

# Components of effective randomized controlled trials of hydrotherapy programs for fibromyalgia syndrome: A systematic review

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**Aim:** Previous systematic reviews have found hydrotherapy to be an effective management strategy for fibromyalgia syndrome (FMS). The aim of this systematic review was to summarize the components of hydrotherapy programs used in randomized controlled trials.

**Method:** A systematic review of randomized controlled trials was conducted. Only trials that have reported significant FMS-related outcomes were included. Data relating to the components of hydrotherapy programs (exercise type, duration, frequency and intensity, environmental factors, and service delivery) were analyzed.

**Results:** Eleven randomized controlled trials were included in this review. Overall, the quality of trials was good. Aerobic exercise featured in all 11 trials and the majority of hydrotherapy programs included either a strengthening or flexibility component. Great variability was noted in both the environmental components of hydrotherapy programs and service delivery.

**Conclusions:** Aerobic exercise, warm up and cool-down periods and relaxation exercises are common features of hydrotherapy programs that report significant FMS-related outcomes. Treatment duration of 60 minutes, frequency of three sessions per week and an intensity equivalent to 60%–80% maximum heart rate were the most commonly reported exercise components. Exercise appears to be the most important component of an effective hydrotherapy program for FMS, particularly when considering mental health-related outcomes.

**Keywords:** hydrotherapy, fibromyalgia syndrome, exercise, effective, components

## Introduction

Fibromyalgia syndrome (FMS) is a common condition characterized by widespread musculoskeletal pain and tenderness. It is frequently associated with other symptoms such as feelings of stiffness, loss of sleep, fatigue, depression, and anxiety.<sup>1</sup>

Treatments for FMS have been evaluated extensively in the literature over the last two decades. A number of systematic reviews have evaluated the effectiveness of exercise for FMS.<sup>2–6</sup> All have found evidence to support the use of exercise, in particular aerobic exercise, in the management of FMS. A recent Cochrane review concluded that moderate intensity aerobic training for 12 weeks may improve overall well-being and physical function in FMS.<sup>2</sup>

Recently, a number of trials and systematic reviews have evaluated the effectiveness of structured exercise programs in warm water (such as hydrotherapy) for FMS. The findings of these trials and systematic reviews suggest that these programs are also effective in the management of FMS, over a range of outcomes. A recent systematic review concluded that there is strong evidence for the use of hydrotherapy in the management of FMS.<sup>7</sup>

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Despite a large volume of research evidence supporting the use of hydrotherapy in the management of FMS, there has not yet been a systematic review which summarizes the components (type of exercise frequency, intensity, duration) of an effective hydrotherapy program for FMS. The aim of this systematic review is to summarize these components, using only randomized controlled trials that have reported significant FMS-related outcomes. This approach may provide clinicians and researchers with a framework for the design of hydrotherapy programs for FMS.

## Methods

### Search strategy

The following medical and allied health-related databases were searched systematically by two independent reviewers in May 2009: AMED, MEDLINE, CINAHL, Embase, PubMed, SPORTSDiscus, Scopus, Physiotherapy Evidence Database (PEDro), and Cochrane Controlled Trials Register. The following search terms were used with appropriate truncations; fibromyalgia, hydrotherapy, ‘aquatic therapy’, ‘aquatic exercise’, ‘aquatic physiotherapy’, balneotherapy, thalassotherapy, physiotherapy, ‘physical therapy’, ‘spa therapy’, exercise, water, and pool. The search was limited to randomized controlled trials published in peer-reviewed journals from 1998 onwards in the English language.

### Inclusion and exclusion criteria

After full text versions of trials were sourced, two authors (LP & ZM) met to discuss their suitability for inclusion. The PICO framework was used to evaluate the suitability of trials for inclusion. PICO (an acronym for population, intervention, comparison and outcome) provides a framework for answering a clinical question.<sup>8</sup> Trials that did not fit PICO criteria or did not provide sufficient detail about the components of their hydrotherapy intervention were excluded. The PICO format used in this review is outlined in Figure 1.

## Quality appraisal

The methodological evaluation of included trials was conducted using the PEDro scale, an 11-point scale which addresses external and internal validity. The first criterion evaluates external validity and is not considered as part of the overall scoring. Criteria 2–11 address internal validity which contribute to an overall score out of 10.<sup>9</sup> Three of the items included in the PEDro scale have been demonstrated to be predictive of systematic error or bias in randomized trials (lack of concealment of allocation, blinding and loss of participants at follow up).<sup>10</sup> The PEDro scale was chosen for this review because of its capacity to detect these potential sources of biases. Critical appraisal of each study was conducted by two independent reviewers (LP & ZM), who met to discuss any variances in scores until consensus was achieved. The 10 PEDro criteria are outlined in Figure 2.

