

2012

The Effectiveness of Warm Water Pool Therapy as Measured by the Fibromyalgia Impact Questionnaire in the Outpatient Setting of Middle-Aged Women who have Fibromyalgia

Sara Hieter
Pacific University

Sara Garfinkel
Pacific University

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Recommended Citation

Hieter, Sara and Garfinkel, Sara, "The Effectiveness of Warm Water Pool Therapy as Measured by the Fibromyalgia Impact Questionnaire in the Outpatient Setting of Middle-Aged Women who have Fibromyalgia" (2012). *PT Critically Appraised Topics*. Paper 32.

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The Effectiveness of Warm Water Pool Therapy as Measured by the Fibromyalgia Impact Questionnaire in the Outpatient Setting of Middle-Aged Women who have Fibromyalgia

Disciplines

Physical Therapy

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Title: The Effectiveness of Warm Water Pool Therapy as Measured by the Fibromyalgia Impact Questionnaire in the Outpatient Setting of Middle-Aged Women who have Fibromyalgia

Clinical Scenario: During our last clinical internships, we both worked at clinics that specialized in warm water aquatic therapy. We saw many patients with fibromyalgia who felt that this treatment was very beneficial. We are interested in determining whether this intervention is useful for this patient population. We will be looking specifically at middle-aged women, as this is the population most frequently affected by this disease. The outcome measure we will examine is the Fibromyalgia Impact Questionnaire (FIQ).

Introduction: Although we both observed pool therapy to be an effective treatment for patients with Fibromyalgia, we were interested in finding out if there was evidence to support this observation. We were interested in the effects of pool therapy on patients' functional outcomes, self-reported pain, strength, aerobic capacity and FIQ scores. Due to the limited research in this area, we narrowed our outcomes measure to focus on the FIQ score.

Clinical Question: Is Pool Therapy more effective than inactivity at decreasing the Fibromyalgia Impact Questionnaire (FIQ) score for middle aged women with Fibromyalgia?

Clinical PICO:

Population – Patients who have Fibromyalgia

Intervention – Warm water pool therapy

Comparison – Inactivity or land-based exercise

Outcome – Fibromyalgia Impact Questionnaire

PEDRO scores

	Tomas-Carus (2008)	Tomas-Carus (2007)	Munguia-Izquierdo
Random	Yes	Yes	Yes
Concealed allocation	Yes	No	Yes
Baseline comparability	Yes	Yes	Yes
Blind subjects	No	No	No
Blind therapists	No	No	No
Blind assessors	Yes	No	Yes
Adequate follow-up	No	Yes	No
Intention-to-treat	No	No	Yes
Between group	Yes	Yes	Yes
Point Estimates/Variability	Yes	Yes	Yes
Total Score	6/10	5/10	7/10

Overall Clinical Bottom Line: Based on the results presented in Tomas-Carus et al. (2008), Tomas-Carus et al. (2007) and Munguia-Izquierdo et al., there is moderate evidence to suggest that for middle aged women with fibromyalgia, an intervention of pool therapy results in a lower Fibromyalgia Impact Questionnaire (FIQ) score when compared to inactivity or normal recreational exercise. Overall, pool therapy appears to have some benefit for patients with fibromyalgia, as measured by the FIQ. Current evidence is limited and further research with larger sample sizes is necessary to draw further conclusions about this treatment.

Search Terms: Fibromyalgia, pool therapy, aquatic therapy, anxiety, depression, exercise

Appraised by: Sara Hieter, SPT and Sara Garfinkel, SPT

School of Physical Therapy

College of Health Professions

Pacific University

Stee1543@pacificu.edu and garf9910@pacificu.edu

Title: The Effectiveness of Warm Water Pool Therapy as Measured by the Fibromyalgia Impact Questionnaire in the Outpatient Setting of Middle-Aged Women who have Fibromyalgia

Clinical Bottom Line: There is moderate evidence to suggest that pool therapy causes statistically significant changes in physical and mental well-being in middle-aged women with fibromyalgia, as measured by the Fibromyalgia Impact Questionnaire (FIQ). According to the Minimal Clinically Important Difference for the FIQ, these results are considered clinically important. At this point, additional research utilizing larger sample sizes will also be beneficial and may allow us to have more confidence in the significance of these results.

