

Ottawa Panel Evidence-Based Clinical Practice Guidelines for Aerobic Fitness Exercises in the Management of Fibromyalgia: Part 1

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Background and Purpose. The objective of this study was to create guidelines for the use of aerobic fitness exercises in the management of adult patients (>18 years of age) with fibromyalgia, as defined by the 1990 American College of Rheumatology criteria.

Methods. Following Cochrane Collaboration methods, the Ottawa Methods Group found and synthesized evidence from comparative controlled trials and formed the Ottawa Panel, with nominated experts from key stakeholder organizations. The Ottawa Panel then developed criteria for grading the recommendations based on experimental design (I for randomized controlled trials, II for nonrandomized studies) and strength of evidence (A, B, C+, C, D+, D, or D-). From the rigorous literature search, 13 randomized control trials and 3 controlled clinical trials were selected. Statistical analysis was based on Cochrane Collaboration methods. Continuous data were calculated with weighted mean differences between the intervention and control groups, and dichotomous data were analyzed with relative risks. Clinical improvement was calculated using absolute benefit and relative difference in change from baseline. Clinical significance was attained when an improvement of 15% relative to a control was found.

Results. There were 24 positive recommendations: 10 grade A, 1 grade B, and 13 grade C+. Of these 24 positive recommendations, only 5 were of clinical benefit.

Discussion and Conclusion. The Ottawa Panel recommends aerobic fitness exercises for the management of fibromyalgia as a result of the emerging evidence (grades A, B, and C+, although most trials were rated low quality) shown in the literature.

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Fibromyalgia (FM) is a rheumatologic disorder that requires the concurrent existence of chronic, widespread musculoskeletal pain and multiple sites of tenderness.¹ Prominent symptoms include fatigue, stiffness, nonrestorative sleep patterns, and memory and cognitive difficulties.² In North America, the prevalence of FM is approximately 5.0% for adult women and 1.5% for adult men, with women aged 55 to 64 years most commonly affected.³

People with FM regularly use medical services.⁴ On average, patients with FM have 10 medical visits, 1 radiographic examination, and 2.5 laboratory examinations per annum.⁴ Hospitalizations occur about once every 3 years, with pain and musculoskeletal- and neurological-related symptoms the most frequent ailments.⁴ The average medical cost for a patient with FM was US \$2,274 in 1996, with hospitalization, drugs, and outpatient services the main contributors to costs.⁴

The etiology and pathogenesis of FM remain relatively unknown,⁵ severely limiting treatment success.⁶ Fewer than 50% of patients experience sufficient symptom relief.⁷

Evidence-based clinical practice guidelines (EBPCGs) are precise statements on recommended interventions that are based on scientific literature and include a graded strength of evidence as well as detail on the specific joints affected, outcomes, and length of intervention. The Ottawa Panel has published EBPCGs for osteoarthritis (OA), rheumatoid arthritis (RA), and stroke. For this study, the Ottawa Panel collaborated to assess the strength of scientific evidence regarding the efficacy of therapeutic exercises for FM. Two documents on FM and therapeutic exercise were constructed due to the volume of information gathered. In this study (part 1 of the

series on management of FM), the Ottawa Panel constructed EBPCGs for aerobic fitness exercises and FM. In part 2 of the series, the Ottawa Panel produced EBPCGs on strengthening exercises for FM.⁸ Although aerobic exercise seems to be overall more beneficial for patients with FM than strengthening exercises,^{9,10} both types of exercise offer patients and their health care professionals potential options for FM symptom management. Specifically, the purpose of this study was to provide effective aerobic fitness guidelines for patients, physiatrists, rheumatologists, physical therapists, occupational therapists, family physicians, kinesiologists, and other health care professionals to assist in the overall management of FM.

Methods

The Ottawa Methods Group is made up of 9 methodologists with extensive experience in constructing EBPCGs. The Ottawa Methods Group contacted several associations that specialize in treating FM to nominate people with clinical experience and subsequently chose 9 people in varied specialties: rheumatology, physiatry, psychology, psychiatry, occupational therapy, and physical therapy. The 9-member Ottawa Methods Group and the 9 researchers selected amalgamated to form the Ottawa Panel.

To assist with this study, the Ottawa Methods Group also assembled a research and support team with expertise in meta-analysis, research methods, and the development and evaluation of EBPCGs. The research team read and analyzed articles and drafted evidence tables, and the Ottawa Methods Group established the inclusion criteria for study design, subject sample, and intervention, as well as outcomes for conducting the literature reviews.

Table 1.
Grading for Recommendations^a

Grade	Clinical Importance	Statistical Significance	Study Design
A	≥15%	$P < .05$	RCT (single or meta-analysis)
B	≥15%	$P < .05$	CCT or observational (single or meta-analysis)
C+	≥15%	Not significant	RCT/CCT or observational (single or meta-analysis)
C	<15%	Not significant	Any study design
D	<15% (favors control)	Not significant	Any study design
D+	<15% (favors control)	Not significant	RCT/CCT or observational (single or meta-analysis)
D-	≥15% (favors control)	$P < .05$ (favors control)	Well-designed RCT with >100 patients (if <100 patients, becomes grade D)

^a RCT=randomized controlled trial, CCT=controlled clinical trial.

The Ottawa Panel constructed the EBPCGs in this report, which follow Appraisal of Guidelines Research and Evaluation (AGREE) criteria (www.agreecollaboration.org).¹¹ The EBPCGs are graded based on level (I for randomized controlled trials [RCTs], II for nonrandomized studies) and strength of evidence (A, B, C, C+, D, D+, or D-). For instance, to receive a grade A recommendation, an RCT had to have an outcome that was both statistically significant and clinically important (ie, an improvement of more than 15% relative to a control based on panel expertise and empiric results). Table 1 presents a summary of the EBPCG grading system.

