ai Chi. When comparing treadmill to no exercise intervention, the no</p>
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	<p>exercise intervention demonstrated higher frequency. The level of stability was also higher in the no exercise intervention than treadmill or Ai Chi. This suggests that the length of time for the comparison phase was too short to determine a clear best treatment. When comparing treadmill to Ai Chi there was a high overlap (71.4%) and low (57.1%) when compared to no exercise. Based on overall change in median cortisol levels, the slope trend line, and the number of sessions resulting in a decrease in cortisol, treadmill was selected as the most effective intervention.</p>
<p>65. Do these findings exceed a minimally important difference?  a. If not, will you still use this evidence?</p>	<p>All three interventions had positive therapeutic effects on cortisol levels in different subjects.</p>
<p><b>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</b></p>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>66. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?</p>	<p>Ai Chi is an appropriate intervention when a pool is available. Treadmill training for 45 min may be a more realistic HEP. No exercise may be appropriate when a patient has flared symptoms and stress.</p>
<p>67. Are the study subjects similar to your patient/ client?  a. If not, how different? Can you use this intervention in spite of the differences?</p>	<p>These subjects are similar to my patient population and the population that is typically affected by FMS.</p>
<p>68. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?</p>	<p>There is very little risk associated with moderate intensity exercises and therefore the benefits would outweigh the risks.</p>
<p>69. Does the intervention fit within your patient/client's stated values or expectations?  a. If not, what will you do now?</p>	<p>Patients with FMS often have high stress levels that can exacerbate symptomology. These interventions would fall in line with my patient's values and goals.</p>
<p>70. Are there any threats to external validity in this study?</p>	<p>This study has very low external validity and it is difficult to extrapolate data to a larger population since the sample size was so small.</p>

<p><b>What is the bottom line?</b></p>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>

## Aquatic vs Land-Based Exercise for Fibromyalgia

<b>Oxford Level of Evidence</b>	<b>3b</b>
<b>Summarize your findings and relate this back to clinical significance</b>	Treadmill training is the most effect in creating a positive therapeutic change in cortisol levels. Moderate intensity walking programs may be effective in reducing stress and sympathetic response in adult women with FMS.

## Intervention – Evidence Appraisal Worksheet

**Citation:** Vitorino DF de M, Carvalho LBC de, Prado GF do. Hydrotherapy and conventional physiotherapy improve total sleep time and quality of life of fibromyalgia patients: randomized clinical trial. *Sleep Med.* 2006;7(3):293-296. doi:10.1016/j.sleep.2005.09.002.

<b>Is the purpose and background information sufficient?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Study Purpose</b> Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>The purpose of this study was to compare hydrotherapy (HT) and conventional physical therapy (CP) on the quality of life (QOL), total sleep time (TST), and total nap time (TNT) in individuals with fibromyalgia (FM).</p>
<p><b>Literature</b> Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study</p>	<p>Authors include relevant background regarding FM. The discuss a gap in literature regarding the effects of aquatic-based therapy on sleep quality in subjects with fibromyalgia.</p>

<b>Does the research design have internal validity?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<ul style="list-style-type: none"> <li>➤ <b>Discuss possible threats to internal validity in the research design. Include:</b></li> <li>➤ <b>Assignment</b></li> <li>➤ <b>Attrition</b></li> <li>➤ <b>History</b></li> <li>➤ <b>Instrumentation</b></li> <li>➤ <b>Maturation</b></li> <li>➤ <b>Testing</b></li> <li>➤ <b>Compensatory Equalization of treatments</b></li> <li>➤ <b>Compensatory rivalry</b></li> <li>➤ <b>Statistical Regression</b></li> </ul>	<p>Assignment: Subjects were randomly allocated. Attrition: Three subjects dropped out of the study. Groups only contained 25 subjects making the sample sizes small and creating low power of results. History: Since the duration of the study took place over several months, it is possible that outside events affected subject performance during the study. This could alter the results and change outcomes. Instrumentation: No instrumentation requiring calibration was used during the study. Maturation: Subjects' emotional or psychological status may have changed during the study altering performance and results. Testing: Subjects were not put in a situation in which they were required to perform tests. The main outcome measures were dream journals and quality of life surveys. Compensatory Equalization of Treatments: Since both groups were involved in exercise groups, it is unlikely that investigators supplemented activities. Compensatory Rivalry: Subjects were aware of what groups they were in. This could affect their</p>