## Data extraction and analysis

Data relating to the components of hydrotherapy interventions were extracted in four main categories:

**Exercise components:** Type of exercise (aerobic, strengthening, flexibility, relaxation, warm up and cool down), duration of each hydrotherapy session in minutes and program in weeks, frequency of sessions per week, intensity of exercises as reported in trials and method of progression of exercise.

**Environmental components:** Equipment used and location of the hydrotherapy intervention.

**Service delivery components:** Co-interventions, nature of supervision (credentials of those supervising the hydrotherapy) and delivery format (group or individual format).

**Outcome measures:** Data relating to the outcomes of hydrotherapy interventions were extracted and organized into three categories; pain or tenderness, quality of life and function. Dichotomous outcomes were reported for each of these categories (significant or nonsignificant between group findings).

Population	Fibromyalgia patients of any age and of both genders, diagnosed by American College of Rheumatology criteria. <sup>1</sup>
Intervention	Hydrotherapy: Any form of active exercise within a warm water environment.
Comparison	Any control or comparison group.
Outcome	Pain/tenderness, quality of life or functional outcome measures.

Figure 1 PICO criteria.

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2. Random allocation
3. Concealed allocation
4. Baseline homogeneity (between groups)
5. Blinding of participants
6. Blinding of therapists
7. Blinding of outcome assessors
8. Drop-out rate less than 15%
9. Intention to treat analysis
10. Between groups statistical comparisons
11. Point measures and measures of variability

Figure 2 PEDro criteria.

## Definitions

Hydrotherapy was defined as having two important elements: warm water immersion and exercise.<sup>11</sup> For the purpose of this review, warm water was defined as a temperature over 30 degrees Celsius, or when water temperature was reported as warm in the trial. Exercise was further defined as *active exercise*, consisting of contraction and relaxation of one or more muscle groups in a structured and organized manner. Trials using warm water immersion without exercise were excluded.

The intensity of aerobic exercise is often measured as a percentage of maximal heart rate ( $\% \text{HR}_{\text{max}}$ ) or percentage of heart rate reserve.<sup>12</sup> Intensity can also be measured as a percentage of an individual's maximal effort, determined by their perceived level of exertion using the Borg Scale, a convenient and valid measure of exercise intensity for aerobic exercise.<sup>13</sup> The original Borg scale rates exertion on a 15-point scale from 6 to 20 and assumes a linear relationship to maximum heart rate.<sup>13</sup>

## Other terminology and definitions

Thalassotherapy has been described as a combination of bathing in sea water in a marine climate with solar radiation.<sup>14</sup> Thalassotherapy itself does not include exercise, but is frequently combined with exercise. Balneotherapy is term derived from the Latin word *balneum* which means *bath*.<sup>15</sup> Like thalassotherapy, balneotherapy involves bathing in mineral or thermal water, and can also involve an

exercise component. Trials investigating the effectiveness of thalassotherapy and balneotherapy were only included in this review if they involved an exercise component.

## Results

### Included and excluded trials

Eleven randomized controlled trials were included in this review. The article by Gowans and colleagues reported on data from their 2001 trial. Six of the 11 trials were published between 2006 and 2009, which may reflect an increasing interest in this area of research in recent years. Figure 3 provides an overview of included and excluded trials.

### Quality of trials

Overall, the trials included in this systematic review were of a good quality. PEDro critical appraisal scores ranged from five<sup>16-18</sup> to eight.<sup>19,20</sup> The majority of trials did not use an intention to treat analysis, which could potentially reduce the validity of their results. However, only one trial reported a drop out rate of over 15%.<sup>14</sup> Individual PEDro criterion scores are listed in Table 1.

## Exercise components

### Type of hydrotherapy program

All 11 trials utilized a warm up, cool down or relaxation period in their hydrotherapy program. In addition, all trials included some form of aerobic exercise. Aerobic exercise included deep water running, active movement of joints against the resistance of the water, jumping, jogging, dancing and low intensity resistance exercises using floatation equipment. Only one trial did not include either a strengthening or flexibility component in their program.<sup>20</sup> One trial included both a strengthening and flexibility component and the remaining nine trials used either a strengthening or a flexibility component, but not both.<sup>21</sup> This may indicate that strengthening and/or flexibility exercises are important components of hydrotherapy programs for FMS. Table 2 summarizes the type of hydrotherapy intervention used in each trial.