Clinical Scenario: During the last clinical internship, we both worked at clinics who specialized in warm water aquatic therapy. We saw many patients with fibromyalgia who felt that this treatment was very beneficial. We are interested in determining whether this intervention is useful for this patient population. We will be looking specifically at middle-aged women, as this is the population most frequently affected by this disease. The outcome measures we will examine are the Fibromyalgia Impact Questionnaire (FIQ).

Clinical Question PICO:

Population – Patients who have Fibromyalgia

Intervention – Warm water pool therapy

Comparison – Inactivity or land-based exercise

Outcome – Fibromyalgia Impact Questionnaire

Search Terms: Fibromyalgia, pool therapy, aquatic therapy, anxiety, depression, exercise

Appraised By: Sara Garfinkel and Sara Hieter, 15 January 2012

Full article reference: Tomas-Carus, P., Gusi, N., Hakkinen, A., Hakkinen, K., Leal, A., & Ortega-Alonso, A. 8 months of physical training in warm water improves physical and

mental health in women with fibromyalgia: A randomized control trial. *J Rehabil Med.* 2008; 40, 248-252.

Article Pico

Population: 33 female subjects age 37-71 who have fibromyalgia

Intervention: Warm water pool therapy

Comparison: Inactivity

Outcomes: FIQ, State-Trait Anxiety Inventory score (STAI), physical fitness as measured by maximal oxygen uptake, hand-grip strength, 10 step stair climbing (weightless), 10 step stair climbing (10 kg weight), 10 m maximal walking speed, sit-and-reach test and balance (single leg balance test with eyes closed).

Blinding: The researchers in this study were blinded. There was no blinding of patients or therapists. This does not appear to be a threat to the validity of this study.

Controls: There was a comparison group and a treatment group, but no placebo group in this study. The control group was inactive, performing no form of exercise. The treatment group received warm water pool therapy.

Randomization: The authors state that the patients were randomly assigned to either the treatment or control group, but the randomization methods were not discussed in the article. The randomization appears to be successful due to the baseline similarities of the two groups in every analyzed category except affected side.

Study:

Study losses: The authors report a loss of five subjects prior to beginning the study due to the attendance at other therapies. Two additional subjects were lost from the treatment group due to failure to attend 95% of the treatment sessions. One subject was lost from the control group due to failure to attend measurement sessions.

Procedure: This study was a randomized prospective study that evaluated the effectiveness of warm water pool therapy in improving physical and mental health in women fibromyalgia. Inclusion criteria were diagnosis of fibromyalgia as specified by the American

College of Rheumatology. Exclusion criteria were history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, severe psychiatric illnesses, diseases that prevent physical loading, pregnancy, attendance at another psychological or physical therapy, or regular physical exercise with more than one exercise session of 30 minutes per week during a two week period in the last five years.

Thirty subjects were included in this study. Fifteen subjects were assigned to the treatment group and 15 were assigned to the control group. The control group therapy consisted of continuation of daily activities, not including any form of physical exercise.

Subjects in the treatment group received therapy three days a week for eight months. Each therapy session included one hour of therapy in a waist-high pool of warm water. Sessions consisted of 10 minutes of warm-up including slow walking, 10 minutes of aerobic exercise (60-65% of maximal heart rate), 20 minutes of mobility and lower extremity strengthening with water resistance and upper extremity strengthening without water resistance, 10 minutes of aerobic exercise (60-65% of maximal heart rate) and 10 minutes of cool down. Sessions were directed by a therapy instructor.

