ABSTRACT

THE EFFECTS OF WHOLE-BODY VIBRATION AND
STRENGTHENING EXECISES FOR FEMALES
WITH FIBROMYALGIA SYNDROME:
A META-ANALYSIS

Objective: The purpose of this meta-analysis was to compare the effectiveness of Whole-Body Vibration (WBV) and strengthening exercises to strengthening exercises or to a multimodal approach of exercises for females between the ages of 50-70 years old with Fibromyalgia Syndrome (FMS).

Methods: Studies analyzing WBV and strengthening exercises were compared to studies analyzing strengthening exercises or a multimodal approach. The studies were analyzed to determine treatment effect size and homogeneity.

Results: Two studies were included in this meta-analysis. For the primary analysis, a small effect size was found favoring WBV and strengthening exercises versus strengthening exercises or a multimodal approach. Similarly, for the secondary analysis that assessed the short-term effect of these 2 treatments, a small effect size was found favoring WBV and strengthening exercises versus strengthening exercises or a multimodal approach.

Conclusion: Within this meta-analysis, the findings reveal that females with FMS will benefit from participating in WBV and strengthening exercises in improving patients' health status when compared to strengthening exercises or a multimodal approach of exercises.

Study Design: A meta-analysis observing the effects of WBV and strengthening exercises versus strengthening exercises or a multimodal approach of exercises in females with FMS.

Samantha Justine Fong
May 2019

THE EFFECTS OF WHOLE-BODY VIBRATION AND STRENGTHENING EXECISES FOR FEMALES WITH FIBROMYALGIA SYNDROME: A META-ANALYSIS

by

Samantha Justine Fong

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For the Department of Physical Therapy:

We, the undersigned, certify that the project of the following student meets the required standards of scholarship, format, and style of the university and the student's graduate degree program for the awarding of the doctoral degree.

Samantha Justine Fong
Project Author

Jennifer Adame-Walker (Chair) Physical Therapy

Jason McOmber Physical Therapy

For the University Graduate Committee:

Dean, Division of Graduate Studies

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BACKGROUND

Fibromyalgia Syndrome

Fibromyalgia Syndrome (FMS) is the second most common chronic condition after osteoarthritis diagnosed by rheumatologists, and estimated to affect over 4 million adults in the United States (U.S.).[1,2,3] According to the U.S. government statistics, 90% of FMS cases are reported in females compared to males.[1] Many studies have shown that FMS usually develops between ages 30-50 years old or after 50 years old with symptoms being more severe in females in comparison to males.[1,2]

Since FMS is predominant in females, female hormones are believed to play a role in the higher incidence rates and in the severity of the disorder.[1,4] While estrogen is an important hormone in females for sexual and reproductive development, it also acts as a protective barrier against pain.[4] Many females complain that fibromyalgia pain is worse just before and during their menstrual cycle. This may be due to hormone fluctuations, as estrogen is shown to decrease right before menstruation and increases again after a female's cycle is complete.[4] Additionally, symptoms are worse for menopausal and postmenopausal females than for females that are still menstruating because of the decreased production of estrogen.[4]

Fibromyalgia Syndrome can result in severe disability and loss of function, making daily tasks challenging and unmanageable.[1,2,5] Not only are these debilitating effects seen in the community and in the home, but they also affect work performance. Decreased ability to function on the job decreases productivity and increases work absenteeism.[5] Adults with FMS miss an average of almost 17 days of work annually compared to 6 days for those without this syndrome.

Contributing factors to poor job performance and missed days at work are correlated to fatigue, inability to concentrate, decreased motivation, and low self-efficacy in the FMS population.[5]

Etiology

The etiology of FMS is not fully understood; however, there are noteworthy factors that seem to trigger this syndrome. One of the main theories to explain FMS is that it relates to abnormal pain messages.[6] Normally, when tissue injury occurs, the nerve endings are responsible for sending pain signals to the spinal cord and to other areas of the brain, such as the medulla, thalamus, and cortex. Once the signal reaches these areas of the brain, the nerve cell responsible for transmitting the signal to the brain is responsible to decrease or amplify the pain signal.[6]

Usually, the brain has the ability to modulate some of these pain messages by sending inhibitory signals down the spinal cord to decrease the upward transmission of the pain signals.[6] However, patients with FMS have developed changes in the way the central nervous system (CNS) processes the pain messages carried throughout the body. In patients with FMS, the dorsal horn neurons become hyperresponsive to nociceptive and nonnociceptive somatic stimulation.[6] This is known as central sensitization, which is characterized by an exaggerated pain response, prolonged duration of pain, and increased pain intensity. This results in patients experiencing hyperalgesia and allodynia.[6]

The second theory is related to chemical imbalances.[6,7] Individuals with FMS have abnormally low levels of serotonin, noradrenaline, and dopamine in their brains. Abnormally low levels of these hormones may be a key factor in the

cause of FMS, as they are important in regulating appetite, behavior, mood, sleep, and response to stressful situations.[6,7]

The third theory is a genetic predisposition which is likely to be a contributing factor to this syndrome.[6] Specific genes that are frequently involved in patients affected by FMS are the serotonin transporter (5-HTT), dopamine receptor, and catechol-O-methyltransferase (COMT). Altered serotonin metabolism and dopamine function in patients with FMS result in them experiencing higher levels of depression, anxiety, and psychological distress. The involvement of COMT has shown to affect the metabolism of catecholamines on the modulation of responses to sustained pain and other stressful stimuli in patients with FMS.[8]

Lastly, the literature has shown that FMS can also be triggered by physical or psychological stress, such as an injury, viruses, vaccinations, infections, or undergoing an operation.[6,7] These conditions can lead to dysregulation of the body's stress system, which is known as the hypothalamic-pituitary-adrenal (HPA) axis. Due to this dysfunction, FMS is likely to develop as a result of abnormal levels of the stress hormone cortisol.[9]

Clinical Presentation and Diagnosis

Individuals with FMS present with chronic widespread musculoskeletal pain, deconditioned muscles, stiffness, fatigue, sleep disturbances, and psychological dysfunctions.[10] The pain that FMS patients experience is generally widespread involving both sides of the body located at the neck, upper back, chest, shoulder, arms, and buttock.[10] Additionally, these individuals experience tender points, defined as localized tender areas throughout the body that cause widespread pain and muscular spasming when palpated. This multifaceted

syndrome has a considerable impact on these patients' daily activities, work capacity, and overall quality of life (QOL).[10,11]