### Duration of hydrotherapy programs

Hydrotherapy program duration ranged from 30 to 60 minutes per session. Seven of the 11 trials used a 60 minute session duration and four trials used either 30 or 35 minutes. In contrast, there was great variability in the total duration of programs, ranging from four to 32 weeks (refer to Table 3). Consistently, trials did not report a rationale for the duration of hydrotherapy sessions or the duration of their overall hydrotherapy program.

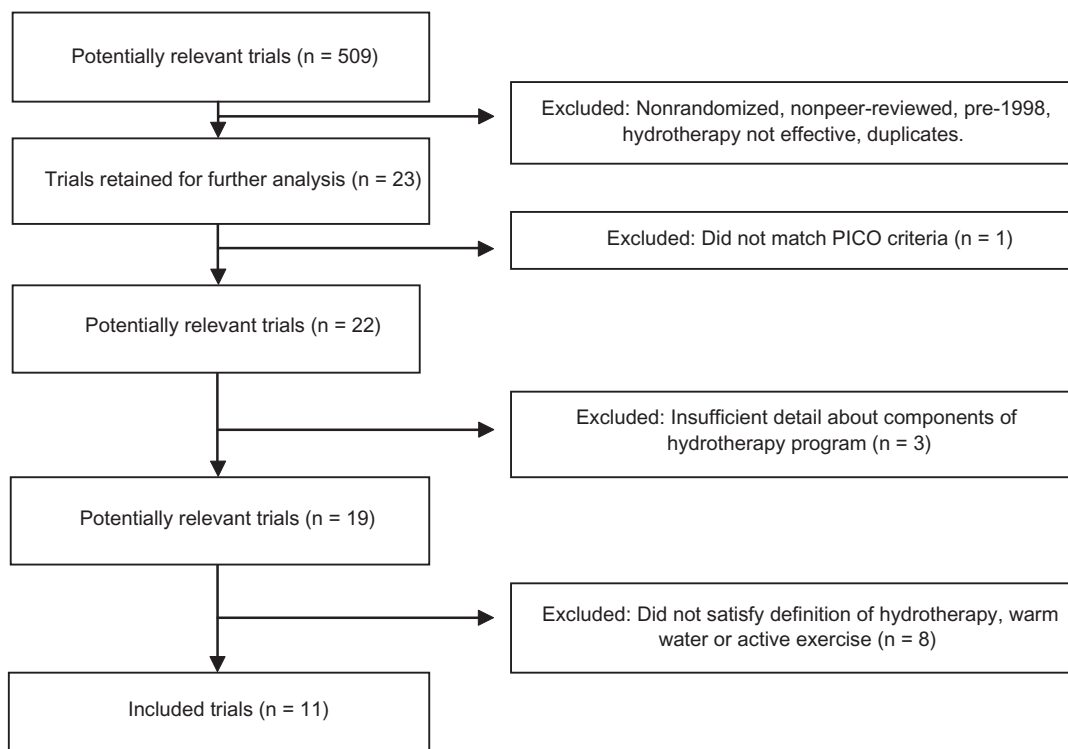


Figure 3 Included and excluded trials.

### Frequency of hydrotherapy programs

Frequency of programs ranged from two to four times per week. The majority of trials used a frequency of three times per week. Two trials used a frequency of twice per week and one trial used a frequency of four times per week (refer to

Table 3). No trial provided an evidence-based justification for the frequency of their hydrotherapy program.

### Intensity of hydrotherapy programs

The intensity of aerobic exercise was reported in eight of the 11 trials. Seven of these trials used a percentage of their subject’s maximum heart rate and one trial used their subject’s rating of perceived exertion on the Borg scale (refer to Table 3).<sup>10,11</sup> The range of exercise intensity used in trials was from 60%–80% HR<sub>max</sub>.

### Method of progression of hydrotherapy programs

Only three trials increased the difficulty of exercise as their participants improved. All three of these trials progressed their programs by increasing exercise intensity (refer to Table 3).

