ABSTRACT

THE ADDITIONAL EFFECT ORTHOTICS ON PAIN AND FUNCTION ON PATIENTS WITH PATELLOFEMORAL PAIN SYNDROME WHO ARE PARTICIPATING IN PHYSICAL THERAPY

Background: PFPS is a chronic debilitating disorder affecting up to 25% of the general population. It affects young women at a higher rate than males and highly active individuals more than the sedentary. Previous research has been conducted comparing 2 treatments for PFPS in terms of pain and function: custom made orthotics (CMO) and PT as well as prefabricated orthotics and PT. Until now, no systematic review or meta-analysis exists comparing the 2 treatment options. The primary objective of this study is to perform a systematic review (where possible) of the evidence for physical therapies and orthotics in the treatment of PFPS.

Methods: A search strategy was devised for eligible studies using the following databases: Medline, PEDro, CINAHL, and Cochrane. Search terms included custom, prefabricated, over-the-counter, orthotics, orthosis, ortheses, PFPS, retro patellar pain, and anterior knee pain. Reference lists of inclusive studies were searched secondarily. Two studies were identified as suitable and were assessed for quality and risk of bias using the PEDro scale. Effect size calculation and meta-analysis were based on a fixed effect model.

Results: Meta-analysis identified moderate effects favoring physical therapy and CMO (pain VAS: standardized mean difference 0.46, 95% confidence interval 0.04 to 0.88), and a moderate effect favoring OTC over no treatment (VAS: -0.34, -0.97 to 0.28). Although there were meaningful effects, a Q variance of 7.34 with a p-value of 0.025 demonstrates heterogeneity. A meta-analysis was
unable to be conducted in reference to function due to the differences in outcome measures across studies.

**Conclusion:** No conclusive statement can be made for the use of orthotics in lieu of PT due to the heterogeneity of the data. More high quality clinical trials required testing the efficacy of the use of orthotics as an additional treatment to PT interventions. Clinicians advised to continue to use their clinical judgment to create a proper plan of care for patients with patellofemoral pain.

Owen Michael Johnston
May 2015
THE ADDITIONAL EFFECT ORTHOTICS ON PAIN AND FUNCTION ON PATIENTS WITH PATELLOFEMORAL PAIN SYNDROME WHO ARE PARTICIPATING IN PHYSICAL THERAPY

by

Owen Michael Johnston

A project
submitted in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy in the Department of Physical Therapy College of Health and Human Services California State University, Fresno

May 2015
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.

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ACKNOWLEDGMENTS

Thanks to Dr. Jenna Sawdon-Bea for being an amazing teacher and chair, Dr. Paul Ullucci (committee member) for providing such intellectual depth, and Dr. Deborah Walker (committee member) for the positive attitude. More importantly, thanks to Dr. Marcia Thompson for believing in me against all odds.
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BACKGROUND

Patellafemoral pain syndrome (PFPS) is one of the most common disorders of the knee affecting up to 25% of the general population, with a higher prevalence in adolescent females and young adult females.\(^1,2,4,9,10\) Furthermore, the incidence is highest in the population that participates in recreational and competitive running, at 25%-65%.\(^4\) Of those affected by PFPS, 94% experience symptoms for up to 4 years and 25% have persistent pain for up to 20 years.\(^6,11\)

A thorough subjective history and objective exam are required during the assessment of suspected individuals with PFPS as it is a condition diagnosed based on symptoms and presentation.\(^6\) Symptoms range from an insidious onset of uniform knee pain, to more specific, retro patellar and anterior knee pain. Symptoms may be exacerbated by ascending or descending stairs, sitting for prolonged periods, squatting, and running.\(^1,4,12-14\) Reports have demonstrated that symptoms may be accompanied with joint instability or crepitus. Objectively, range of motion of the knee is typically unaffected,\(^1,4\) however, symptoms may be provoked by 2 special tests: Clarke’s sign and Fairbank’s apprehension test. Clarke’s sign has been demonstrated in the literature to have a sensitivity that ranges from 0.29-0.49 and a specificity spectrum of 0.67-0.95.\(^41-43\) Similarly, Fairbank’s test has been shown to display a sensitivity of 0.07-0.37 and a specificity of 0.7-0.92.\(^43-45\) Despite the impact, chronicity, and prevalence of PFPS, the etiology is not fully understood.\(^6,8\)