Literature Search

An *a priori* literature search was conducted by a library scientist using modified search strategies¹² recommended by the Cochrane Collaboration.¹³ The primary focus of the search was methods and study interventions used as opposed to study outcomes. Bias was minimized by applying a systematic approach to the search, study selection, and data extraction and synthesis. Several electronic databases were used: MEDLINE, EMBASE (Current Contents), the Cumulative Index to Nursing and Allied Health (CINAHL), AMED, the Cochrane Controlled Trials Register up to December 2006, the registries of the Cochrane Field

of Rehabilitation and Related Therapies and the Cochrane Musculoskeletal Group, and the Physiotherapy Evidence and Database (PEDro). The library scientist updated the literature search every 6 months from the first week of October 2004 to the last week of December 2006.

Study Inclusion/Exclusion Criteria

Type of interventions. For this study, aerobic fitness exercises included both land- and water-based exercises of moderate to high intensity using large muscle groups in rhythmic, continuous motions.¹⁴ Such exercises typically are performed over a prolonged period to increase maximal oxygen uptake or cardiorespiratory fitness.¹⁵ As part of the aerobic fitness programs, some studies¹⁶⁻²² included strengthening, flexibility, and relaxation components. *Strengthening exercises* were defined as isotonic or isometric resistance exercises with the purpose of increasing the maximal force generated by a specific muscle or muscle group.¹⁵ *Flexibility (stretching) exercises* were defined as exercises that move a joint through a range of motion.¹⁵ Lastly, *relaxation exercises* were defined as a form of stress management to calm physiologic responses (eg, heart rate) and psychological responses (eg, feelings of anxiety). Examples are yoga (eg, slower-paced yoga such as Hatha), self-hypnosis, progressive muscular re-

laxation, breathing exercises, and biofeedback.¹⁵ Excluded interventions included, but were not limited to, surgery of all joints, medication, and thermal biofeedback (Tab. 2).

Type of study designs. Comparative controlled studies with comparison groups that examined aerobic fitness and people with FM were included: RCTs, controlled clinical trials (CCTs), cohort studies, and case-control studies. Controlled clinical trials are similar to RCTs, except that CCTs are either not randomized or not appropriately randomized.²³ Head-to-head studies (eg, walking versus stretching) also were included.

Studies were excluded if they lacked a comparison group (eg, uncontrolled cohort studies), were case studies, had a 20% dropout rate, or had a sample of fewer than 5 patients per group. Abstract-only studies were excluded because they did not have sufficient data for analysis. In addition, studies published in a language other than English or French were excluded due to time constraints and translation costs (Tab. 2). Studies also were excluded if participants and outcomes did not meet designated criteria.

Type of participants. Studies of adult patients (>18 years of age) diagnosed with FM, as defined by the 1990 American College of Rheuma-

Table 2.
Inclusion and Exclusion Criteria

Inclusion	Exclusion
<p>Interventions</p> <ul style="list-style-type: none"> • Eligible control groups: untreated and active physical therapy treatments and educational pamphlets (no surgery, drugs, or injections) • Eligible interventions: therapeutic exercise related to aerobic fitness as defined by the Ottawa Panel 	<p>Interventions</p> <ul style="list-style-type: none"> • Surgery of all joints (ie, the effect of postsurgery but not the effect of the surgery itself is an eligible physical therapy intervention) • Medication (eg, phonophoresis with medications) • Thermal biofeedback • Acupuncture • Assistive devices • Conservation of energy/sleep strategies • Electroanalgesia and other electrotherapy interventions, including electrical stimulation, TENS, ultrasound, laser therapy and diathermy, and EMG biofeedback • Manual therapy/massage • Patient education • Splinting and orthoses • Thermotherapy, including balneotherapy • Sensory intervention • Psychosocial interventions • Multidisciplinary team intervention • Cognitive-behavioral intervention • Multiple interventions (“physiotherapy,” including ice, heat, massage, TENS, ultrasound, and so on or combinations of interventions) • Strengthening exercises only • Exercises combined with an education program
<p>Study Designs</p> <ul style="list-style-type: none"> • Randomized controlled trials • Controlled clinical trials • Cohort studies • Case-control studies • Head-to-head comparison of strength and flexibility studies 	<p>Study Designs</p> <ul style="list-style-type: none"> • Case series/case reports • Uncontrolled cohort studies • Data (graphics) without a mean and SD • Sample size of <5 patients per treatment group • Studies with dropout rate of >20%
<p>Participants</p> <ul style="list-style-type: none"> • Outpatients or inpatients • Diagnosis of fibromyalgia • Age groups >18 y • Mixed population only if patients with fibromyalgia are in majority 	<p>Participants</p> <ul style="list-style-type: none"> • OA • RA • Cancer (and other oncologic conditions) • No known pathology or impairments • Pulmonary conditions • Neurologic conditions • Pediatric conditions (no juvenile arthritis) • Juvenile arthritis • Cardiac conditions • Dermatologic conditions • Psychiatric conditions • Myofascial pain syndrome • Chronic fatigue syndrome • Multiple conditions

(Continued)

tology criteria,¹ were included. Subjects had to be medically stable and mentally competent. The amount of time since disease onset was not a requirement of FM diagnostic criteria. Studies were excluded if participants had chronic pain syndrome, chronic fatigue syndrome, or myofascial pain, although some may argue that there is difficulty in differentiating symptoms of these disorders from FM. Studies were ex-

cluded if participants had any of the following conditions: (1) cancer or other oncological conditions, (2) cardiac conditions, (3) dermatologic conditions, (4) serious cognitive deficits or severe communication problems, (5) major medical problems that could interfere with the rehabilitation process or incapacitate functional status, or (6) primary psychiatric conditions (Tab. 2).

Type of outcomes. Studies were included if they assessed any of the following outcomes: quality of life, pain, fatigue, sleep, global perceived effect, or depression. Studies were excluded if outcomes were biochemical measures or serum markers (Tab. 2).