Outcome measures: The outcomes measures included in this study are the FIQ, STAI and physical fitness. The FIQ measures physical function, feeling bad, pain, fatigue, morning tiredness, stiffness, anxiety and depression using a 20 item questionnaire. The STAI measures anxiety using a 20 item questionnaire. Physical fitness was measured by maximal oxygen uptake, hand-grip strength, 10 step stair climbing (weight-less), 10 step stair climbing (10 kg weight), 10 m maximal walking speed, sit-and-reach test and balance (single leg balance test with eyes closed). The reliability of these measures was not reported. The authors did not discuss the threshold for Minimal Clinically Important Difference (MCID).

Summary of internal validity:

We identified four minor threats to validity and one major threat; therefore this study would be categorized as having fair internal validity. Although the authors state that the study was randomized, the specific randomization process was not discussed and therefore cannot be analyzed for validity; this can be considered a minor threat. Although blinding of therapists and patients did not occur in this study, it would have been very difficult considering that patients and therapists would be aware whether or not the patient was receiving the treatment. However,

a Hawthorne effect may have occurred. Therefore, is also a minor threat to the internal validity. Additionally, the outcome measures were not validated within this study. Therefore, the lack of validation in this study is a minor threat to internal validity. The other minor threat is some failure to control for differences between subjects. Finally, although subjects were excluded if they participated in a regular exercise program, activities categorized as exercise are not defined. Therefore, it is possible that some subjects were participating in some form other form of exercise, which may have jeopardized the results of the study.

The major threat to internal validity that I identified is the small sample size. This causes the study to lack power and likely causes the statistics to lack strength. Based on the results of the statistical testing, it is possible that if a larger sample size had been used for this study, more confidence could be felt with the results.

Evidence:

Table 1: Evidence Based Statistics

	Baseline	8 months	Change Score	Percent change (%)
Control Group	63+/-13	65+/-10	2	3.2
Treatment Group	61+/-12	52+/-16	-9	14.7

Table 2: P value and Confidence Intervals based on Change Scores

P value	0.017
95% Confidence Interval	(-18, -5)

Table 1 presents evidence based statistics that were calculated by the authors of the study. Mean values for baseline and control groups were presented in the study and we extrapolated the change score and percent change values. The P value was presented as 0.017, which is a statistically significant change between baseline and eight months. Despite the p value showing significance in the data, the 95% confidence is fairly large (-18,-5), causing us to lack some confidence in the results. The authors do not include an Intent to Treat analysis, however, we did

not feel that these statistics were necessary, as the authors explain the causes for all of the study losses.

We calculated the Percent Change in order to determine whether these results were clinically relevant based on the Minimal Clinically Important Difference (MCID). According to Bennett et al. the MCID for the FIQ is 14%. We found that the percent change for the treatment group was 14.7%, which means that these results are clinically important.

Applicability of study results:

Similarity to my patients: The subjects in this study are a good representation of the patients I am treating, but represent a wider age distribution.

Benefits vs. Costs: Because this type of treatment utilizes a warm water pool, it is necessary that therapists have access to this type of pool. It may be necessary to rent a pool for therapy if a clinic does not have a pool at their facility. This could end up being quite expensive; therefore it is necessary to examine reimbursement for this category of therapy to determine whether it is cost effective.

This program spanned eight months with three sessions a week of supervised therapy. This is a significant portion of time and may not be realistic in an outpatient orthopedic setting. With fee-for-service insurance, this therapy program may not be financially feasible for many patients.

There are no adverse effects associated with this treatment and based on the results of this study, this treatment has a statistically significant effect on FIQ scores. Because this is a fairly simple treatment and subjects tend to enjoy their time in the pool, we feel that this treatment is very beneficial, despite some lack of confidence in the results. We believe that if subjects had any gains in their FIQ scores, this treatment would be valuable, due to the nature of fibromyalgia. In our experiences, any treatment that alleviates pain in a chronic pain condition should be considered in their treatment.