	performance or subjective responses on outcome measures. Statistical Regression: No outliers were identified.
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<b>Are the results of this therapeutic trial valid?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<b>71. Did the investigators randomly assign subjects to treatment groups?</b> a. If no, describe what was done b. What are the potential consequences of this assignment process for the study's results?	Subjects were randomly assigned.
<b>72. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</b> a. If they were not similar – what differences existed?	Groups were homogenous at the start of the exam.
<b>73. Did the subjects know to which treatment group they were assign?</b> a. If yes, what are the potential consequences of the subjects' knowledge for this study's results	The subjects knew which group they were assigned to.
<b>74. Did the investigators know who was being assigned to which group prior to the allocation?</b> a. If they were not blind, what are the potential consequences of this knowledge for the study's results?	The investigators were blinded to who was being assigned to which groups.
<b>75. Were the groups managed equally, apart from the actual experimental treatment?</b> a. If not, what are the potential consequences of this knowledge for the study's results?	Groups were managed equally. They had similar exercise routines and were given the same instruction for sleep journals and outside activity.
<b>76. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</b> a. If not, what are the potential consequences of this knowledge for the study's results?	Authors suggest that further time may be needed due to FM's chronicity.
<b>77. Did all the subjects originally enrolled complete the study?</b> a. If not how many subjects were lost? b. What, if anything, did the authors do about this attrition? c. What are the implications of the attrition and the way it was handled with respect to the study's findings?	Three subjects dropped out. This decreases the sample size which lowers external validity.
<b>78. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</b>	There was intention to treat.

<p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	
<p><b>Are the valid results of this RCT important?</b></p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>79. What were the statistical findings of this study?</p> <p>a. When appropriate use the calculation forms below to determine these values</p> <p>b. Include: tests of differences? With p-values and CI</p> <p>c. Include effect size with p-values and CI</p> <p>d. Include ARR/ABI and RRR/RBI with p-values and CI</p> <p>e. Include NNT and CI</p> <p>80. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</p>	<p>The two groups presented were similar prior to start of study. HT group demonstrated greater improvements in total sleep time (TST) (<math>p &lt; 0.01</math>). All subjects had an increase of at least 1 hour compared to the 19 CP subjects (<math>p = 0.04</math>). Both groups demonstrate decreased total nap time (TNT), but more improvement was seen in HT group (<math>p &lt; 0.05</math>). Both groups showed significant improvement in SF-36 questionnaire and no difference was seen between groups.</p>
<p>81. Do these findings exceed a minimally important difference?</p> <p>a. If not, will you still use this evidence?</p>	<p>There is no minimally important difference identified for TST or TNT. However, QOL did show minimally important difference.</p>
<p><b>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</b></p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p>82. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?</p>	<p>Both interventions would be possible at my current location, but not all outpatient clinics have pool areas.</p>
<p>83. Are the study subjects similar to your patient/ client?</p> <p>a. If not, how different? Can you use this intervention in spite of the differences?</p>	<p>Yes, the subjects used are similar to my patient. Adult woman with fibromyalgia.</p>
<p>84. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?</p>	<p>There is little risk involved with either exercise program.</p>
<p>85. Does the intervention fit within your patient/client's stated values or expectations?</p> <p>a. If not, what will you do now?</p>	<p>Yes. The goals of these interventions are to decrease symptomology of FM.</p>
<p>86. Are there any threats to external validity in this study?</p>	<p>Small sample size. Only adult female subjects.</p>

**What is the bottom line?**

## Aquatic vs Land-Based Exercise for Fibromyalgia

<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<b>PEDRO Score (see scoring at end of form)</b>	<b>8/10</b>
<b>Summarize your findings and relate this back to clinical significance</b>	HT treatment was more effective in improving TST and TNT when compared to CP intervention. Both groups showed improvements in QOL.