Study Selection

Two reviewers received Cochrane process training from the Ottawa

Table 2.
Continued

Inclusion	Exclusion
<p>Outcomes</p> <ul style="list-style-type: none"> ● Absenteeism, sick leave, return to work (if available) ● Balance status ● Cardiopulmonary function ● Coordination status ● Costs (economics) ● Disease activity ● Edema ● EMG activity ● Fatigue ● Flexibility ● Functional status, activities of daily living (self-care activities) ● Gait status ● Global perceived effect ● Girth, volume ● Inflammation ● Joint imaging ● Medication intake (if reported) ● Muscle strength, endurance, and power ● Pain ● Patient adherence ● Patient satisfaction ● Postural assessment ● Quality of life ● Range of motion, flexibility, mobility ● Side effects (if reported) ● Sleep ● Swelling ● Psychosocial measures such as depression, home and community activities, leisure, social roles, and sexual function 	<p>Outcomes</p> <ul style="list-style-type: none"> ● Biochemical measures ● Serum markers

^a TENS=transcutaneous electrical nerve stimulation, EMG=electromyographic, OA=osteoarthritis, RA=rheumatoid arthritis.

Panel and independently assessed the studies provided by the literature search. Each reviewer constructed a list of included and excluded articles using the inclusion and exclusion criteria created by the Ottawa Panel (Tab. 2) and provided justification for their selections. The level of agreement between the reviewers was tested for interrater reliability with the Cohen kappa coefficient ($\kappa = \frac{\text{Pr}(a) - \text{Pr}(e)}{1 - \text{Pr}(e)}$)* in a previous Ottawa Panel study.²⁴ A senior methodologist and a clinical expert from the Ottawa Panel compared the reviewers' lists of included and excluded studies, and a final judgment was made by the Ottawa Panel through consensus.

* $\text{Pr}(a)$ =observed agreement between raters, $\text{Pr}(e)$ =probability of agreement.

Data Extraction and Methodological Quality Assessment

The same 2 reviewers independently recorded details (ie, population characteristics, interventions, study design, allocation concealment, comparative outcomes, and period of measurement) from the selected articles using predetermined extraction forms. Methodological quality was assessed with the Jadad scale.²³ The Jadad scale is a 5-point scale with reported reliability and validity that awards 2 points for randomization, 2 points for double blinding, and 1 point for explanation of participant withdrawal. Studies with a Jadad scale score of ≥ 3 are typically viewed as being of higher methodological quality. The Ottawa Panel agreed to include trials that had a score of < 3 if they met inclusion and

exclusion criteria (Tab. 2). The Ottawa Panel gave more weight to the randomization component because most exercise studies are unable to obtain points through the double-blind category, as it often is not possible to blind participants to an exercise intervention. Quality scores from the Jadad scale were utilized to interpret results, and any discrepancy in methodological scoring by the 2 reviewers was resolved by the senior methodologist.

Data Analysis

In the present study, Cochrane Collaboration methods were used for statistical analysis.²⁵ Much of the data could not be pooled because many key study characteristics (eg, population, interventions, outcomes) were not comparatively similar. For instance, outcomes (eg,

pain) may have been identical, but the measurement method selected (eg, questionnaire) differed. Due to magnitude of variation among studies, continuous data were calculated using weighted mean differences (WMDs) instead of standard mean differences between intervention and control groups. A WMD is “a method of meta-analysis used to combine measures on continuous scales (eg, weight), where the mean, standard deviation, and sample size in each group are known.”²⁶ To assess clinical improvement, absolute benefit and relative difference in change from baseline were calculated. *Absolute benefit* is improvement found in the treatment group minus improvement in the control group.²⁷ *Relative difference* is the absolute benefit divided by the baseline mean (weighted for the intervention and control groups).²⁷

Dichotomous data, or data that can be divided into 2 categories, were calculated with relative risks. A *relative risk* is “the ratio of risk in the intervention group to the risk in the control group. The risk (proportion, probability, or rate) is the ratio of people with an event in a group to the total in the group.”²⁶ With dichotomous data, the percentage of improvement was calculated as the difference in the percentage of improvement between the intervention and control groups.²⁸ Clinical significance was obtained when an improvement of 15% relative to a control was demonstrated. The 15% value was chosen by the Philadelphia Panel,²⁸ who are experts in musculoskeletal practice, and was approved by the rheumatology and biostatistician experts of the Ottawa Panel. For greater detail of the statistical analysis, see our previous Ottawa Panel publication.²⁷ Figures were created with Cochrane Collaboration methods²⁵ and were constructed for each included study to illustrate effect size.

Results

Literature Search

A total of 1,000+ articles on therapeutic exercises and FM were found, and of these, 116 articles were identified as potentially relevant. Using the inclusion and exclusion criteria, 16 studies on aerobic fitness programs and FM ultimately were selected. The other 100 articles were excluded due to: absence of a control group, insufficient statistical data, literature reviews only, an attrition rate of >20%, abstract only, control groups of subjects who were healthy, written in foreign language, therapeutic exercise confounded with education session, case reports, and descriptive-only studies.

Methodological Quality

Applying the Jadad scale, 6 out of the 16 trials were of high methodological quality (≥ 3),^{16,17,29-32} with scores ranging from 3 to 5. The remaining trials^{9,18-22,33-36} were of low methodological quality, with scores of 1 or 2.

Aerobic Fitness

In Figures 1, 2, and 3 and in the Supplemental Figures (available online only at www.ptjournal.org), the vertical line signifies no difference between the 2 conditions (eg, pool-based exercise versus land-based exercise). The horizontal line for each trial represents the standard deviation of the WMD and includes a point estimate (ie, the square box in the center of the line) and upper and lower 95% confidence intervals (95% CIs) of the difference between the 2 conditions. For a particular outcome, if the lower 95% CI falls to the right of the vertical line, the 2 groups are statistically different.²⁷

As shown in Table 3, to receive a grade of A, an RCT had to have an outcome that was both statistically significant and clinically important (an improvement of more than 15%

relative to a control, based on panel expertise and empiric results). Grade A outcomes were found for: pain relief^{9,16,19,32} (outcome for study by Gusi et al¹⁹ illustrated in Fig. 1), psychological well-being,³³ endurance,^{22,33} anxiety,³³ self-efficacy,³³ depression,³⁴ quality of life,^{9,19-21,32} muscle strength (force-generating capacity),¹⁹ cardiorespiratory fitness,^{9,19,32} physician general awareness,¹⁹ and flexibility.⁹

A grade B recommendation was given to a CCT or observational study that had a statistically significant, clinically important benefit. Only 1 outcome received a grade B recommendation: pain relief.³⁵