Feasibility of treatment: Due to the wide availability of warm water pools at health clubs, aquatic centers and retirement centers, this treatment is very feasible. With the availability of a warm water pool, the treatment is feasible for both patients and therapists because it does not require any more time than a land based treatment session. Due to limited insurance coverage, to accomplish a long-term treatment program it will be necessary for patients to learn a self-

directed program to complete outside of sessions with follow-ups with a therapist as needed to progress. Additional quality research is necessary to determine the true effectiveness of this treatment.

Summary of external validity: The internal validity of this study does not appear to compromise the ability to generalize the results of this study. The subject sample is very similar to the patients that we treated in our clinics, therefore based on this and our risk-benefit analysis, we feel comfortable applying the results to our patients. With more research into this therapy, we feel that the results of this study could be extrapolated to most middle-aged women with fibromyalgia.

Title: The Effectiveness of Warm Water Pool Therapy as Measured by the Fibromyalgia Impact Questionnaire in the Outpatient Setting of Middle-Aged Women who have Fibromyalgia

Clinical Bottom Line: There is not strong evidence to suggest that pool therapy causes statistically significant changes in physical and mental well-being in middle-aged women with fibromyalgia, as measured by the Fibromyalgia Impact Questionnaire (FIQ). However, according to the Minimal Clinically Important Difference for the FIQ, these results could be considered clinically important. At this point, additional research utilizing larger sample sizes will also be beneficial and may allow us to have more confidence in the significance of these results.

Clinical Scenario: During the last clinical internship, we both worked at clinics who specialized in warm water aquatic therapy. We saw many patients with fibromyalgia who felt that this treatment was very beneficial. We are interested in determining whether this intervention is useful for this patient population. We will be looking specifically at middle-aged women, as this is the population most frequently affected by this disease. The outcome measures we will examine is the Fibromyalgia Impact Questionnaire (FIQ).

Clinical Question PICO:

Population – Patients who have Fibromyalgia

Intervention – Warm water pool therapy

Comparison – Inactivity or land-based exercise

Outcome – Fibromyalgia Impact Questionnaire

Search Terms: Fibromyalgia, pool therapy, aquatic therapy, anxiety, depression, exercise

Appraised By: Sara Garfinkel and Sara Hieter, 15 January 2012

Full article reference: Tomas-Carus, P., Hakkinen, A., Gusi, N., Leal A., Hakkinen, K., Ortego-Alonso, A. Aquatic Training and Detraining on Fitness and Quality of Life in Fibromyalgia. *Med Sci Sports Exerc.* 2007; 39(7), 1044-1050.

Article Pico

Population: Thirty-four female subjects with fibromyalgia

Intervention: Warm water pool therapy training and subsequent detraining

Comparison: Inactivity (instructed not to change daily activities)

Outcomes: Fibromyalgia Impact Questionnaire (FIQ), SF-36 (physical function, role of physical problems, body pain, general health perception, vitality, social function, role of emotional problems, mental health), physical fitness (maximal oxygen uptake, hand grip strength, climbing 10 steps without added weight, climbing 10 stairs with 10 kg, 10m walking speed, sit and reach, balance)

Blinding: The blinding in this research was not discussed by the authors of this study. We can hypothesize that subjects and therapists were not blinded due to the nature of this treatment. We do not know whether the researchers were blinded, however, this does not appear to be a threat to the validity of this study.

Controls: There was one control group and one treatment group in this study. The control group consisted of 17 subjects with fibromyalgia. The control group was instructed not to change their physical activity habits.

Randomization: The authors state that the patients were randomly assigned to either the treatment or control group, but the randomization methods were not discussed in the article. The randomization appears to be successful due to the baseline similarities of the two groups in every analyzed category except affected side.