The definitive cause of PFPS is debatable and several theories have arisen as to an exact mechanism. Misalignment of the patella on the lateral femoral condyle resulting in lateral tracking is a key area discussed in the research.\(^1-2\) A model from past literature that explains the relationship between an unaligned
patella, quadriceps force, and patellofemoral (PF) kinematics assumed that
alterations in the force balance around the knee leads to altered PF kinematics
(“patellar maltracking”), ultimately causing PF pain. The patella may be
malaligned through various musculoskeletal, neurological, and functional
compensations.

At the knee, an increase in “Q” angle and tightness in the retinacular
structures can contribute to PF pain. Clinically, the definition of Q-angle refers to
a 2 dimensional angle formed by 2 vectors extending from the anterior patella to
the anterior superior iliac spine (ASIS) and the tibial tuberosity. An accepted
type states that a Q-angle greater than 15º is indicative of increased lateral
quadriceps force and displaces the patella during dynamic activities. However,
Q-angle measurement alone has been demonstrated as unreliable and provides
minimal patellar kinematics, and therefore researchers have cautioned clinicians as
using it as a guide for rehabilitation or invasive interventions.

Another theory regarding the causative factor for PFPS deals with the
biomechanics at the hip. Previous literature has reported that excessive hip
adduction and internal rotation may cause the knee to move medially with respect
to the foot. As a result, a compensatory movement pattern of the tibia and
foot/ankle occurs, resulting in abduction and pronation respectively. Furthermore
this increased dynamic knee valgus has been linked to hip abductor weakness
potentially resulting in a Trendelenburg or “compensated” Trendelenburg sign.
Trendelendburg is defined in the literature as a contralateral hip droop during
single limb support and compensated Trendelenburg as a lateral trunk lean as a
compensatory mechanism to inhibit the hip drop in the same scenario. Both
postures are maladaptive and increase the likelihood of knee pain.
Pathomechanics of the foot have been theorized in the literature to affect the knee.\textsuperscript{1,4,15,40} Increased subtalar joint pronation of the foot and ankle complex can cause compensatory internal tibial rotation and abduction during the stance phase of gait.\textsuperscript{40} This compensation can biomechanically cause increased tibial abduction and therefore increase the likelihood of dynamic knee valgus through further adduction and internal rotation of the knee.\textsuperscript{4} In terms of pain and function, there is a mountain of evidence demonstrating that physical therapy interventions can decrease the symptoms in patients suffering with PFPS by correction of the above stated impairments.\textsuperscript{1-3,6-9,15,18-19}

Foot orthoses have been used as an adjunct to physical therapy interventions as a means of structurally correcting the unaligned patella from bottom to top, by means of inhibiting subtalar joint pronation. In theory, patellar tracking is improved, thereby decreasing anterior knee pain.\textsuperscript{19} Concurrently working from the hip to the foot by strengthening weakened muscle groups, stretching shortened tissues and/or functionally training with neuromuscular re-education has shown to be efficacious treatment for PF pain.\textsuperscript{3,5,6-7} Research has been conducted comparing the use of custom made orthotics (CMO), over-the-counter orthotics (OTC), flat inserts as sham orthotics, physical therapy, and/or a combination to treat PFPS.\textsuperscript{1,2,4-6}

Both CMO and OTC orthotics “work” either psychologically through placebo, or mechanically by altering the ground reaction forces at the interface of the orthotic.\textsuperscript{20} The literature has demonstrated that both orthotic types have a positive effect on pain and function through both mechanisms, however, the evidence is not definite. On the other hand, a recent systematic review and meta-analysis provided strong statistical evidence that individuals with PF pain have significant strength deficits in hip abduction, extension, and external rotation.
warranting PT intervention to treat these deficits. Therefore, a meta-analysis comparing prefabricated orthotics with custom orthotics in patients with PF pain participating in physical therapy is justified. The author’s hypothesis is that the patients receiving CMO will demonstrate a greater reduction in pain and an increase in function when compared to studies in which patients utilized prefabricated orthotics. The null hypothesis includes that there will be no difference between the groups receiving CMO plus PT and OTC orthotics plus PT.
METHODS