Grade C+ was given to an RCT or CCT that demonstrated clinical importance but lacked statistical significance. Grade C+ outcomes included: quality of life,^{9,17-20,29-32} depression^{29,32,33} (outcome for study by Assis et al²⁹ illustrated in Fig. 2), pain relief^{9,16,17,20,31,32} (outcome for study by Jentoft et al¹⁷ illustrated in Fig. 3), self-efficacy,³³ endurance,^{17,33} muscle strength,¹⁹ patient global awareness,³⁰ psychological well-being,²¹ and sleep quality.³²

Grade C was given in the absence of both clinical importance and statistical significance. Grade C outcomes were found for: quality of life,^{9,16,17,19,21,22,29,31,33,34,36} cardiorespiratory fitness,^{9,17,20-22,29,31-33,35} pain relief,^{9,16,17,19-21,29-33} psychological distress,¹⁶ range of motion,^{18,33} depression,^{32,33} anxiety,^{9,33} endurance,^{17,22,33} psychological well-being,^{21,33} muscle strength,¹⁷ self-efficacy,^{17,31} mobility,¹⁷ sleep quality,^{30,32} psychological profile,³⁶ physician global assessment,³¹ flexibility,^{9,22} perceived exertion,^{20,22} balance,²² coordination,²² muscle strength,²² and patient global assessment.²²

A grade D recommendation was given to studies showing a clinical

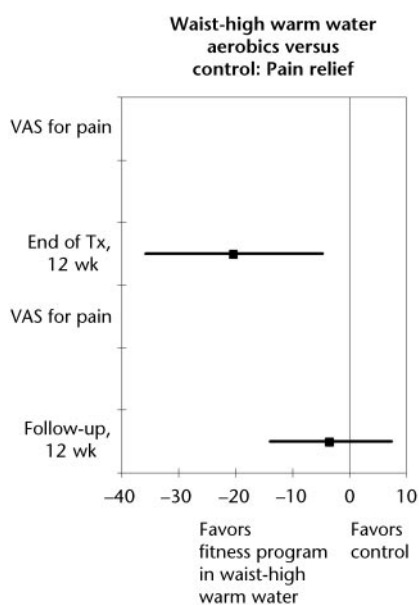


Figure 1. Waist-high warm water aerobics versus control: pain relief. Data from study by Gusi et al (2006).¹⁹ VAS=visual analog scale, Tx=treatment.

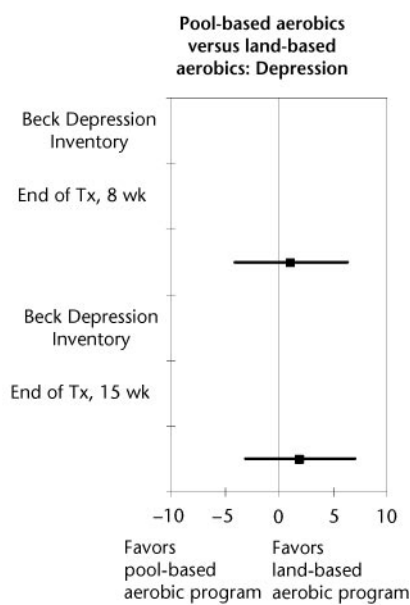


Figure 2. Pool-based aerobics versus land-based aerobics: depression. Data from study by Assis et al (2006).²⁹ Tx=treatment.

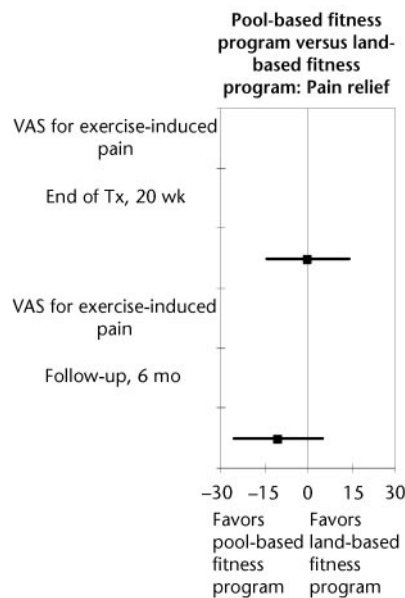


Figure 3. Pool-based fitness program versus land-based fitness program: pain relief. Data from study by Jentoft et al (2001).¹⁷ VAS=visual analog scale, Tx=treatment.

importance of <15% (favoring control). Outcomes that received a grade of D were: pain relief,^{18,33-36} psychological well-being,³³ range of motion,³³ quality of life,³³ muscle strength,¹⁹ psychological profile,³⁶ cardiorespiratory fitness,²² and muscle strength.²²

A grade D+ recommendation occurred when an RCT or CCT showed a clinical importance of >15% (favoring control). The grade D+ recommendations included: quality of life,^{19,20,36} muscle strength,¹⁹ pain relief,²⁰ psychological well-being,²⁰ and depression.³²

Finally, there were no grade D- recommendations or RCTs that displayed a clinical benefit of >15% (favoring control) with statistical significance.

See the Appendix for more detailed results related to the main positive recommendations.

Discussion

The aim of this study was to evaluate the efficacy of aerobic fitness for the management of symptoms of FM. Regarding studies that implemented only aerobic exercise components^{9,29-36} (as opposed to a program with strengthening, flexibility, and relaxation components), it remains inconclusive as to whether gains in aerobic conditioning are correlated with decreases in symptoms of FM given the limitations noted. Nonetheless, some support was found for inclusion of aerobic fitness exercises, even for participants (most often in the comprehensive fitness programs) who did not reach and maintain higher intensity levels but who reported benefits similar to those reported by participants in strict aerobic exercise programs.²⁰⁻²²

Limitations

Although some included studies strictly implemented aerobic exercise programs, other studies incorpo-

rated a diversity of interventions. For example, in addition to aerobic exercise, Da Costa et al¹⁶ implemented stretching and strengthening exercises dependent on the needs of the participants. Because the programs were highly individualized, it is not possible to determine which aspect of a program was beneficial for participants with FM. Similarly, lack of consensus among health care specialists and researchers on FM outcome measures (eg, pain) and instruments (eg, visual analog scale) across studies was another limitation. This was especially problematic when trying to evaluate the efficacy of a specific exercise intervention.³⁷