Aside from patient's description of symptoms, they are also diagnosed according to the American College of Rheumatology (ACR) criteria.[11] Originally, in 1990, the ACR criteria included chronic widespread pain throughout the axial skeleton bilaterally, cranially, and caudally for at least 3 months in duration with tenderness at 11 or more of 18 specified sites.[11,12,13] The location of the 18 tender points is presented in Table 1. In 2010, the ACR revised this criterion, eliminating the need to assess tender points. Instead, the criteria required a detailed interview to evaluate the total body using the Widespread Pain Index (WPI) and the Symptoms Severity (SS) scale. In order to be diagnosed with FMS, patients had to either score ≥7 on the WPI and ≥5 on the SS scale or score 3 to 6 on the WPI and ≥9 on the SS scale.[10,11] Additionally, the patient must have experienced symptoms at a similar level for 3 months or longer and not have any other condition that would explain the pain.[2,11,12] Currently, there is not a cure for FMS, but there are various treatments available to control and improve patients' symptoms to increase their overall QOL.

Traditional Modes of Exercise

Due to the numerous symptoms of FMS, patients are usually treated using a combination of approaches, including medications, cognitive behavioral therapy (CBT), and exercise.[12] Busch et al. demonstrate how regular exercise is one of the cornerstones of FMS management.[12] Although studies differ with regard to the most effective type of exercise, as well as its degree of impact on fibromyalgia symptoms, the majority of the research suggests a therapeutically beneficial relationship between fibromyalgia and strength training.[14,15]

Initially, strengthening exercises were overlooked in the initial treatment for FMS as it was thought that this approach would exacerbate patients' symptoms and cause muscle damage.[15]Also, deconditioned muscles were thought to increase this populations' vulnerability to microtrauma during daily exposure to mechanical strain related to posture or physical activity.[15] However, current research has suggested that strength training may slow the cycle of deconditioning and encourage FMS patients to participate in daily activities and prevent them from injuring themselves.[15,16] Other benefits of strength training include decreased cortisol response to stress, decreased anxiety, depression, and sleep disturbances.[16] Strength training also increases pain thresholds immediately after 1 bout of resistance exercise in healthy individuals.

Kingsley et al. found that females with FMS who participated in a 12-week progressive training program made significant improvement in strength without experiencing episodes of exacerbations or muscle damage.[15] Similarly, in a systematic review, females with FMS who participated in a strengthening program for 16 to 21 weeks demonstrated increased progress in their overall well-being, physical function, pain level, tenderness, and muscular strength.[16] Due to the various benefits of strength training, this mode of exercise is beneficial for individuals with FMS.[16]

While strengthening exercises are an effective intervention in treating patients with FMS, the benefits of land-based aerobic exercise in combination with strengthening and stretching also appear effective in reducing FMS symptoms and improving physical function.[17] Because FMS encompasses many factors, research has begun to focus on the benefits of treating this population with a multimodal treatment approach that contains multiple modes of exercises.[18] For example, a 6-week exercise program involving aerobic exercise, strengthening, and flexibility

was superior to a relaxation program in improving FMS patients' tender point score and aerobic fitness.[19] Similarly, another study found that a 6-month exercise program comprised of aerobic training, strengthening, and flexibility, was more effective when compared to the control group that continued normal activity on improving their overall functional health status.[19]

Although exercising has many therapeutic effects in treating patients with FMS, some individuals become intolerant to exercise, resulting in poor adherence to home exercise programs.[14,20] This concern is of interest to many researchers and may be resolved once researchers have determined the most effective type of exercise, intensity, duration, and frequency when treating patients with FMS.[14,15,18] Recently, researchers have begun to explore the effects of a wide range of exercise techniques that extend beyond the conventional exercise training modes, such as strength training, aerobic exercise, and flexibility. One of the newly applied exercise interventions to treat patients with FMS is Whole-body Vibration (WBV).[8,21,22]

Whole-Body Vibration

Whole-body Vibration is a mode of exercise recently utilized for its positive effects on pain and balance as well as on the neural, muscular, and skeletal systems in various patient populations.[23-27] Whole-body Vibration is a low impact training that is easy to apply to untrained and older people with low levels of fitness.[23,10] This intervention is a forced mechanical oscillation where energy is transferred from the vibration device to the human body. The vibration signals activate the sensory receptors, involving the muscle spindles, which results in a tonic vibration reflex.[24,25]

This tonic vibration reflex is characterized by a transfer of vibrations to the muscular tendon system which is accompanied by repetitive muscle spindle stretches, resulting in benefits for improving muscular strength, flexibility, pain, bone density, and balance.[24,25] Research indicates that different parts of the body have a natural frequency at which they resonate, and for the lower extremity, the frequency ranges between 10 to 50 Hertz (Hz).[26] While setting an optimal vibration frequency appears to be highly individualized and varies within the literature, the studies showing positive muscle training effects used frequencies between 20 to 45 Hz.[26] A vibration frequency below 20 Hz induces muscular relaxation, whereas frequencies greater than or equal to 50 Hz causes severe muscle soreness.[10,26]

Studies show that females with FMS have significantly lower isometric and isokinetic strength in the quadriceps femoris than healthy individuals, suggesting that there is a defect in neural activity in muscles of FMS patients.[27] This decrease in knee extensor strength in patients with FMS has been associated with pain, gait disorders, and may also contribute to balance problems.[27] While balance problems are the sixth most frequent symptom present in patients with FMS, (affecting about 45% of patients), these balance issues make FMS patients more likely to experience increased risk of falling.[27] Therefore, possible explanations for the effectiveness of WBV on muscle function in patients with FMS include increased motor unit synchronization, co-contraction of synergistic muscles, and increased inhibition of antagonistic muscles in response to the repetitive vibration.[27]