### Environmental components

Most of the trials included in this review used a pool environment. One trial was conducted in the sea.<sup>14</sup> Seven trials used equipment, either heart rate monitors or flotation devices to provide flotation or resistance to movement.<sup>14,17–22</sup> Of the 11 trials, only one described the mineral or chemical content of the water.<sup>23</sup>

Table 1 Individual PEDro criteria

Author	PEDro criteria											Total
	2	3	4	5	6	7	8	9	10	11		
Altan et al	1	0	1	0	0	1	1	0	1	1	6	
Assis	1	1	1	0	0	1	1	1	1	1	8	
De Andrade et al	1	1	1	0	0	1	0	0	1	1	6	
Evcik et al	1	0	1	0	0	0	1	0	1	1	5	
Gowans et al	1	0	1	0	0	0	1	1	1	1	6	
Gowans et al and Gowans et al (follow up)	1	0	1	0	0	0	1	1	1	1	6	
Gusi et al	1	0	1	0	0	0	1	0	1	1	5	
Jentoft et al	1	0	1	0	0	1	1	0	1	1	6	
Ide et al	1	1	1	0	0	1	1	0	1	1	7	
Tomas-Carus et al	1	0	1	0	0	0	1	0	1	1	5	
Tomas-Carus et al	1	1	1	0	0	1	1	0	1	1	7	

Abbreviation: PEDro, physiotherapy evidence database.

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**Table 2** Hydrotherapy interventions

Author	Warm up	Aerobic	Strength	Flexibility	Cool down or relaxation
Altan et al	√	√	x	√	√
Assis	√	√	x	√	√
De Andrade et al	√	√	x	√	√
Evcik et al	√	√	x	√	√
Gowans et al	√	√	x	√	√
Gowans et al	√	√	x	√	√
Gusi et al	√	√	√	x	√
Jentoft et al	√	√	√	√	√
Ide et al	√	√	x	x	√
Tomas-Carus et al	√	√	√	x	√
Tomas-Carus et al	√	√	√	x	√

**Notes:** √, present; x, not present.

### Service delivery components

Five trials used either education or land-based exercise as a co-intervention<sup>26,21,23–26</sup>. No other co-interventions were reported in trials. All trials reported supervising their hydrotherapy program. Only five trials reported the credentials of the person supervising their program and all five of these trials were supervised by a physiotherapist

(physical therapist).<sup>14,16,19,21,23</sup> All trials used a group hydrotherapy format.

### Outcome measures

In accordance with the inclusion criteria of this systematic review, all 11 trials reported statistically significant outcomes in favor of hydrotherapy, either as a between-group measure

**Table 3** Components of interventions

Author	Duration (minutes)	Duration (weeks)	Frequency (sessions per week)	Intensity (excluding warm up and cool down)	Method of progression
Altan et al	35	12	3	NR	NR
Assis	60	15	3	HR (anaerobic threshold)	Increased intensity after 8 weeks (increased HR)
De Andrade et al	60	12	3	Borg 12–13 (15 point scale)	Increased intensity after 2 weeks (increased Borg Scale to 12–13)
Evcik et al	35	5	3	NR	NR
Gowans et al	30	6	2	60%–75% HR <sub>max</sub>	NR
Gowans et al	30	23	3 (0–6 weeks) 1 (6–23 weeks)	60%–75% HR <sub>max</sub>	Increased intensity of aerobic component to match target HR
Gusi et al	60	12	3	65%–75% HR <sub>max</sub>	NR
Jentoft et al	60	20	2	60%–80% HR <sub>max</sub>	NR
Ide et al	60	4	4	NR	NR
Tomas-Carus et al	60	12	3	65%–75% HR <sub>max</sub>	NR
Tomas-Carus et al	60	32	3	60%–65% HR <sub>max</sub>	NR

**Abbreviations:** HR, heart rate; NR, not reported.

or as a pre-post measure. Nine trials reported significant between-group measures for one of the following outcomes: pain/tenderness, quality of life, or function.<sup>14,16–18,20,22,24–26</sup> Seven trials included a follow up period, most commonly after a de-training period or a period of no intervention.<sup>16–18,21,23,24,26</sup> The outcome measures used to determine the effectiveness of hydrotherapy in each trial are summarized in Table 4. Between-groups measures are delineated from pre-post measures.