Study:

Study losses: The authors report that one subject was lost from the treatment group following the beginning of the therapy program. This loss was attributed to a personal accident and had no relation to the therapy program.

Procedure: This study was a randomized prospective study that evaluated the effectiveness of warm water pool therapy in improving physical and mental health in women with fibromyalgia. Inclusion criteria were women who fulfilled the American College of Rheumatology classification criteria for a diagnosis of Fibromyalgia and experienced axial

skeleton pain. Exclusion criteria were history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, severe psychiatric illness, any patients that have diseases preventing physical loading and pregnancy. Subjects were also excluded if they were attending psychological or physical therapy or had a history of one intensive exercise session of 30 minutes during a two week period in the last five years.

Thirty-four subjects with fibromyalgia were included in this study. Seventeen subjects were assigned to the therapy group and 17 were assigned to the fibromyalgia control group. The control group's therapy consisted of maintaining normal daily physical activities. The treatment group attended therapy sessions for 12 weeks and then participated in a detraining program for 12 weeks.

The treatment group therapy consisted of warm water pool therapy. The pool therapy program consisted of 10 minutes of slow walking as a warm up, 10 minutes of aerobic exercise (65-75% maximal heart rate), 20 minutes of overall mobility and strengthening and 10 minutes of aerobic exercise (65-75% maximal heart rate) and 10 low intensity cool down exercises. Subjects in the treatment group received therapy three days a week for 12 weeks.

Outcome measures: Fibromyalgia Impact Questionnaire (FIQ), SF-36 (physical function, role of physical problems, body pain, general health perception, vitality, social function, role of emotional problems, mental health), physical fitness (maximal oxygen uptake, hand grip strength, climbing 10 stairs without weight, climbing 10 stairs with 10 kg, 10m walking speed, sit and reach, balance). The reliability of most measures was reported to be satisfactory. The authors did not discuss the threshold for Minimal Clinically Important Difference (MCID).

Summary of internal validity:

We identified two minor threats to validity and one major threat; therefore this study would be characterized as having fair internal validity. Although patients and therapists were not blinded in this study, it would have been very difficult considering that patients and therapists would be aware whether or not the patient was receiving the treatment. The lack of blinding may have led to a Hawthorne effect occurring. Therefore, the lack of patient and therapist blinding is also a minor threat to the internal validity. The other minor threat is some failure to control for differences between subjects. Although subjects were excluded if they participated in a regular exercise program, activities categorized as exercise are not defined. Therefore, it is possible that

some subjects were participating in some form other form of exercise, which may have jeopardized the results of the study.

The major threat to internal validity that we identified is the small sample size. This causes the study to lack power and likely causes the statistics to lack strength. Based on the results of the statistical testing, it is possible that if a larger sample size had been used for this study, a statistically significant difference could have been observed in the results.

Evidence:

Table 1: Evidence Based Statistics

	Baseline	12 weeks	Change Score	Percent change (%)
Control Group	59+/-16	60+/-17	1	1.7
Treatment Group	63+/-20	52+/-19	-11	17.5

Table 2: P value and Confidence Intervals based on Change Scores

P value	0.197
95% Confidence Interval	(-19,-4)

Table 1 presents evidence based statistics that were calculated by the authors. Means for the treatment and control groups at baseline and 12 weeks were reported in the study. From these data we extrapolated the change scores for each group. The p-value was reported as 0.197 which is not a statistically significant change. These data also have a fairly large confidence interval, which would not allow us to feel comfortable generalizing these results, had significance been shown. The authors do not include an Intent to Treat analysis, however, we did not feel that these statistics were necessary, as the authors explain the causes for all of the study losses.

We calculated the Percent Change of the FIQ scores in order to examine these data from a clinical relevancy perspective. According to Bennett et al. the Minimal Clinically Important Difference for the FIQ is a 14% change. Although the results of this study were shown not be statistically significant, according to the MCID, the 17.5% change in the FIQ scores of the

treatment group can be considered clinically important. However, this difference may be due to chance because the original results of the study are not statistically significant.