### Pedro Scoring System:

#### Internal Validity Score (scored out of 8)

Criteria	Rating
25. Subjects were <b>randomly allocated</b> to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received.)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
26.	
<b>27. Allocation was concealed.</b>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
28. The groups were <b>similar at baseline</b> regarding the most important prognostic indicators.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
29. There was <b>blinding of all subjects.</b>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
30. There was <b>blinding of all therapists</b> who administered the therapy.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
31. There was <b>blinding of all assessors</b> who measured at least one key outcome.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
32. Measures of at least one key outcome were obtained from <b>more than 85% of the subjects</b> initially allocated to groups.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
33. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by <b>"intention to treat"</b> .	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
<b>Statistical reporting score (scored out of 2)</b>	
34. The results of <b>between-group statistical comparisons</b> are reported for at least one key outcome	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
35. The study provides both <b>point measures</b> and <b>measures of variability</b> for at least one key outcome.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
36. <b>Eligibility criteria</b> were specified (not included in score).	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:

Adapted from : Jewell, D. Guide to Evidence Based Physical Therapy Practice.  
Jones  
and Bartlett Publishers, Sudbury, MA 2008

## Intervention – Evidence Appraisal Worksheet

**Citation:** Assis MR, Silva LE, Alves AMB, et al. A randomized controlled trial of deep water running: clinical effectiveness of aquatic exercise to treat fibromyalgia. *Arthritis Rheum.* 2006;55(1):57-65. doi:10.1002/art.21693.

<b>Is the purpose and background information sufficient?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>Study Purpose</b>                      Stated clearly?                      Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis.                      A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?</p>	<p>The purpose of this study was to evaluate the effectiveness of water and land-based aerobic exercise on symptoms associated with fibromyalgia (FM).</p>
<p><b>Literature</b>                      Relevant background presented?                      A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic.                      Describe the justification of the need for this study</p>	<p>Authors include relevant literature including the diagnosis for FM and current treatments. The authors identify a gap in the current available research regarding the effectiveness of aquatic therapy.</p>

<b>Does the research design have internal validity?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p>➤ <b>Discuss possible threats to internal validity in the research design. Include:</b></p> <ul style="list-style-type: none"> <li>➤ <b>Assignment</b></li> <li>➤ <b>Attrition</b></li> <li>➤ <b>History</b></li> <li>➤ <b>Instrumentation</b></li> <li>➤ <b>Maturation</b></li> <li>➤ <b>Testing</b></li> <li>➤ <b>Compensatory Equalization of treatments</b></li> <li>➤ <b>Compensatory rivalry</b></li> <li>➤ <b>Statistical Regression</b></li> </ul>	<p>Assignment: Deep water running (DWR) and land-based exercise (LBE) groups were homogenous at the start of the study. All subjects were randomly allocated.</p> <p>Attrition: Four subjects from each group dropped out during the intervention. The sample size in both groups is relatively small and further loss of subjects lowers the power of the results.</p> <p>History: External events could impact the subjects' performance and alter results.</p> <p>Instrumentation: HR was assessed using tools that require calibration. If instruments are not calibrated correctly this may alter the intensity that subjects exercise at and in turn alter results.</p> <p>Maturation: Since this study lasted for several months, there is a chance that subjects' emotional, physical, psychological and spiritual status may change, affecting their performance on outcome measures.</p> <p>Testing: All questionnaires have been shown to have good validity and reliability.</p> <p>Compensatory Equalization of Treatments: Since both groups were receiving interventions, it is unlikely that the investigators supplemented activities.</p>

	<p>Compensatory Rivalry: No mention of subject blinding was made. It is possible that if subjects gained knowledge of the other group, their performance would be altered, skewing their results.</p> <p>Statistical Regression: Authors do not mention any outliers at the onset of the study.</p>
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<b>Are the results of this therapeutic trial valid?</b>	
<i>Appraisal Criterion</i>	<i>Reader's Comments</i>
<p><b>87. Did the investigators randomly assign subjects to treatment groups?</b></p> <p>a. If no, describe what was done</p> <p>b. What are the potential consequences of this assignment process for the study's results?</p>	<p>All subjects were randomly assigned.</p>
<p><b>88. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?</b></p> <p>a. If they were not similar – what differences existed?</p>	<p>Both groups were similar at the start of the study. Demographics of the groups was included.</p>
<p><b>89. Did the subjects know to which treatment group they were assign?</b></p> <p>a. If yes, what are the potential consequences of the subjects' knowledge for this study's results</p>	<p>Subjects did know what groups they were assigned to. No mention regarding the subjects' knowledge of the other group. This knowledge could affect their performance on outcome measures.</p>
<p><b>90. Did the investigators know who was being assigned to which group prior to the allocation?</b></p> <p>a. If they were not blind, what are the potential consequences of this knowledge for the study's results?</p>	<p>Investigators were blinded to who was being assigned to which group prior to allocation.</p>
<p><b>91. Were the groups managed equally, apart from the actual experimental treatment?</b></p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>Groups were managed equally. They performed the same amount of exercise and at the same intensity. Subjects were given the same instruction for outside participation and could continue their current pharmacologic treatments.</p>
<p><b>92. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?</b></p> <p>a. If not, what are the potential consequences of this knowledge for the study's results?</p>	<p>Authors mention that longer follow-up time should be investigated in future research due to FM's chronicity.</p>
<p><b>93. Did all the subjects originally enrolled complete the study?</b></p> <p>a. If not how many subjects were lost?</p> <p>b. What, if anything, did the authors do about this attrition?</p> <p>c. What are the implications of the attrition and the way it was handled with respect to the study's findings?</p>	<p>4 subjects dropped out of each group. The authors did not include their data. This decreased sample size which decreases external validity.</p>