A limitation inherent in the construction of EBPCGs is the occurrence of conflicting evidence both between and within studies. For example, in the study by Da Costa et al,¹⁶ the pain relief outcome received a grade of A, in contrast to the study by Gandhi et al,¹⁸ in which pain relief re-

Ottawa Panel EBPCGs for Aerobic Fitness Exercises in the Management of Fibromyalgia

Table 3.
Evidence-based Clinical Practice Guidelines for Aerobic Fitness Exercises^a

	Description of Trial	Study Design and N	Grade A	Grade B	Grade C+	Grade C	Grade D	Grade D+
Assis et al (2006) ^{29,b}	3 sessions of 60 min per week for 15 wk	RCT N=60	N/A	N/A	Quality of life Depression	Quality of life Cardiopulmonary function Pain relief	N/A	N/A
Da Costa et al (2005) ¹⁶	1–2 hr per week for 12 wk	RCT N=80	Pain relief	N/A	Pain relief Quality of life	Quality of life Pain relief Psychological distress	N/A	N/A
Gandhi et al (2002) ¹⁸	90 min, 2 times a week, for 10 wk	CCT N=22	N/A	N/A	Quality of life	ROM, knee and hip	Pain relief	N/A
Gowans et al (2001) ³³	3 sessions per week for 23 wk	RCT N=31	Psychological well-being Endurance Anxiety Self-efficacy	N/A	Depression Self-efficacy Endurance	Depression Anxiety Endurance Psychological well-being Quality of life Pain relief ROM, knee Cardiopulmonary function	Psychological well-being ROM, knee Quality of life Pain relief	N/A
Gowans et al (2002) ³⁴	3 sessions per week for 23 wks	RCT N=31	Depression	N/A	N/A	Quality of life	Quality of life	N/A
Gusi et al (2006) ¹⁹	60 min, 3 times a week, for 12 wk	RCT N=35	Pain relief Quality of life Muscle strength	N/A	Quality of life Muscle strength	Pain relief Quality of life Muscle strength	Muscle strength	Quality of life Muscle strength
Jentoft et al (2001) ^{17,c}	60 min, 2 times a week, for 20 wk	RCT N=44	N/A	N/A	Quality of life (PB and LB) Pain relief (PB) Endurance (PB)	Endurance Pain relief Quality of life Self-efficacy Muscle strength Cardiopulmonary function Mobility	N/A	N/A
McCain et al (1988) ^{30,d}	3 sessions of 60 min per week for 20 wk	RCT N=42	Cardiopulmonary function Physician global assessment	N/A	Pain relief Patient global assessment	Pain relief Sleep quality	N/A	N/A
Meiworm et al (2000) ³⁵	Average of 2 or 3 sessions of 20–30 min per week for 12 wk	CCT N=39	N/A	Pain relief	N/A	Cardiopulmonary function	Pain relief	N/A
Nicholas and Glenn (1994) ³⁶	3 sessions per week for 8 wk	CCT N=24	N/A	N/A	N/A	Psychological profile Quality of life	Pain relief Psychological profile	Quality of life
Schachter et al (2003) ^{31,e}	Group 1: 1 session daily for 16 wk Group 2: 2 sessions per day separated by at least 4 hr for 16 wk	RCT N=107	N/A	N/A	Quality of life Pain relief	Cardiopulmonary function Pain relief Quality of life Self-efficacy Physician global assessment	N/A	N/A

(Continued)

Table 3.
Continued

	Description of Trial	Study Design and N	Grade A	Grade B	Grade C+	Grade C	Grade D	Grade D+
Valim et al (2003) ^{9,f}	3 sessions of 45 min per week for 20 wk	RCT N=60	Cardiopulmonary function Pain relief Quality of life Flexibility (F) Quality of life (F)	N/A	Pain relief Quality of life Quality of life (F)	Cardiopulmonary function Quality of life Anxiety Flexibility Pain relief	N/A	N/A
van Santen et al (2002) ²⁰	Group 1: 60 min, 2 times per week, for 24 wk; subjects were encouraged to attend a third session	RCT N=87	Quality of life	N/A	N/A	Pain relief Cardiopulmonary function Perceived exertion	Pain relief Psychological well-being Quality of life	N/A
van Santen et al (2002) ^{21,g}	Group 1: 60 min, 3 times per wk, for 20 wk Group 2: 60 min, 2 times per week, for 20 wk Subjects were encouraged to attend a third session	RCT N=33	Quality of life (HI and LI)	N/A	Quality of life (HI and LI) Pain relief (HI) Psychological well-being (LI)	Pain relief Quality of life Psychological well-being Cardiopulmonary function	N/A	N/A
Verstappen et al (1997) ²²	Group 1: 2 sessions per week for 6 mo; subjects were encouraged to add 1–2 sessions weekly	RCT N=87	Endurance	N/A	N/A	Flexibility Cardiopulmonary function Perceived exertion Balance Coordination Muscle strength Endurance Patient global assessment Quality of life	Cardiopulmonary function Muscle strength	N/A
Wigers et al (1996) ³²	Group 1: 3 sessions of 45 min per week for 14 wk (total of 40 sessions or 30 hr)	RCT N=40	Quality of life Pain relief Cardiopulmonary function	N/A	Pain relief Depression Quality of life Sleep quality	Sleep quality Depression Pain relief Cardiopulmonary function	N/A	Depression

^a RCT=randomized controlled trial, CCT=controlled clinical trial, N/A=not available, ROM=range of motion.

^b The study by Assis et al involved pool-based aerobics versus land-based aerobics; all recommendations pertain to pool-based aerobics.

^c The study by Jentoft et al involved a pool-based fitness program versus a land-based fitness program; "PB" refers to positive effects of the pool-based fitness program, and "LB" refers to positive effects of the land-based fitness program.

^d The study by McCain et al involved cycling versus flexibility; all recommendations concern the effects of cycling.

^e The study by Schachter et al involved long bouts of low-impact aerobics versus short bouts of low-impact aerobics; recommendations found only for long bouts of low-impact aerobics.