Applicability of study results:

Similarity to my patients: The subjects in this study are a good representation of the patients I am treating, but represent a wider age distribution.

Benefits vs. Costs: Because this type of treatment utilizes a warm water pool, it is necessary that therapists have access to this type of pool. It may be necessary to rent out a pool for therapy if a clinic does not have a pool at their facility. This could end up being quite expensive; therefore it is necessary to examine reimbursement for this category of therapy to determine whether it is cost effective.

This program spanned 12 weeks with three sessions a week of supervised therapy. This is a significant portion of time and may not be realistic in an outpatient orthopedic setting. With fee-for-service insurance, this therapy program may not be financially feasible for many patients.

Based on the results of this study, this treatment does not have a statistically significant effect on Fibromyalgia symptoms as measured by the FIQ. However, because there was a clinically important percent change in the FIQ scores, we believe that this treatment is beneficial for patients. In addition, this treatment is comfortable, safe and enjoyable for patients. There are no adverse effects associated with this treatment.

Feasibility of treatment: Due to the wide availability of warm water pools at health clubs, aquatic centers and retirement centers, this treatment is very feasible. With the availability of a warm water pool, the treatment is feasible for both patients and therapists because it does not require any more time than a land based treatment session. Due to limited insurance coverage, to accomplish a long-term treatment program it will be necessary for patients to learn a self-directed program with follow-ups with a therapist as needed to progress. Additional quality research is necessary to determine the true effectiveness of this treatment.

Summary of external validity: The internal validity of this study does not appear to compromise the ability to generalize the results of this study. The subject sample is very similar to the patients that we treated in our clinics, therefore based on this and our risk-benefit analysis,

we feel comfortable applying the results to our patients. With more research into this therapy, we feel that the results of this study could be extrapolated to most middle-aged women with fibromyalgia.

Title: The Effectiveness of Warm Water Pool Therapy as Measured by the Fibromyalgia Impact Questionnaire in the Outpatient Setting for Middle-Aged Women with Fibromyalgia

Clinical Bottom Line: There is not strong evidence to suggest that pool therapy causes statistically significant changes in physical and mental well-being, as measured by the Fibromyalgia Impact Questionnaire (FIQ). We believe that due to subjects' use of medications during the trial, the change in FIQ scores may not have been an accurate representation of the effects of aquatic therapy. At this point, additional research utilizing larger sample sizes will be beneficial.

Clinical Scenario: During our last clinical internships, we both worked at clinics that specialized in warm water aquatic therapy. We saw many patients with fibromyalgia who felt that this treatment was very beneficial. We are interested in determining whether this intervention is useful for this patient population. We will be looking specifically at middle-aged women, as this is the population most frequently affected by this disease. The outcome measure we will examine is the Fibromyalgia Impact Questionnaire (FIQ).

Clinical Question PICO:

Population – Middle-aged women with fibromyalgia

Intervention – Warm water pool therapy

Comparison – Inactivity

Outcome – Fibromyalgia Impact Questionnaire (FIQ)

Search Terms: Fibromyalgia, pool therapy, aquatic therapy, anxiety, depression, exercise

Appraised By: Sara Garfinkel and Sara Hieter, 15 January 2012

Full article reference: Munguia-Izquierdo, D., Legaz-Arrese, A. Assessment of the effects of aquatic therapy on global symptomology in patients with fibromyalgia syndrome: a randomized control trial. *Arch Phys Med Rehabil.* 2008;89:2250-2257.

Article Pico

Population: Fifty-three female patients, aged 18-60 years old, with fibromyalgia and 25 healthy subjects

Intervention: Warm water pool therapy

Comparison: Inactivity (instructed not to change daily activities)

Outcomes: Tender point counts (syringe calibrated), Fibromyalgia Impact Questionnaire (FIQ), sleep quality (measured by Pittsburgh Sleep Quality Index), physical (endurance strength to low loads test), psychological (measured by State-Trait Anxiety Inventory (STAI)), cognitive function (measured by paced auditory serial addition task), adherence 12 months after completion of the study.