Additionally, the literature has presented the benefits of WBV in increasing flexibility. Because the vibration platform involves mechanical stretching, this enables the machine to reduce the stiffness of tendons, intramuscular connective tissue, and possibly other passive skeletal structures, allowing joints to gain

extensible range of motion and flexibility.[28] While the literature has revealed that there are strengthening and flexibility benefits of WBV, there has been minimal evidence regarding sufficient aerobic benefits with this device. In community-dwelling adults, it was found that oxygen uptake and heart rate slightly increased while performing squats on a vibration platform. Considering that the relative stress induced by the WBV on the cardiorespiratory system might be increased in the community-dwelling population, this device might also be sufficient in producing changes in cardiorespiratory fitness in other patient populations in the long term.[29]

The literature has also demonstrated that WBV has been used to reduce chronic pain in patients, including patients with FMS. Parraca et al. found that patients with FMS demonstrated decreased pain after participating in WBV exercises, whereas patients who participated in exercises alone did not.[27] Because WBV training is low impact training, it is an appealing method to apply in decreasing FMS patients' pain and soreness. Since people with chronic muscle pain tend to avoid exercise or anything that exacerbates their pain, they often experience muscle atrophy or wasting away of the muscle.[30] WBV training stimulates the muscles and prevents atrophy in the safest possible way for people with this condition. While the mechanism of this device's ability to reduce pain is undefined, the literature has discussed possible reasons. One possible explanation involves the Gate Control Theory.[30] This theory suggests that activation of mechanoreceptors and A-β (beta) fibers competes with central and peripheral nociceptive activity at the dorsal horn of the spinal cord and results in reduction of second order nociceptive activity, which subsequently reduces pain perception in a manner similar to transcutaneous electrical nerve stimulation (TENS).[14,30] Another

possible explanation is that vibrations activate skin somatic receptors, thus masking pressure and touch processes.[26]

A randomized control trial (RCT) comparing WBV with strengthening exercises to no treatment was conducted in female subjects with FMS.[29] The strengthening exercises performed on the vibration platform consisted of static squats maintained at a 45-degree angle in a tandem stance. The results supported WBV with strengthening exercises in improving the subjects' health status measured by the Fibromyalgia Impact Questionnaire (FIQ).[31] The FIQ is frequently used in clinical and research settings.[32] It is an instrument designed to quantitate the overall impact of FMS over many dimensions, such as function, pain level, fatigue, sleep disturbances, and psychological distress.[7] Even though the mechanism as to why WBV presents with positive outcomes in the FMS population is unclear, the findings suggest that including this intervention while performing strengthening exercises may be beneficial.

Hypothesis and Purpose

Based on the current literature, common interventions that are effective in improving the health status of FMS patients include strength training, aerobic exercise, stretching, and WBV with strengthening exercises. In this meta-analysis, operational definitions include: strengthening exercises consisted of static and dynamic squats that are performed on the vibration platform or alone. A multimodal treatment will include aerobic, strengthening, and flexibility exercises. While current research shows that both of these interventions are effective, there is inconclusive evidence in determining which one is more beneficial. Therefore, the current problem is that no meta-analysis exists that compares WBV with strengthening exercises to strength training alone or to a multimodal approach in

determining which is more advantageous for individuals with FMS. The purpose of this meta-analysis is to focus on the effects of WBV with strengthening exercises versus strengthening exercises alone or a multimodal approach of exercises in females with FMS as assessed by the FIQ. The hypothesis is that WBV with strengthening exercises will improve patients' health status when compared to strengthening exercises alone or to a multimodal approach in females with FMS, between ages of 50 and 70 years old, as measured by the FIQ. The stated null hypothesis is that there will be no statistical significance when comparing WBV with strengthening exercises to strengthening exercises alone or to a multimodal approach of exercises in females with FMS, measured by the patients' health status on the FIQ.

METHODS

Search Criteria

The study design was developed to follow PRISMA standards and guidelines. The following databases were used for this meta-analysis: U.S. National Library of Medicine National Institutes of Health (PubMed), ScienceDirect, and EBSCO Plus. EBSCO Plus was utilized to search the following databases: CINAHL, Cochrane Central Register of Controlled Trials, and Academic Search Ultimate. Keywords and mesh words used in this search included "Whole body Vibration," "Whole body Vibration and Fibromyalgia," "Fibromyalgia and physical therapy," "Fibromyalgia and strengthening exercises," "Fibromyalgia and exercises," and "Fibromyalgia." A manual search of previous systematic reviews and meta-analyses was also conducted. The search was limited to RCT published in peer-reviewed journals from 2004 to 2017 in the English language. The search was held within the limits of the inclusion and exclusion criteria.

Inclusion and Exclusion Criteria

The inclusion criteria were females ages 50-70 years old, participants who are diagnosed with FMS according to the American College of Rheumatology Criteria (1990, 2010), WBV treatment with strengthening exercises, participants participated in strengthening exercises, participants participated in a multimodal approach of exercises, participants participated in an exercise training session prior to intervention, and FIQ for an outcome measure. Studies were excluded if participants were diagnosed with an inflammatory rheumatic disorder, infectious diseases, cardiovascular or respiratory diseases, presence of recent fractures, psychiatric disorders, or subjects who were performing structured physical activity

for at least 2 days a week or had psychological therapy during the 6 months prior to the study.

Outcome Measure

The outcome measure used in this meta-analysis was the FIQ. It is a self-administered outcome measure that is frequently used to measure FMS patients' status, progress, and outcomes.[31] This outcome measure was designed to measure the components of health status that are believed to be most affected by FMS. These include: physical function, work, general well-being, pain, sleep, fatigue, stiffness, anxiety, and depression. The maximum score is 100. The literature has shown that the average FMS patient scores about a 50, whereas severe patients usually score greater than 70. In a current study, the Minimal Clinically Important Difference (MCID) on the FIQ has shown to be 8.1.[33] The FIQ holds excellent internal validity (Cronbach's alpha=0.90) as well as a test-retest reliability of 0.84.[34]

Assessment of Study Quality

All studies used in the statistical analysis portion of this meta-analysis were scored using the 11-item PEDro scale. The PEDro scale was developed to evaluate the quality of RCT in determining the internal and external validity when evaluating physical therapy interventions.[35] The specific criterion of the PEDro scale is to help in identifying the risk of bias in each study.[35] This scale is based on 11 criteria. Each satisfied criterion is awarded 1 point to the total of the PEDro score. However, the first criterion is not included as part of the PEDro score due to its external validity threat. A PEDro score of 6 to 10 reflects a low risk of bias; a score of 4 to 5 reflects moderate risk of bias, and a score of 3 or lower reflects a

high risk of bias.[36] Each of the studies used in this meta-analysis were evaluated with the PEDro scale for quality and risk of bias.