^f The study by Valim et al involved a walking program versus a flexibility program; recommendations followed by "(F)" pertain to effects of flexibility program.

^g The study by van Santen et al involved a high-intensity fitness program versus a low-intensity fitness program; "HI" refers to positive effects found due to the high-intensity fitness program, and "LI" refers to positive effects found as result of the low-intensity fitness program.

ceived a grade of D. In parallel, the outcomes for quality of life in the study by van Santen et al²¹ received both a grade of A and a grade of C+. Across studies, the diversity in results is most likely the result of different samples, exercise outcomes, exercise interventions, or study designs utilized, which is why the study data could not be pooled. Within studies, the discrepancy often refers to different components of the instrument. For example, the outcomes for quality of life in the study by van Santen et al²¹ received a grade of A for social activities of the questionnaire but a grade of C+ for mobility. The heterogeneity of studies selected can lead to the above conflicting evidence, which consequently prevents sound conclusions from being drawn. In future studies, the Ottawa Panel will select studies, if possible, that can be pooled more easily.

Lastly, many studies were eliminated from this report due to small sample sizes, high attrition rates, and lack of fitness program detail (eg, type, duration, frequency, intensity, progression of exercise training).³⁷ There is some evidence that multiple subgroups (eg, patients with depression, patients without depression) of the FM population exist,³⁸ and thus fitness programs may be beneficial for only select FM subgroups. Nevertheless, aerobic exercise is a relatively inexpensive and convenient activity that provides numerous clinically important and statistically significant benefits.

Implications for Practice

The Ottawa Panel found emerging evidence to support the use of aerobic fitness programs for the overall management of FM. Most improvements found were for quality of life and pain relief. Aerobic fitness exercises also were found to greatly increase endurance, which, in turn,

greatly improved the everyday functional mobility of patients.

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Appendix.Evidence-Based Clinical Practice Guidelines (EBPCGs) Related to Aerobic Fitness^a

EBPCGs Related to Aerobic Fitness Versus Control

Aerobics versus control, level I (1 RCT, N=40)³²: grade A for quality of life (more than 30% reduction in VAS score for lack of energy), pain relief (pain distribution, VAS for pain and tender-point dolorimetry), and cardiopulmonary function (work capacity) at end of treatment at 14 weeks (clinically important benefit demonstrated); grade C+ for pain relief (more than 30% reduction in VAS score for pain) and depression (more than 30% reduction in VAS for depression) at end of treatment at 14 weeks, for quality of life (VAS for lack of energy) and sleep quality (VAS for sleep disturbance) at end of treatment at 14 weeks and at 4-year follow-up, and for pain relief (pain distribution) at 4-year follow-up (clinically important benefit demonstrated without statistical significance); grade C for sleep quality (more than 30% reduction in VAS score for sleep disturbance) and depression (VAS for depression) at end of treatment at 14 weeks, for pain relief (VAS for pain and tender-point dolorimetry) and cardiopulmonary function (work capacity) at 4-year follow-up (no benefit demonstrated); grade D+ for depression (VAS for depression) at 4-year follow-up (clinically important benefit favoring control demonstrated without statistical significance).

Walking versus control, level II (1 CCT, N=24)³⁶: grade C for psychological profile (BSI for general severity index and positive symptom total) and quality of life (SIP for psychological dimension) at end of treatment at 8 weeks (no benefit demonstrated); grade D for pain relief (MPQ for number of items chosen and pain rating index) and psychological profile (BSI for positive symptom distress index) at end of treatment at 8 weeks (no benefit demonstrated but favoring control); grade D+ for quality of life (SIP for physical dimension) at end of treatment at 8 weeks (clinically important benefit favoring control demonstrated without statistical significance).

Pool- and land-based aerobics versus control, level I (2 RCTs, N=147)^{33,34}, level II (1 CCT, n=39)³⁵: grade A for depression (CES-D³⁴), psychological well-being (MHI for positive affect³³ and anxiety³³), and endurance (6-minute walk test³³) at end of treatment at 23 weeks, for anxiety (STAI³³) and self-efficacy (ASES for pain³³) at end of treatment at 12 and 23 weeks, for psychological well-being (MHI for depression³³) at end of treatment at 6 and 23 weeks, and for self-efficacy (ASES for symptoms³³) at end of treatment at 6, 12, and 23 weeks (clinically important benefit demonstrated); grade B for pain relief (number of tender points³⁵) at end of treatment at 12 weeks (clinically important benefit demonstrated); grade C+ for depression (BDI for total score³³) at end of treatment at 12 and 23 weeks, for depression (BDI for cognitive/affective³³) and self-efficacy (ASES for function³³) at end of treatment at 6, 12, and 23 weeks, for endurance (6-minute walk test³³) at end of treatment at 12 weeks, for self-efficacy (ASES for pain³³) at end of treatment at 6 weeks, and for depression (BDI for somatic³³) at end of treatment at 23 weeks (clinically important benefit demonstrated without statistical significance); grade C for depression (BDI for total score³³), anxiety (STAI³³), and endurance (6-minute walk test³³) at end of treatment at 6 weeks, for depression (BDI for somatic³³) and psychological well-being (MHI for positive affect and anxiety³³) at end of treatment at 6 and 12 weeks, for perceived exertion (15-point scale for perceived exertion³³) and psychological well-being (MHI for behavioral/emotional control³³) at end of treatment at 6, 12, and 23 weeks, for psychological well-being (MHI for emotional ties³³), quality of life (FIQ for total score³³), pain relief (number of tender points³³), and ROM (knee extension at 60° and 120°³³) at end of treatment at 6 and 23 weeks, for cardiopulmonary function (peak $\dot{V}O_2$, heart rate, and performance on ergometer³⁵), and psychological well-being (MHI for depression³³) at end of treatment at 12 weeks, for quality of life (FIQ for depression³³) at end of treatment at 23 weeks; grade D for psychological well-being (MHI for emotional ties³³), ROM (knee extension at 60° and 120°³³), pain relief (number of tender points³³ and average pain of tender points, VAS for pain, and pain distribution³⁵), and quality of life (FIQ total score³³) at end of treatment at 12 weeks, and for quality of life (FIQ for anxiety³⁴) at end of treatment at 23 weeks.