Blinding: There was no blinding of patients or therapists, however the researchers in this study were blinded. This does not appear to be a threat to the validity of this study.

Controls: There were two control groups and a treatment group in this study. The control groups consisted of one group with fibromyalgia and one group of healthy subjects. Both control groups were instructed not to change their physical activity habits.

Randomization: The authors state that the subjects with fibromyalgia were randomly assigned to either the treatment or control group using a computer randomization program. Results of the randomization process were unknown until subjects agreed to participate in the study. The randomization appears to be successful due to the baseline similarities of the two groups.

Study:

Study losses: The authors report that six subjects were lost from the treatment group following the beginning of the therapy program. Two of these subjects were lost due to dropping out during the trial, three were lost due to failure to attend 75% of trial sessions and one was lost due to failure to attend the assessment session. One subject was lost from the fibromyalgia control group due to failure to attend the assessment session. No subjects were lost from the healthy control group.

Procedure: This study was a randomized prospective study that evaluated the effectiveness of warm water pool therapy in improving physical and mental health in women with fibromyalgia. Inclusion criteria were women aged 18-60 years old who fulfilled the American College of Rheumatology classification criteria for a diagnosis of fibromyalgia. Exclusion criteria were history of morbid obesity, known cardiopulmonary diseases, endocrine or allergic disturbances (uncontrolled), severe trauma, frequent migraines, inflammatory rheumatic diseases, severe psychiatric illnesses, diseases that prevent physical loading, pregnancy, attending other types of physical or psychological therapy or subjects with a history of regular physical activity more strenuous than slow paced walking a maximum of two times per week over four months.

Fifty-three subjects with fibromyalgia and 25 healthy subjects were included in this study. Twenty-nine subjects were assigned to the therapy group, 24 were assigned to the fibromyalgia control group and 25 were assigned to the healthy subject control group. The control groups' therapy consisted of maintaining normal daily physical activities. The treatment group attended therapy sessions for 16 weeks.

The treatment group therapy consisted of warm water pool therapy. The pool therapy program consisted of 10 minutes of slow walking as a warm up, 10-20 minutes of strengthening exercises, 20-30 minutes of aerobic exercise at 50-80% of their maximal heart rate and 10 minutes of low intensity and relaxation cool down exercises. Subjects in the treatment group received therapy three days a week for 16 weeks.

Outcome measures: Tender point counts (syringe calibrated), Fibromyalgia Impact Questionnaire (FIQ), sleep quality (measured by Pittsburgh Sleep Quality Index), physical (endurance strength to low loads test), psychological (measured by State-Trait Anxiety Inventory (STAI)), cognitive function (measured by paced auditory serial addition task), adherence 12 months after completion of the study. The authors reported that the reliability and validity of the FIQ as an outcome measure was adequate. The authors did not discuss the threshold for Minimal Clinically Important Difference (MCID).

Summary of internal validity:

We identified one minor threat to validity and two major threats; therefore we would categorize this study as having fair internal validity. Although patients and therapists were not blinded in this study, it would have been very difficult considering that patients and therapists would be aware whether or not the patient was receiving the treatment. However, a Hawthorne effect may have occurred. Therefore, the lack of patient and therapist blinding is a minor threat to the internal validity.

The two major threats to internal validity that we identified are the small sample size and the potential differences between groups that are not controlled for. The small sample size causes the study to lack power and likely causes the statistics to lack strength. Based on the results of the statistical testing, it is possible that if a larger sample size had been used for this study, a statistically significant change in FIQ score may have been observed. In this study all subjects were allowed to continue daily activities, medications and visits to medical professionals. We believe that this issue, specifically the continuation of medications, may have affected the validity of this study. If subjects were allowed to continue their normal medications, some of the change observed may have been due to the medications or pain may have been underreported due to dulling effects from the medications.