### Trends in outcomes

In accordance with the inclusion criteria for this systematic review, all included trials reported significant physical FMS-related outcomes. However, 10 out of 11 trials also reported significant mental health outcomes (depression or anxiety), as either a subscale of a health-related quality of life outcome measure or as a depression or anxiety orientated outcome measure. Three trials reported significant pre-post mental health outcomes following treatment or at follow up<sup>16,21,26</sup> Six trials reported significant between-group outcomes immediately following their intervention phase.<sup>14,18–20,22,25</sup> The remaining two trials

reported significant between-group mental health outcomes at both the end of their intervention phase and after a follow up period.<sup>17,23</sup>

Seven of the 11 trials reported more than one statistically significant outcome (between-groups), but all seven of these trials used a nonintervention comparison group (refer to Table 4). Four of the five trials that reported more than one significant outcome (pre-post) used an exercise-based comparison group (land-based, home-based or water-based exercise). The remaining trial compared hydrotherapy to balneotherapy without exercise.

### Discussion

The effectiveness of various forms of hydrotherapy in the management of FMS has been established in recent years through a number of randomized controlled trials and systematic reviews. This systematic review aimed to summarize the components of randomized controlled trials that have reported significant FMS-related outcomes. Clinicians seeking to design evidence-based hydrotherapy programs for FMS could be guided by the findings of this review.

**Table 4** Outcome measures and follow up periods

Author	Statistically significant outcomes following treatment			Statistically significant outcomes at follow up			Comparison group
	Pain or tenderness	Quality of life	Function	Pain or tenderness	Quality of life	Function	
Altan et al	√*	√*	√*	√*	√*	√*	Balneotherapy (no exercise)
Assis	√*	√*	√*	NA	NA	NA	Land-based exercise
De Andrade et al (pool group)	√*	√*	x	NA	NA	NA	Sea water
De Andrade et al (sea group)	√*	√*	√	NA	NA	NA	Pool water
Evcik et al	√*	√*	√*	√	√*	√*	Home-based exercise
Gowans et al	NA	√	√	NA	√*	√*	No intervention
Gowans et al	x	√	√	NA	NA	NA	No intervention
Gowans et al (follow up to Gowans et al)	NA	NA	NA	x	√	√	
Gusi et al	√	√	√	x	x	x	No intervention
Jentoft et al	√*	√*	√*	x	x	x	Land-based exercise
Ide et al	√	√	√	NA	NA	NA	No intervention
Tomas-Carus et al	√	√	√	√	x	x	No intervention
Tomas-Carus et al	√	√	√	NA	NA	NA	No intervention

**Notes:** √, statistically significant between-group findings; x, not statistically significant between group findings; NA, not applicable; NR, not reported; \*pre-post measures only.

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## Exercise components

### Type of hydrotherapy program

Aerobic exercise, with a warm-up and a cool-down or relaxation period were common features of the hydrotherapy programs analyzed in this systematic review. This is consistent with the subgroup analyses of other systematic reviews on the effectiveness of general exercise programs for FMS.<sup>2-4</sup>

### Duration

The findings of this review suggest that a hydrotherapy session of between 30 and 60 minutes is of a sufficient duration to make significant changes to a range of outcomes for FMS. This review also demonstrates that programs of a relatively short duration (4–6 weeks) can still result in improved outcomes. Great variability is seen in the overall durations of the programs used in trials. Program duration may have been determined by a range of factors including what was convenient to study administrators or participants. No trial stated a rationale or referred to the literature to justify the duration of their hydrotherapy program.

### Frequency

Although the majority of trials included in this review used a frequency of three sessions per week, this review demonstrates that a hydrotherapy program conducted twice a week can also lead to positive outcomes for FMS. The chosen frequency of sessions in clinical practice may depend on financial, organizational, motivational or time-related factors. Although an exercise prescription of twice a week is below that suggested by physical fitness guidelines, the findings of this review suggest that twice weekly hydrotherapy is as effective as more frequent hydrotherapy.<sup>27</sup> This finding may have implications for those who are not able to attend hydrotherapy more than twice a week.

### Intensity

Of the trials that accurately reported their exercise intensity, a range of exercise intensity of 60%–80% HR<sub>max</sub> was observed. This review did not attempt to classify exercise intensity into low, moderate and high categories, but it seems reasonable to consider 60%–80% HR<sub>max</sub> as a moderate range of exercise intensity. This finding is consistent with the subgroup analysis of a recent Cochrane review on the effectiveness of general exercise for FMS.<sup>2</sup> Heart rate monitors and patient-rated scales of perceived exertion are possible methods that can be used to standardize the intensity of hydrotherapy exercise in a clinical setting.

### Method of progression

A patient who is compliant with an exercise program should ideally progress to more challenging exercises as

their pain, function and quality of life improve. Only three trials reported progressing the difficulty of their program as their participants improved.<sup>14,19,25</sup> As a result, based on the findings of this review, a strong statement regarding the most appropriate method of progression of programs cannot be made.