Statistical Analysis

All data used in this meta-analysis were from the results sections of each study with provided tables and graphs. The data extracted from each study consisted of the means, standard deviations (SD), and sample sizes for FIQ in subjects with FMS. For one study, the means and SD were calculated through an online data generator from the raw data provided by the author of the article via email. These subjects either participated in WBV with strengthening exercises or performed strengthening exercises or a multimodal approach of exercises alone. The means and SD were used to determine effect sizes and 95% confidence intervals (CI) between groups for the FIQ. To compare the effects of each group, a sub analysis of time was implemented. Therefore, the results from 6 weeks, 3 months, and 6 months from the studies were compiled and used in this meta-analysis to compare each group.

The Q value was used to determine the homogeneity or heterogeneity of the combined studies. A Q value higher than the degrees of freedom (DF) and a p value less than an alpha level of 0.05, indicated that the studies were heterogeneous. Conversely, a Q value lower than the DF and a p value higher than an alpha level of 0.05, indicated that the studies were homogeneous. Effect sizes were used to measure the treatment effect of the pooled studies. For this study, the following effect sizes were used: small effect ≥0.2, medium effect ≥0.5, and large effect ≥0.8.[37] Effect sizes and 95% CI were provided in Figure 2 and Figure 3 on forest plots for between groups for the stated outcome measure.

RESULTS

Study Selection

The initial database search produced 99 articles; however, during the identification process, after reviewing the titles and abstracts, a total of 34 studies were appropriate for an in-depth review to determine eligibility for inclusion in the meta-analysis. During the initial screening, 20 studies were excluded because they were not experimental studies, did not include the appropriate population, and the control groups did not consist of physical therapy exercises. Following the second screening, 12 studies were excluded due to duplicates of articles, no intervention group, and insufficient statistical information leaving 2 studies for qualitative synthesis. See Figure 1 for the study selection consort. For individual study characteristics included in this meta-analysis, see Table 3. Alev et al.[22] and Sanudo et al.[10] were compared at short-term follow up and long-term follow-up for health status measured by the FIQ.

Characteristics of Included Studies

The quality of each study was assessed by 1 evaluator using the PEDro scale and critical appraisal sheets. For the studies included, the most commonly unsatisfied criteria included concealed allocation, blinding of subjects, blinding of therapists, and intention to treat. The PEDro scale and scores are presented in Table 2. PEDro scores must be considered to interpret the implications of this meta-analysis.

Two studies were included in this meta-analysis.[10,22] One study examined the effects of WBV and strengthening exercises as compared to strengthening exercises alone.[21] The other study investigated the effects of WBV and strengthening exercises in comparison to a multimodal approach of exercises.[10]

Both studies measured each subject's health status using the FIQ. The characteristics of the studies varied and are summarized in Table 3.

The main differences between the 2 studies included differences in baseline data, duration of treatment, variation of WBV parameters, variation in WBV dosing, a supplementary exercise session for one of the intervention groups, and time of collection for post-test data.[10,22] For the WBV groups, the type of strengthening exercises varied. The strengthening exercises included a variety of static and dynamic bilateral and single leg squats at various knee angles. The knee angles ranged from 90 to 130 degrees.[10,22] Additionally, the duration of each study ranged from 4 to 6 weeks.

Furthermore, post-test data was collected at various times frames for both of the studies. These time frames were at 6 weeks, 3 months, and 6 months. One of the studies reported statistically significant results in the intervention group compared to the control group at 6 months of the FIQ.[22] In comparison, both groups in the second study demonstrated significant improvements in FIQ scores at 6 weeks from baseline.[10]

Data Analysis

The hypothesis of this meta-analysis was that WBV with strengthening exercises would improve patients' health status when compared to strengthening exercises alone or to a multimodal approach in females with FMS, between ages of 50 and 70 years old, as measured by the FIQ. This analysis favors the hypothesis with a small effect size (-0.31). The null hypothesis stating that there will be no statistical significance when comparing WBV with strengthening exercises to strengthening exercises alone or to a multimodal approach of

exercises in females with FMS, measured by the patients' health status on the FIQ is rejected.

Primary Analysis: FIQ Between Group Comparison

The data indicated that the grand effect size of the between group comparison of the intervention group was small (-0.31). The grand ES did cross zero, therefore indicating that the intervention may not have had a significant effect on the participants in the studies. [ES (95% CI) = -0.31 (-0.89, 0.28) p = 0.600, Q = 0.274] (see Figure 2). A low Q value of 0.274 associated with a high p value of 0.600 indicated that the studies were homogeneous. This data are illustrated in a forest plot in Figure 2.

Secondary Analysis: Short-Term Effect of FIQ

When comparing the short-term effect of the FIQ between groups at 6 weeks and 3 months, the results still yielded a small effect size (-0.22). The grand effect size did cross 0, indicating that the intervention may not have had a significant effect on the participants in the studies. [ES (95% CI) = -0.22 (-0.80, 0.36) p = 0.397, Q = 0.717] (see Figure 3). A low Q value of 0.717 associated with a high p value of 0.397 indicated that the studies were homogeneous. This data are illustrated in a forest plot in Figure 3.

DISCUSSION

The purpose of this meta-analysis was to compare the effectiveness of WBV and strengthening exercises versus strengthening exercises alone or to a multimodal approach of exercises in females with FMS, aged 50 to 70 years old. The meta-analysis confirmed the stated hypothesis that WBV and strengthening exercises would show improved health status in females with FMS as seen by a small effect size on the FIQ. While evidence does support benefits of both interventions, no meta-analysis exists attempting to determine the more superior treatment for the FMS population. This meta-analysis aims to provide that information.

This discussion will evaluate the primary meta-analysis results relative to the PICO for females with FMS. A secondary analysis was included to assess the short-term effects of the intervention in relation to the FIQ. The measured variable was patients' health status based on the FIQ. This discussion will examine the limitations of the 2 studies used in this meta-analysis and identify the gaps in FMS research that remain unaddressed. Additionally, implications from this meta-analysis will be discussed with respect to clinical relevance in the context of treating patients with FMS.