<p><b>94. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)?</b></p> <p>a. If not, what did the authors do with the data from these subjects?</p> <p>b. If the data were excluded, what are the potential consequences for this study's results?</p>	<p>There was intention to treat analysis.</p>
<p><b>Are the valid results of this RCT important?</b></p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p><b>95. What were the statistical findings of this study?</b></p> <p>a. When appropriate use the calculation forms below to determine these values</p> <p>b. Include: tests of differences? With p-values and CI</p> <p>c. Include effect size with p-values and CI</p> <p>d. Include ARR/ABI and RRR/RBI with p-values and CI</p> <p>e. Include NNT and CI</p> <p><b>96. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?</b></p>	<p>There were no significant differences between groups at baseline. Both DWR and LBE groups showed a mean decrease in VAS of 36% from baseline (p &lt; 0.001). No difference between groups was identified. Following 8 weeks, 50% of LBE subjects reported improvement per Patient Global Assessment of Response to Therapy (PGART) and at 15 weeks, 73% demonstrated improvements. Seventy percent from the DWR group demonstrated improvements at 8 and 15 weeks. No differences noted between groups (p = .028). Both groups had improved FIQ scores at 3 different measurements (p &lt; 0.001) and greater improvements were seen in the DWR group at week 15 (p = 0.033). Both groups showed improvements in Beck's Depression Inventory (BDI) with no difference between groups (p= 0.066). Both groups demonstrated improvements in the SF -36 questionnaire with no difference between groups. LBE groups showed greater improvement in anaerobic threshold (p = 0.021).</p>
<p><b>97. Do these findings exceed a minimally important difference?</b></p> <p>a. If not, will you still use this evidence?</p>	<p>Findings exceed a minimally important difference.</p>
<p><b>Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?</b></p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p><b>98. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?</b></p>	<p>Deep water running is not available at my clinical setting, but may be available at other outpatient settings.</p>
<p><b>99. Are the study subjects similar to your patient/ client?</b></p> <p>a. If not, how different? Can you use this intervention in spite of the differences?</p>	<p>The subjects are similar to my patient. Female with FM between the ages of 18 and 60 years.</p>
<p><b>100. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?</b></p>	<p>Yes. Walking on land or in water has relatively no risk.</p>

Aquatic vs Land-Based Exercise for Fibromyalgia

<p><b>101. Does the intervention fit within your patient/client's stated values or expectations?</b>                  a. If not, what will you do now?</p>	<p>Yes. These interventions are aimed at improving symptomology associated with FM.</p>
<p><b>102. Are there any threats to external validity in this study?</b></p>	<p>Small sample size. All female subjects.</p>

<p><b>What is the bottom line?</b></p>	
<p><i>Appraisal Criterion</i></p>	<p><i>Reader's Comments</i></p>
<p><b>PEDRO Score (see scoring at end of form)</b></p>	<p><b>8/10</b></p>
<p><b>Summarize your findings and relate this back to clinical significance</b></p>	<p>Walking is a cheap and easily accessible exercise to treat FM, but some individuals are limited in weight-bearing activities this second to pain associated with FM or other comorbidities including osteoarthritis. This study illustrates that water-based aerobic exercise is equally as effective as land-based therapy, but may have additional advantages for populations unable to perform excessive weight-bearing activities. Aquatic exercise is a viable form of low-impact aerobic exercise for individuals with FM.</p>