## Environmental components

Most of the hydrotherapy programs analyzed in this review were conducted in pool environments and did not describe the mineral or chemical content of the water. Sea water or water with added minerals or chemicals may help to increase compliance with hydrotherapy programs or promote relaxation or enjoyment, both of which could potentially improve the outcomes of hydrotherapy programs. Equipment that provides flotation or resistance to movement may increase the type of exercises that can be prescribed as a part of a hydrotherapy program, and may help those supervising hydrotherapy programs to prescribe exercises for those with co-morbidities.

## Service delivery components

Despite the fact that only five of the 11 trials included in this review reported the credentials of those supervising their program, it is noted that all five programs were supervised by physiotherapists. Professional supervision may be an important component of hydrotherapy programs for FMS.

## Outcome measures

All of the trials that reported significant between-group outcomes compared hydrotherapy to a no intervention group. In contrast, the majority of trials that reporting no significant difference between their intervention and comparison groups used an exercise-based comparison group. In these trials (comparing two forms of exercise) both groups had improved. Exercise therefore appears to be a very important component of a hydrotherapy program for FMS (as opposed to passive water-based therapies). A direct comparison of passive and active water-based therapies is beyond the scope of this review.

## Mental health-related outcomes

In addition to physical outcomes, 10 out of 11 trials reported significant mental health-related outcomes. Anxiety and depression are two conditions which are commonly associated with FMS.<sup>7,22</sup> Improved anxiety and depression-related outcomes were reported immediately following intervention periods and after follow up periods in a number of trials. One trial demonstrated no significant difference between

a hydrotherapy group and a passive balneotherapy group over a range of outcomes.<sup>23</sup> However, depression scores were significantly lower both immediately following intervention and at follow up (between group measures). This finding may indicate that although passive treatments of FMS in warm water can lead to improvements in FMS-related outcomes, the exercise component may be more important in changing depression-related outcomes. This is consistent with the findings of systematic reviews on the effectiveness of exercise in the management of mild to moderate clinical depression.<sup>28–31</sup>

### Limitations of this review

As with any research, this systematic review also has some limitations. Firstly, the very nature of a systematic review inhibits a broad and diverse approach to the literature. For example, this systematic review is limited to randomized controlled trials published in the last 10 years. It is possible the literature published prior to this period may be relevant to the review question. Similarly, while all attempts were made to interrogate and access all relevant literature, it is possible some publications may have been missed in the search process. This could have been due to access to relevant databases, use of alternate key words and varying terminologies. However, as this review identified more than 10 randomized controlled trials on the same topic, the body of evidence to inform the review question is considerable. Secondly, this review only presents components of hydrotherapy programs that are effective and does not consider components of hydrotherapy programs that are ineffective.

### Clinical implications

This systematic review builds on the findings of previous systematic reviews and randomized controlled trials on this topic. Clinicians can utilize the findings of this review in the creation of their own hydrotherapy programs for FMS. According to the findings of this review, the exercise component of a hydrotherapy program for FMS should include some form of aerobic activity. Including a warm-up, cool-down or relaxation period as well as either a flexibility or strength-based component, for a duration of at least four weeks at a frequency of three times per week is also recommended. Self-rated depression or anxiety scales can be used to monitor mental health outcomes.

### Directions for future research

Hydrotherapy for FMS is a topic which was been evaluated extensively in the literature in recent years. Nevertheless

there are still some aspects to this topic which require further evaluation. Further research is required to determine the most appropriate duration of hydrotherapy programs for FMS, and whether improvements can be maintained when programs are continued independently. This information is of interest from both a clinical and an economic perspective. More research comparing passive water-based therapies to hydrotherapy would also be of value from an economic perspective.

### Conclusion

Aerobic exercise, warm up and cool-down periods and relaxation exercises are common features of hydrotherapy programs reported in randomized controlled trials that have reported significant FMS-related outcomes. Flexibility and strength-based exercises were also commonly utilized. Treatment durations of 60 minutes, frequencies of three sessions per week and exercise intensities equivalent to 60%–80% HR<sub>max</sub> were the most common exercise components used in programs. When considering exercise, environmental, and service delivery components, exercise appears to be the most important factor in hydrotherapy programs, particularly when considering mental health-related outcomes.

### Disclosures

The authors report no conflicts of interest in this work.

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