Review of Meta-Analysis Results

This meta-analysis demonstrated that WBV combined with strengthening exercises has a small effect in improving patients' health status in females with FMS. The primary analysis supports the alternate hypothesis that females with FMS between ages 50 to 70 years old will increase their health status after a WBV and strengthening training treatment when compared to strengthening alone or to a multimodal approach. This analysis had a small effect size and was homogenous,

indicating that the intervention had a small effect on the patients and that there were similarities between the 2 studies. The secondary analysis, which assessed the effects of the intervention at short-term, also had a small effect size and was homogenous. This sub-analysis was important because it demonstrated how WBV and strengthening exercise is effective in improving patients' health status if used as an intervention for at least 6 weeks. Therefore, the results from both analyses indicate a small effect size and homogeneity between the 2 studies. Even though the results from both analyses favored the intervention with a small effect size and were homogenous, there were still various validity threats and limitations present within the studies.

Lack of Evidence for Meta-Analysis

Due to the lack of research to fulfill the PICO criterion, there was a limited amount of studies included in this meta-analysis. A total of 2 randomized studies were included in this meta-analysis. Since this meta-analysis included minimal evidence, the findings should be assessed cautiously, as this is not a valid representation for this given population. Additional research is warranted that encompasses the characteristics of this current PICO question in order to identify more conclusive and reliable evidence when treating the FMS population.

Limitations from Studies

The 2 meta-analyzed studies were assessed with respect to the variable of patients' health status. They were assessed for validity threats and limitations. The major limitations from the studies include the following: results in PEDro scores, difference in baseline data of participants, small sample sizes, duration of studies, variation in collection of post-treatment data, variation in dosing, variation in parameter of the intervention, differences within the conventional exercises, and

procedural difference between the intervention groups. These limitations will be discussed in detail in the following sections.

One source of a potential validity threat is the results of the PEDro scores from the 2 studies included in this meta-analysis. For one of the studies,[22] the PEDro score was 5, which is indicative of a moderate risk of bias. The second study[10] had a PEDro score of 7, which is indicative of a low risk of bias. The moderate risk of bias from one of the studies is a source of a validity threat that must be considered. The 2 studies lacked blinding of participants, blinding of the therapist administering the interventions, and concealed allocation. The lack of blinding influences the participant's performance and the researcher's judgement throughout the studies.

Also, because the participants were not randomly allocated into each group, the decision about whether or not to include a person in a study could be influenced by knowledge of whether the subject was to receive treatment or not.[38] In one of the studies,[22] the participants mean values in the intervention and control group started at different baselines in relation to the FIQ. The intervention group (WBV and strengthening) began with a mean value of 52.4, whereas the control group began with a mean value of 58.7. Due to the lack of concealed allocation in this study, participants with lower baseline scores on the FIQ may have been purposely placed in the intervention group. This variation in data between the 2 groups may have increased the risk of bias since the groups were not given the same opportunity to start at similar baselines, affecting the outcome of each treatment.

Additionally, because the participants in this study[22] started at different baseline values in the intervention and control group, this also poses an internal validity threat. A study examining the MCID in the FIQ found that an 8.1 change

in the outcome measure score is clinically significant.[33] At baseline for this study,[22] the intervention and control group started at an approximately 6-point difference, which is close to the MCID change. Compared to the significant difference in scores at baseline, the total change from baseline to post-test scores either demonstrated a significantly small improvement or lack of improvement from the treatments. Additionally, the difference represented by the effect size was much less than the MCID, making the results from this study inconclusive and unreliable. Even though the analysis of this study favored the intervention with a small effect size, it is difficult to interpret this data to be valid because the baseline scores were not considered for the analysis.

Not only does this study pose an internal validity threat with different baseline scores, but it also presents a statistical validity threat.[21] Because the original means and SD were not provided in this study, this information was calculated through an online data generator from the raw data provided by the author of the article via email. This process may have also resulted in risk of error, leading to a validity threat in this analysis and uncertainty when interpreting the results.

The small sample sizes among the 2 studies may present as another possible source of validity threat. Between the 2 studies involved in this meta-analysis, the intervention group (WBV and strengthening) had a total of 24 participants and the control group (strength training or multimodal approach) had a total of 22 participants. In one of the studies, there was 1 participant who dropped out in the intervention group and 3 participants who dropped out in the control group.[10] The reasons for dropping out included illness, work commitments, and injury.[10] Given that FMS is estimated to affect over 4 million adults in the United States, the findings from the meta-analysis should be taken cautiously, as this is not a valid

representation for this given population. This is one of the reasons why further research is warranted for the FMS population, which will be discussed later in the section.

Another potential source leading to a validity threat is the duration of each study between the intervention and control groups. For one of the studies, the intervention and control group underwent a 4-week treatment duration. Whereas, the second study was a 6-week treatment duration. Therefore, the treatment duration between groups might lead to risk of bias since the groups are not given the same opportunity to improve. Additionally, the long-term effects of WBV and strengthening exercises versus strength training alone was examined at 3 months and 6 months in only one of the studies. There was no additional post-test measurements in the second study, which examined WBV and strengthening exercises versus a multimodal approach of exercise. Therefore, it is unclear whether these 2 treatments have a significant long-term effect in improving patients' health status.

Another limitation is the variation in dosing and exercise procedures between the 2 studies. The difference in dosing refers to the amount of sets, repetitions, and holds for each mode of exercise. In one of the studies,[22] the intervention and control group had similar dosing protocols, which entailed performing 6 different kinds of isometric and dynamic strengthening exercises 2 times a week for 6 repetitions and 30 seconds each. The only difference involved performing the exercises with or without vibration. However, in the second study,[10] the intervention and control group participated in the same exercise training session 2 times per week for approximately 1 hour. The modes of exercises included aerobic (4-6 intervals of 2-3 minutes), flexibility (8-9 exercises; 1 set, 3 repetitions, 30 second hold), and strengthening exercises (8 exercises, 1

set, 8-10 repetitions with 1-3 kg). Due to the lack of detail in this study,[10] it is inconclusive as far as the specific exercises that these participants performed in this class. In addition to this exercise training session, the intervention group also participated in WBV and strengthening exercises 3 times a week. The strengthening exercises on the vibration platform consisted of isometric bilateral and unilateral squats with variation in dosing. Isometric bilateral squats were performed for 3 sets with 45 second holds, whereas isometric unilateral squats were performed for 4 sets with 15 second holds. Having different dosing and exercise procedures between the 2 studies may confound the results of the meta-analysis because one form of training might be more effective than the other.