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Home-based aerobics versus control, level I (1 RCT, N=80)¹⁶: grade A for pain relief (VAS for upper-body pain) at end of treatment at 12 weeks and at 9-month follow-up (clinically important benefit); grade C+ for pain relief (VAS for upper-body pain) at 3-month follow-up and for quality of life (FIQ total score) at 3- and 9-month follow-ups (clinically important benefit without statistical significance); grade C for quality of life (FIQ total score) at end of treatment at 12 weeks, for pain relief (VAS for lower-body pain) at end of treatment at 12 weeks and at 3- and 9-month follow-ups, and for psychological distress (global severity index) at 3- and 9-month follow-ups (no benefit).

Fitness program versus control, level I (2 RCTs, N=174)^{20,22}; level II (1 CCT, N=22)¹⁸: grade A for endurance (quadriceps femoris muscle)²² and quality of life (AIMS total score²⁰ at end of treatment at 6 months (clinically important benefit); grade C+ for quality of life (FIQ total score) at end of treatment at 10 weeks¹⁸ (clinically important benefit without statistical significance); grade C for ROM (shoulder, side-bend, and hip flexion) at end of treatment at 10 weeks,¹⁸ for pain relief (VAS for pain)²⁰ and flexibility (sit-and-reach²²) at end of treatment at 6 months, and for cardiopulmonary function (peak workload^{20,22} and peak heart rate²²), perceived exertion (peak Borg Scale score^{20,22} and peak Borg Scale score 50W²² [W is peak workload with ergometer]), balance (body balance and ball bouncing²²), coordination (hand-plate tapping²²), muscle strength (vertical jump and handgrip strength²²), endurance (sit-ups²²), patient global assessment for well-being,²² and quality of life (VAS for general fatigue and SIP total score and physical dimension²²) at end of treatment at 6 months (no benefit); grade D for pain relief (number of tender points and tender-point severity) at end of treatment at 10 weeks¹⁸ and for cardiopulmonary function (peak heart rate 50W²²), muscle strength (arm pull strength²²), pain relief (number of tender points and myalgic score for tender points²⁰), psychological well-being (SCL-90-R for psychological distress²⁰), and quality of life (SIP for psychological dimension²⁰) at end of treatment at 6 months (no benefit demonstrated but favoring control).

Waist-high warm water aerobics versus control, level I (1 RCT, N=35)¹⁹: grade A for pain relief (VAS for pain) and quality of life (EQ-5D utility) at end of treatment at 12 weeks and for quality of life (EQ-5D self-care dimension and anxiety/depression dimension) and muscle strength (strength of the left knee concentric flexors at 60°) at end of treatment at 12 weeks and at 12-week follow-up (clinically important benefit); grade C+ for quality of life (EQ-5D mobility dimension) and muscle strength (strength of the right knee and left knee concentric extensors at 60° and strength of the right shoulder abductors at 60°) at end of treatment at 12 weeks and at the 12-week follow-up, for quality of life (EQ-5D daily living dimension and pain/discomfort dimension) and muscle strength (strength of the right knee concentric flexors at 60° and 210° and strength of the left knee concentric flexors at 210°) at end of treatment at 12 weeks, and for muscle strength (strength of the right knee eccentric extensors at 60°) at follow-up at 12 weeks (clinically important benefit without statistical significance); grade C for pain relief (VAS for pain), quality of life (EQ-5D daily living dimension and pain/discomfort dimension), and muscle strength (strength of the right knee concentric flexors at 60° and 210°) at the 12-week follow-up, for muscle strength (strength of the right knee eccentric extensors at 60°, strength of the right shoulder adductors at 60°, and strength of the left shoulder abductors at 60°) at end of treatment at 12 weeks, and for muscle strength (strength of the right and left knee concentric extensors at 210° and strength of the left knee eccentric extensors at 60°) at end of treatment at 12 weeks and at the 12-week follow-up (no benefit); grade D for muscle strength (strength of the right shoulder adductors at 60°) at the 12-week follow-up and for muscle strength (strength of the left shoulder adductors at 60°) at end of treatment at 12 weeks and the 12-week follow-up (no benefit demonstrated but favoring control); grade D+ for quality of life (EQ-5D utility) and muscle strength (strength of the left knee concentric flexors at 210° and strength of the left shoulder abductors at 60°) at the 12-week follow-up (clinically important benefit favoring control).

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EBPCGs Related to Aerobic Fitness Versus Another Type of Exercise Therapy

Cycling versus flexibility, level I (1 RCT, N=42)³⁰: grade A for cardiopulmonary function (peak work capacity at 170 beats per minute) and physician global assessment (physician assessment of disease activity, number of patients) at end of treatment at 20 weeks (clinically important favoring cardiovascular training [bicycle ergometer] benefit demonstrated); grade C+ for pain relief (myalgic score and VAS for pain) and patient global assessment (patient assessment of disease activity, number of patients) at end of treatment at 20 weeks (clinically important benefit favoring cardiovascular training [bicycle ergometer] demonstrated without statistical significance); grade C for pain relief (pain distribution) and sleep quality (sleep disturbance) at end of treatment at 20 weeks (no benefit demonstrated).

Walking versus stretching program, level I (1 RCT, N=60)⁹: grade A for cardiopulmonary function (ventilatory anaerobic threshold and treadmill test) and pain relief (number of tender points and pain score) at end of treatment 10 and 20 weeks and for quality of life (FIQ total score) at end of treatment at 20 weeks (clinically important benefit favoring walking program); grade A for flexibility (sit and reach) and quality of life (SF-36 for role-emotional, mental health, and mental component summary) at end of treatment at 20 weeks and for quality of life (SF-36 for bodily pain) at end of treatment at 10 weeks (clinically important benefit favoring stretching); grade C+ for pain relief (VAS for pain) at end of treatment at 20 weeks, for depression (BDI) at end of treatment at 10 and 20 weeks, for quality of life (FIQ total score) at end of treatment at 10 weeks, and for quality of life (SF-36 for role-physical) at end of treatment at 10 weeks (clinically important benefit favoring walking program demonstrated without statistical significance); grade C+ for quality of life (SF-36 for role-emotional, vitality, mental health, and mental component summary) at end of treatment at 10 weeks and for quality of life (SF-36 for role-physical and general health) at end of treatment at 20 weeks (clinically important benefit favoring stretching demonstrated without statistical significance); grade C for cardiopulmonary function (maximal $\dot{V}O_2$, resting heart rate, maximal heart rate, and heart rate at ventilatory anaerobic threshold), quality of life (SF-36 for physical functioning, role-social, and physical component summary), and anxiety (STAI for state and trait) at end of treatment at 10 and 20 weeks, for flexibility (sit-and-reach), quality of life (SF-36 for general health), and pain relief (VAS for pain) at end of treatment at 10 weeks, and for quality of life (SF-36 for bodily pain and vitality) at end of treatment at 20 weeks (no benefit demonstrated).