Evidence:

Table 1: Evidence Based Statistics

	Baseline	16 weeks	Change Score	95% Confidence Interval	Percent change (%)
Control Group	63.6+/-16.7	62.7	-0.9	(-4.8 to 2.9)	1.4
Treatment Group	68.2+/-13.4	63.1	-5.1	(-8.9 to 1.3)	7.4

Table 1 presents evidence based statistics that were calculated by the authors. Change scores were presented in the article and the 16 week scores were extrapolated from that data. The P value of the difference between change scores for the control and treatment groups was reported as 0.122, which is not a statistically significant change. These data also have large confidence intervals, which do not allow us to feel confident in the results had they shown statistical

significance. The authors do include an Intent to Treat analysis, however, we did not feel that it was necessary to use these data, as the reasons for all study losses were explained by the authors. We also calculated the Percent Change in order to determine whether these results were clinically relevant based on the Minimal Clinically Important Difference (MCID). According to Bennett et al. in order to be considered clinically relevant, the data must show a change of 14% or more. A change of this magnitude was not observed in this study, therefore the results are not considered clinically important.

Applicability of study results:

Similarity to my patients: The subjects in this study are a good representation of the patients we are treating, but represent a wider age distribution.

Benefits vs. Costs: Because this type of treatment utilizes a warm water pool, therapists are required to have access to this type of pool. It may be necessary to rent out a pool for therapy if a clinic does not have a pool at their facility. This could end up being expensive; therefore it is necessary to examine reimbursement for this category of therapy to determine whether it is cost effective.

There are no reported adverse effects associated with this treatment. Many subjects did show improvements with this treatment, although they were not statistically significant. Therefore, for those subjects who did have improvements in their scores, this might be a beneficial treatment especially because this is a chronic pain condition.

Based on the results of this study, this treatment does not have a statistically significant effect on FIQ scores. However, we hypothesize that with a larger sample size statistically significant improvements may have been observed.

Feasibility of treatment: Due to the wide availability of warm water pools at health clubs, aquatic centers and retirement centers, this treatment is very feasible. With the availability of a warm water pool, the treatment is feasible for both patients and therapists because it does not require any more time than a land based treatment session. Due to limited insurance coverage, to accomplish a long-term treatment program it will be necessary for patients to learn a self-directed program to complete outside of sessions with follow-ups with a therapist as needed to progress. Additional quality research is necessary to determine the true effectiveness of this treatment.

Summary of external validity: The internal validity of this study does not appear to compromise the ability to generalize the results of this study. The subject sample is very similar to the patients that we treated in our clinics, therefore based on this and our risk-benefit analysis, we would feel comfortable applying the results to our patients if the change in FIQ scores had been statistically significant.

Synthesis/Discussion

The purpose of this study was to determine whether Pool Therapy was more effective than inactivity, land-based strength training or aerobic training at improving Fibromyalgia Impact Questionnaire scores. After reviewing the literature we found that Pool Therapy has been shown to be moderately effective, however, we do not feel that we were able to definitively answer our question. There is limited research in this area of study and it was difficult to find any consistency in comparison groups. Because we were not able to find land-based or aerobic exercise protocols that were similar enough to directly compare, therefore, we chose to focus only on inactivity as a comparison.

All of the studies chosen shared similar methodological quality. Common threats that were observed in each of our articles were small sample size, lack of blinding and failure to control for potential differences between patients within the study. We did not feel that blinding was a significant threat, as it would be difficult to blind subjects to this treatment. Overall, we found that according to the available literature, Pool Therapy is a moderately effective treatment for Fibromyalgia. More research is necessary with larger sample sizes and improvement in methods controlling differences between patients.

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