The variation in parameters for the intervention group is another potential source leading to a validity threat in this meta-analysis. Currently, there is a variety of WBV platform settings (i.e., vibration mode, frequency, amplitude, and exposure duration) that have been used in the literature and the controversial findings may explain the inexistence of specific training standards for this device.[10,21-23,25] Alev et al. demonstrated that frequencies lower than 20 Hz may evoke muscular relaxation and frequencies greater than or equal to 50 Hz may cause muscle soreness and unpleasant sensations. In one of the studies in this analysis, the set parameters for the vibratory platform consisted of a frequency of 30 Hz and an amplitude of 2 mm.[22] The parameters for the second study consisted of a frequency of 20 Hz and an amplitude of 2-3 mm.[10] Due to the different parameters for the vibration device, the results from this meta-analysis must be interpreted cautiously, as 1 set parameter may have been more advantageous over the other.

Side Effects of Whole-Body Vibration

While there are many therapeutic effects of using WBV, there are also potential minor side effects that have been recognized in the literature. The most common side effects appear to be transient itching, erythema of the lower limbs, lower extremity edema, and muscle soreness.[38] These symptoms have shown to resolve within the first 3 to 10 WBV training sessions with no harmful effects to the body. From a study in 2004, Crewther et al. found that 17 untrained adults experienced itching of the lower limbs, hot sensation in the lower extremity, nausea, cramping, calf pain, as well as low back and hip discomfort.[39] These subjects were exposed to WBV at varying frequencies (10 Hz, 20 Hz, and 30 Hz), amplitudes (1.25 mm, 3 mm, and 5.25 mm), and performed static squatting exercises (standing double leg, standing single leg, and semi squat). It was observed that these side effects most commonly occurred at 30 Hz, which was the highest frequency.[39] Additionally, Cronin et al. observed that untrained adult subjects experienced jaw, neck, and lower extremity pain following 5 minutes of WBV with a frequency of 26 Hz and an amplitude of 6 mm.[39] Their pain subsided 7 to 10 days following treatment.

From both of these studies, it was concluded that the high frequency, high amplitude, and high acceleration forces associated with the WBV resulted in the subjects experiencing adverse side effects. Another possible explanation for these side effects in both of these studies may be related to their position on the vibration platform. Because the subjects stood on 1 leg with the knee slightly flexed, this small knee angle may have reduced the ability to lessen the vibration, leading to an increase in the transmission of vibration to the upper body.[39] Given that there are potential minor side effects related to WBV, the application of this

intervention should be used with caution at high frequency, high amplitude, and high acceleration forces among populations more susceptible to injury.

Cost Benefit Analysis of Whole-Body Vibration

In addition to the potential side effects that can arise from using WBV, this intervention presents other barriers to clinical use, such as limited portability and high cost. This exercise intervention can cost up to $12,000.[40] In comparison, conventional exercise training modes, such as strength training, aerobic exercise, and stretching are cost effective with the price dependent upon the consumers choice in equipment. Moreover, these modes of exercise are easily portable. Given the cost analysis of WBV, consumers have the option to purchase this device and practice this intervention as a supplement to other conventional exercises.

Clinical Implications

Based on this meta-analysis, the implications for clinical practice suggest that WBV with strengthening exercises can be a more effective treatment for females with FMS when compared to strengthening exercises alone or to a multimodal approach of exercises. Specifically, in this meta-analysis, physical therapists adhering to a WBV and strengthening exercise treatment can improve patients' health status with a small effect size.

Even though WBV with strengthening exercises was found to be more effective than strengthening exercises alone or to a multimodal approach of exercises, the results should be interpreted with caution. Caution is noted due to the limited number of studies presented in this meta-analysis, various sources of validity threats, and the gaps that currently exist in the FMS research. Additionally, more consistent, methodologically designed studies that yield high PEDro scores and do not encompass validity threats are needed to make more

concrete decisions on effectiveness of treatments. Despite the minimal effectiveness that WBV and strengthening exercises showed over strengthening alone and to a multimodal approach of exercises, it is important to realize that the interventions used in the comparison group have also proven to be effective at improving patients' health status in individuals with FMS. Therefore, strengthening exercises or a multimodal approach should not be completely disregarded as consideration in the treatment of FMS.

Implications for Research

Future studies should focus on involving a larger sample size and including participants with similar baseline characteristics. This will provide a smaller margin of error and less of an internal validity threat for FMS research. Additionally, future studies should control for procedural characteristics between each group, such as the duration of the study, dosing, parameters for WBV, and the type of exercise performed in each group. Again, this will help in having less internal validity threats and ensure similarity within the research. Although, FMS has shown to predominantly affect females compared to males, it may be worthwhile for future studies to include a variation in gender when assessing the effects of these treatments. Lastly, it may be valuable for future research to examine the long-term effects of WBV with strengthening exercises and observe how patients' health status is affected.

Conclusion

From the studies included in this meta-analysis, it can be concluded that WBV with strengthening exercises is effective at improving patients' health status in individuals with FMS when compared to strengthening or to a multimodal approach of exercises with a small effect size. In regard to the short-term effects,

patients adhering to this intervention can improve their health status, especially after 6 weeks of treatment. These findings are true for females with FMS, however, more consistent research needs to be implemented in order to make strong conclusions about the effectiveness of WBV and strengthening versus strengthening or to a multimodal approach of exercises with a variation in females and males. Despite the various internal validity threats and gaps in the current literature, the studies used in this meta-analysis support WBV and strengthening exercise as an effective intervention for the treatment of FMS.