Long bouts of low-impact aerobics versus short bouts of low-impact aerobics, level I (1 RCT, N=107)³¹: grade C+ for quality of life (FIQ for physical impairment and “feel good”) and pain relief (VAS for pain) at end of treatment at 8 and 16 weeks and for quality of life (AIMS2 for walking and bending and FIQ total score, stiffness and depression) at end of treatment at 8 weeks (clinically important benefit demonstrated without statistical significance favoring long bouts of low-impact aerobics programs); grade C for cardiopulmonary function (peak $\dot{V}O_2$ and treadmill test), pain relief (pain distribution), quality of life (AIMS2 for mobility and affect and FIQ for fatigue, rested and anxiety), and self-efficacy (CPSS for pain, functional tasks and symptoms) at end of treatment at 8 and 16 weeks and for quality of life (AIMS2 for walking and bending and FIQ total score, stiffness and depression), physician global assessment (physician’s global evaluation), and pain relief (myalgic score for tender points) at end of treatment at 16 weeks (no benefit demonstrated).

Pool-based aerobics versus land-based aerobics (walking or jogging), level I (1 RCT, N=60)²⁹: grade C+ for quality of life (FIQ total score [RD 20%]) at end of treatment at 15 weeks, for quality of life (FIQ for anxiety [RD 15%]) at end of treatment at 8 weeks, and for quality of life (SF-36 for role-emotional [RD 16%, 25%] and FIQ for depression [RD 28%, 32%]) and depression (BDI [RD 22%, 18%]) at end of treatment at 8 and 15 weeks (clinically important benefit favoring pool-based aerobic exercise demonstrated without statistical significance); grade C for quality of life (FIQ total score) at end of treatment at 8 weeks, for quality of life (FIQ for anxiety) at end of treatment at 15 weeks, and for cardiopulmonary function ($\dot{V}O_2$ at anaerobic threshold and peak $\dot{V}O_2$), pain relief (VAS for pain), and quality of life (SF-36 for physical and mental component summary) at end of treatment at 8 and 15 weeks (no benefit demonstrated).

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High-intensity fitness program versus low-intensity fitness program, level I (1 RCT, N=33)²¹: grade A for quality of life (AIMS for social activities) at end of treatment at 20 weeks (clinically important benefit favoring high-intensity fitness program); grade A for quality of life (AIMS for dexterity and activities of daily living) at end of treatment at 20 weeks (clinically important benefit favoring low-intensity fitness program); grade C+ for quality of life (AIMS for mobility, social role, anxiety, and physical activity) and pain relief (VAS for pain) at end of treatment at 20 weeks (clinically important benefit favoring high-intensity fitness program without statistical significance); grade C+ for quality of life (VAS for general sense of well-being and AIMS for pain) and psychological well-being (SCL-90-R for psychoticism) at end of treatment at 20 weeks (clinically important benefit favoring low-intensity fitness program without statistical significance); grade C for pain relief (number of tender points and myalgic score for tender points), quality of life (AIMS for depression and health perception), psychological well-being (SCL-90-R for psychological distress, phobic anxiety, anxiety, depression, somatization, obsession/compulsion, interpersonal sensitivity, hostility, and sleep), and cardiopulmonary function (peak workload with ergometer) at end of treatment at 20 weeks (no benefit).

Pool-based fitness program versus land-based fitness program, level I (1 RCT, N=44)¹⁷: grade C+ for quality of life (FIQ for anxiety and depression) at end of treatment at 20 weeks and for pain relief (VAS for exercise-induced pain) and endurance (shoulder endurance time) at 6-month follow-up (clinically important benefit favoring pool-based fitness exercise without statistical significance); grade C+ for quality of life (FIQ for “feel good”) at end of treatment at 20 weeks (clinically important benefit favoring land-based fitness exercise without statistical significance); grade C for endurance (shoulder endurance time) and pain relief (VAS for exercise-induced pain) at end of treatment at 20 weeks, for quality of life (FIQ for anxiety and depression and “feel good”) at 6-month follow-up, and for quality of life (FIQ for pain, fatigue, rested, stiffness, and physical impairment), self-efficacy (ASES for pain and other symptoms), muscle strength (grip strength of dominant hand), cardiopulmonary function (cardiovascular capacity), and mobility (walking speed) at end of treatment at 20 weeks and at 6-month follow-up (no benefit).

²¹ RCT=randomized controlled trial, VAS=visual analog scale, BSI=Brief Symptom Inventory, MPQ=McGill Pain Questionnaire, SIP=Sickness Impact Profile, CES-D=Center for Epidemiologic Studies–Depression Scale, MHI=Mental Health Inventory, STAI=State-Trait Anxiety Inventory, ASES=Arthritis Self-efficacy Scale, BDI=Beck Depression Inventory, FIQ=Fibromyalgia Inventory, ROM=range of motion, SCL-90-R=Symptom Check List-90-Revised, Spanish version of EQ-5D=5 dimensions of the Health-Related Quality of Life and Pain Scale (mobility, self-care, daily activities, pain and discomfort, and anxiety or depression), SF-36=36-Item Short-Form Health Survey, $\dot{V}O_2$ =oxygen uptake, AIMS2=Arthritis Impact Measurement Scales 2, CPSS=Chronic Pain Self-efficacy Scale, RD=relative difference, AIMS=Arthritis Impact Measurement Scales.