### Pedro Scoring System:

#### Internal Validity Score (scored out of 8)

Criteria	Rating
37. Subjects were <b>randomly allocated</b> to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received.)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
38.	
<b>39. Allocation was concealed.</b>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
40. The groups were <b>similar at baseline</b> regarding the most important prognostic indicators.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
41. There was <b>blinding of all subjects.</b>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
42. There was <b>blinding of all therapists</b> who administered the therapy.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Where:
43. There was <b>blinding of all assessors</b> who measured at least one key outcome.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
44. Measures of at least one key outcome were obtained from <b>more than 85% of the subjects</b> initially allocated to groups.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
45. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by <b>"intention to treat"</b> .	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
<b>Statistical reporting score (scored out of 2)</b>	
46. The results of <b>between-group statistical comparisons</b> are reported for at least one key outcome	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
47. The study provides both <b>point measures</b> and <b>measures of variability</b> for at least one key outcome.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:
48. <b>Eligibility criteria</b> were specified (not included in score).	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Where:

Adapted from : Jewell, D. Guide to Evidence Based Physical Therapy Practice. Jones and Bartlett Publishers, Sudbury, MA 2008

**Appendix B: Reference Inclusion/Exclusion Criteria Table**

## Aquatic vs Land-based Exercise for Fibromyalgia

#	Author(s)	Inclusion Criteria	Exclusion Criteria
1	Sevimili D, et al (2015)	Subjects had a diagnosis of fibromyalgia from a specialist in the clinic of Physical Medicine and Rehabilitation Department, Faculty of Medicine, Cukurova University.	Postmenopausal, under 18 or over 50 years of age, cardiovascular issues, Cushing Syndrome.
2	Cazzola M, et al (2010)	RCT's published between 1985 and 2010 using outcome measures for mental function, physical function, pain, and number of tender points.	Studies simultaneously using differed types of physical exercise or multimodal treatment strategies.
3	Jentoft E S, et al (2001)	Patients were referred by general practitioners. Women between 20 and 60 years of age, diagnosed with fibromyalgia per American College of Rheumatology.	Presence of comorbidities including inflammatory rheumatic diseases, hypothyroidism, heart and lung diseases.
4	Munguia-Izquierdo D, et al (2008)	Women between the ages of 18 and 60 with diagnosis of fibromyalgia (per American College of Rheumatology).	Presence of comorbidities including morbid obesity, cardiopulmonary diseases, endocrine or allergic disturbances, severe trauma, frequent migraines, inflammatory rheumatic disease, and severe psychiatric illness.
5	Bednar M L, et al (2004)	Studies including: <i>Population</i> of women or men at least 18 years of age, with diagnosis of fibromyalgia (meeting American College of Rheumatology diagnostic criteria). <i>Interventions:</i> aquatic or land-based exercise <i>Study design:</i> RCT's <i>Outcome measure:</i> Fibromyalgia Impact Questionnaire	Studies including: Modalities (ultrasounds, electrical stimulation, vibration, biofeedback, massage), acupuncture, cognitive-behavior, pharmacotherapy, chiropractic, homeopathy, psychotherapy, thalassotherapy, multidisciplinary, comorbidities (chronic fatigue syndrome, complex regional pain syndrome).
6	Kelley C, et al (2008)	Patients referred from local pain clinic and met the following: physician's diagnosis of fibromyalgia, had fibromyalgia for at least 2 months, were women between 25 and 65 years, had physician's prescription for exercise and aquatic therapy, not have taken any steroidal medication for at least one	None listed.

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		week prior to start of study, had no other major medical conditions	
7	Vitorino D F M, et al (2006)	Female patients aged 30 to 60 years, diagnosed with fibromyalgia (per American College of Rheumatology criteria).	None Listed.
8	Assis M R, et al (2006)	Sedentary women with diagnosis of fibromyalgia (per American College of Rheumatology classification criteria). Between the ages of 18-69 years, unchanged drug regimen for at least 4 weeks.	Symptomatic cardiac failure, uncontrolled thyroid disturbances, BMI greater than 40, infectious contagious skin diseases, CAD, pulmonary disease, neurologic disease, rheumatic disease hindering their ability to exercise.