Nonetheless, strengthening and a multimodal approach of exercises should continue to be used in the treatment of FMS due to the positive effects for improving patients' health status. As multiple types of exercise have demonstrated to provide significant health benefits to those with FMS, it is more important for this population to remain physically active, regardless of which mode of exercise they choose to participate.[41] Most importantly, as clinicians, it is our role to help individuals with FMS in gaining self-efficacy and encouraging them to participate in physical activity, in hopes that it will improve their overall QOL.[41]

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TABLES

Table 1. The American College of Rheumatology Tender Point Criteria

Pain in 11 of 18 tender point sites on palpation
1. **Occipital**: bilateral, at the suboccipital muscle insertions 2. **Low cervical**: bilateral, at the anterior aspects of the intertransverse spaces at C5-C7 3. **Trapezius**: bilateral, at the mid-point of the upper border. 4. **Supraspinatus**: bilateral, at origins, above the scapula spine near the medial border. 5. **Second rib**: bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces. 6. **Lateral epicondyle**: bilateral, 2 cm distal to the epicondyles. 7. **Gluteal**: bilateral, in upper outer quadrants of buttocks in anterior fold of muscle. 8. **Greater trochanter**: bilateral, posterior to the trochanteric prominence. 9. **Knee**: bilateral, at the medial fat pad proximal to the joint line.

Table 2. Methodological Quality Using PEDro Score

PEDro Criteria	**Alev, 2017**	**Sanudo, 2010**
Eligibility criteria were specified	1	1
Random allocation of subjects	1	1
Allocation was concealed		
Similar groups at baseline	1	1
Subjects blinded		
Therapists administering treatment blinded		
Assessors blinded	1	1
One key outcome obtained from 85% of subjects initially allocated to groups		1
'Intention to treat' used for analysis of one key outcome		
Between-group statistics for one key outcome reported		1
Point measures and measures of variability for one key outcome	1	1
Total	**5/10**	**7/10**

Table 3. Summary of Study Characteristics

Study	Design	Sample Size (n)	Mean Age	Intervention and Control Group	Length of Study	Outcome Measure
Alev et al. 2010	Level 1 RCT	**WBV & strengthening exercises** = 10 **Strengthening exercises (CG)** = 10	**WBV group** = 56.2 ± 3.2 **Control group** = 58.1 ± 2.3	**WBV group**: static and dynamic squats on WBV for 4 weeks, 2x a week 30 Hz frequency and 2 mm amplitude. **Control group**: performed same exercises as WBV group without vibration on the same platform 2x a week for 4 weeks.	4 weeks	FIQ at 3 months and 6 months
Sanudo et al. 2017	Level 1 RCT	**WBV & strengthening exercises** = 14 **Multimodal exercises (CG) (aerobic, strengthening, & flexibility)** = 12	**WBV group** = 57.89 ± 6.23 **Control group** = 60.13 ± 9.42	**WBV group**: bilateral and unilateral static squats on WBV for 6 weeks, 3x a week 20 Hz frequency and 2 mm amplitude. **Control group**: performed a multimodal approach of exercises included aerobic, strengthening, and flexibility 2x a week for 6 weeks.	6 weeks	FIQ at 6 weeks

Table 4. Results: Effect Size of Patients' Health Status Comparing WBV and Strengthening Exercises to Strengthening Exercises or a Multimodal Approach Without Respect to Time

STUDY		
Alev, 2017 WBV and Strengthening vs Strengthening	ES	-0.13
	CI LOWER	-1.01
	CI UPPER	0.75
Sanudo, 2010 WBV and Strengthening vs Multimodal Approach	ES	-0.44
	CI LOWER	-1.22
	CI UPPER	0.34
GRAND TOTAL	ES	-0.31
	CI LOWER	-0.89
	CI UPPER	0.28

Table 5. Results: Effect Size of Short-Term Effect of Patients' Health Status Comparing WBV and Strengthening Exercises to Strengthening Exercises or a Multimodal Approach with Respect to Time

STUDY		
Alev, 2017 WBV and Strengthening vs Strengthening	ES	0.06
	CI LOWER	-0.81
	CI UPPER	0.94
Sanudo, 2010 WBV and Strengthening vs Multimodal Approach	ES	-0.44
	CI LOWER	-1.22
	CI UPPER	0.34
GRAND TOTAL	ES	-0.22
	CI LOWER	-0.80
	CI UPPER	0.36

FIGURES

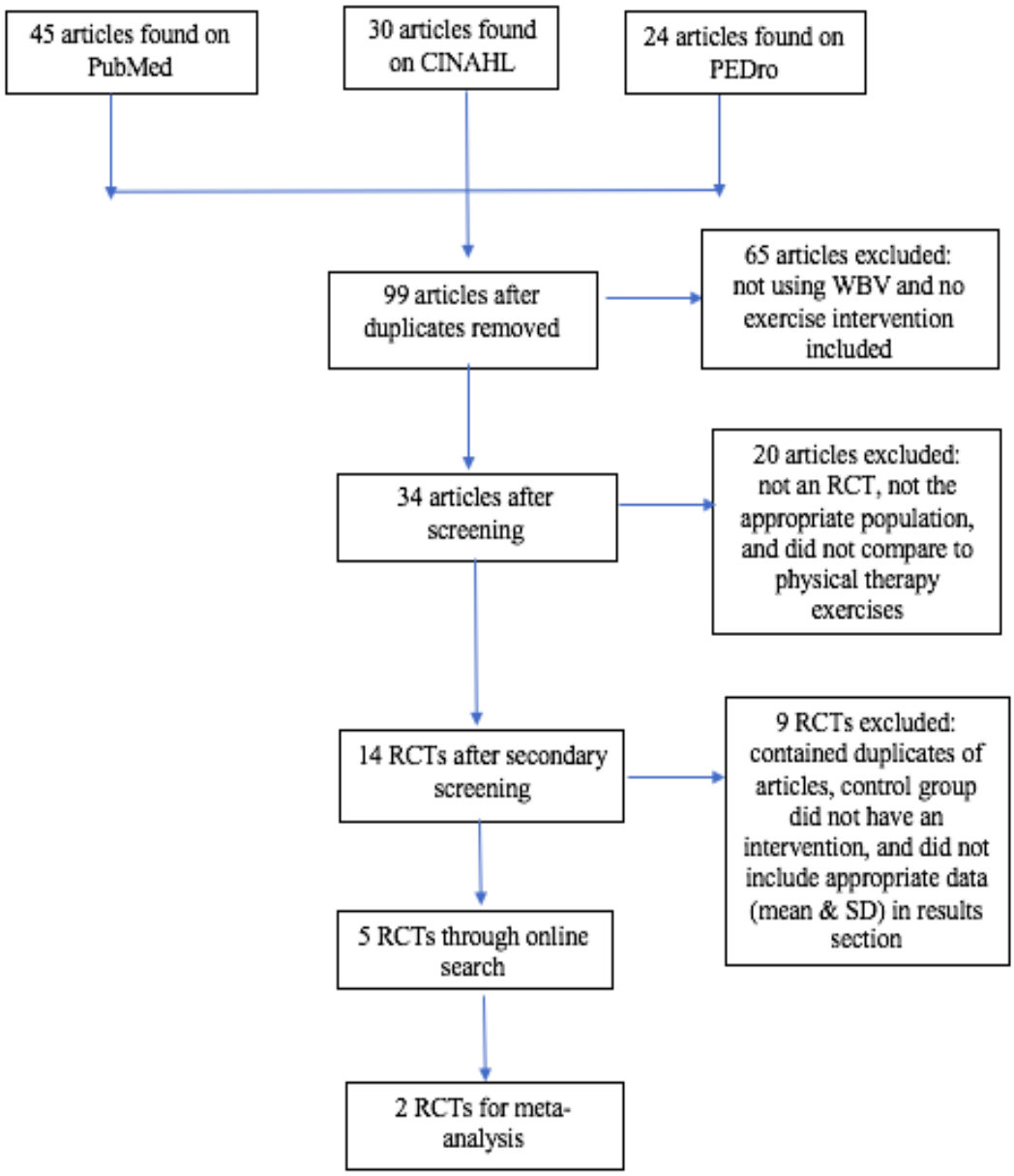

Figure 1. Consort

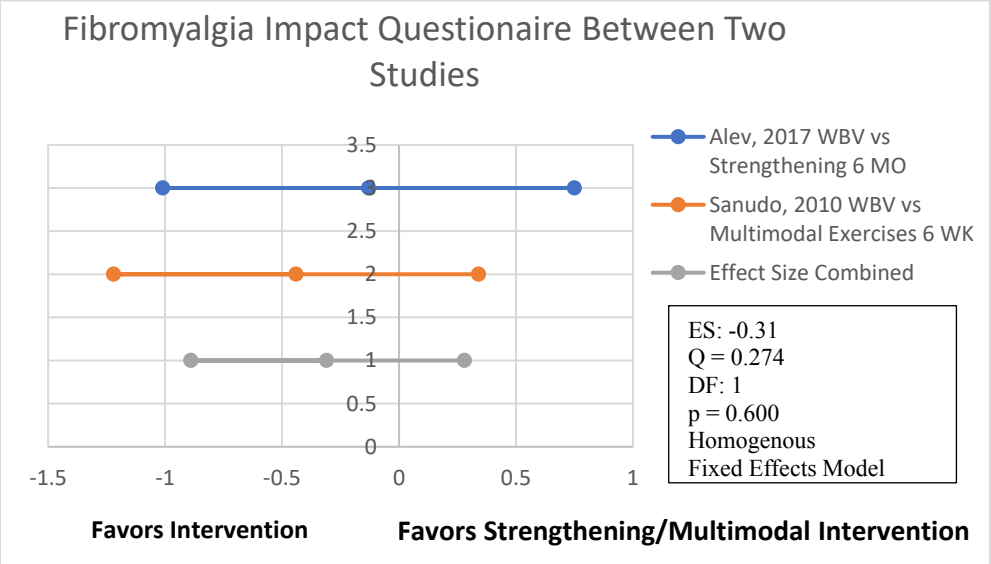

Figure 2. Effect size of WBV and strengthening exercises vs. strengthening exercises or to a multi-modal approach

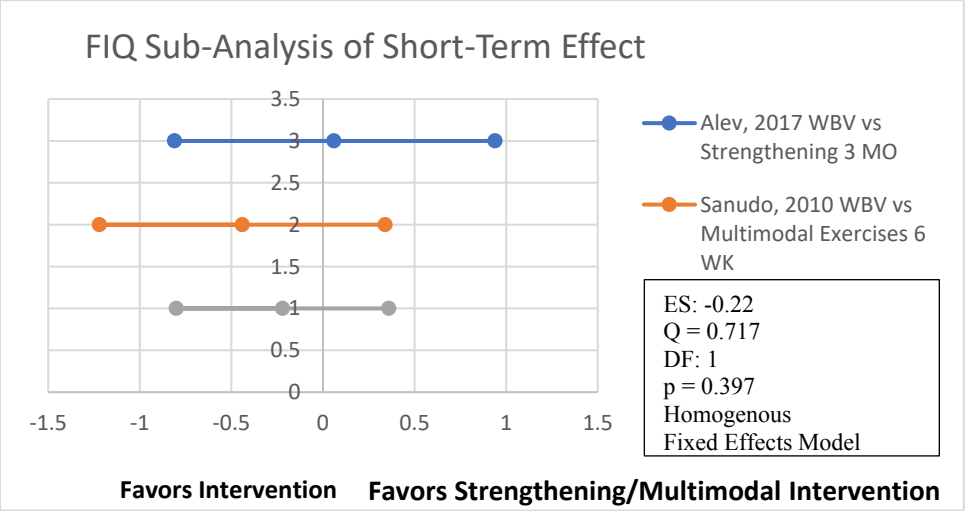

Figure 3. Effect size of short-term effect of WBV and strengthening exercises vs. strengthening exercises or to a multi-modal approach

APPENDIX: PEDRO SCALE

PEDro scale

1. eligibility criteria were specified	no ❑ yes ❑ where:
2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ❑ yes ❑ where:
3. allocation was concealed	no ❑ yes ❑ where:
4. the groups were similar at baseline regarding the most important prognostic indicators	no ❑ yes ❑ where:
5. there was blinding of all subjects	no ❑ yes ❑ where:
6. there was blinding of all therapists who administered the therapy	no ❑ yes ❑ where:
7. there was blinding of all assessors who measured at least one key outcome	no ❑ yes ❑ where:
8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ❑ where:
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ❑ yes ❑ where:
10. the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ❑ where:
11. the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ❑ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999

Notes on administration of the PEDro scale:

All criteria	**Points are only awarded when a criterion is clearly satisfied**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.