This study was developed in consultation with the PRISMA guidelines.23

Inclusion/Exclusion Criteria

Studies eligible for inclusion included randomized control trials (RTCs) or clinical control trials (CCTs) which evaluated the efficacy of the addition of orthotics to an exercise program established by a physio or physical therapist for treatment of PFPS in adolescents and young adults. For the purpose of this study, adolescents and young adults were defined as any male or female that fell into the age group of 13-40 years of age. This age group was pre-selected because population that are older than 40 are typically experiencing knee pain due to patellofemoral joint (PFJ) osteoarthritis.24 PFPS was established as unilateral anterior knee pain or retro patellar pain with an insidious onset of 6 or more weeks and where symptoms were aggravated by one of the following functional activities: sitting, running, jumping, squatting or ascending/descending stairs; diagnosis was made by a licensed healthcare or medical practitioner. Furthermore, the term foot orthotic was broken up into 2 subcategories: custom and prefabricated. Prefabricated orthotics included any shoe insert that was previously made in an industrial fashion or sold over-the-counter. Custom orthotics included a shoe insert that had some portion of custom design by a physio or physical therapist not limited to custom feet molds and/or hind foot and/or forefoot postings.

Studies were excluded from this analysis if the participants had any other musculoskeletal condition; previous surgery; history of trauma to the knee; neurological dysfunction; previous treatment such as physio/physical therapy orthotics, or use of anti-inflammatory drugs within the last year.
Identification of Studies

A comprehensive strategy was devised in order to search the following databases for studies that qualified for this meta-analysis: Medline, Physiotherapy Evidence Database (PEDro) (see Appendix), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Cochrane. The terms used for the search Medline included: custom OR prefabricated OR over-the-counter orthotics, orthosis, orthoses AND patellofemoral pain syndrome OR retro patellar pain OR anterior knee pain. The search strategy was adapted for use in the other databases individually to promote the largest number of studies as the other databases lacked in vastness. Similar to Sussmilch-Leitch et al\textsuperscript{16} a secondary searching technique utilized was reviewing the reference list of eligible studies.

Data Extraction and Analysis

One author screened titles and abstracts of all studies (OJ). If the studies seemed appropriate per judgment of the reviewer, the entire article was read for inclusion into this study. One other participant (JS) was consulted with to verify the eligibility of the selected studies. Each study was assessed by with the Physiotherapy Evidence Database (PEDro) scale, for risk of bias as it has been demonstrated to be both reliable and valid in the literature.\textsuperscript{19}

Data extraction was performed by one author (OJ) and included time, diagnostic criteria, and outcome measures for pain and function. If data was not clearly defined in the study, an electronic message was sent to the point of contact for retrieval of the missing information. Using a fixed effect model of 2 groups, a meta-analysis was performed comparing OTC orthotics and CMO in terms of the VAS after 6 weeks of treatment. A meta-analysis could not be performed for function because the studies selected utilized different functional scales and therefore a comparison would be illogical.
RESULTS

The search strategy yielded 69 total results, and the abstracts were scanned per protocol outlined in the methods. Of the 69 studies, 6 were selected for further review. Careful scanning of the references listed in the selected studies added 2 more studies that required for review leaving a total of 8. From that, 4 studies were excluded due to the nature of the inclusion criteria. Lastly, 2 studies that looked very promising were excluded for the reason that their participants had bilateral knee pain rather unilateral. Two studies were ultimately selected in order to make 4 comparisons (see Figure 1).

Looking at effect size alone, the meta-analysis demonstrated moderate effects favoring CMO plus PT when compared to OTC with PT at 6 weeks (pain VAS: standardized mean difference 0.46, 95% confidence interval 0.04 to 0.88), as well as a large difference in the effect between OTC and PT when compared to PT alone at 6 weeks (VAS: 0.69, 0.27 to 1.11). Furthermore, there was a moderate effect favoring OTC over no treatment at all at 6 weeks (VAS: -0.34, -0.97 to 0.28). Although there are meaningful effects, a relatively large Q variance of 7.34 (Q>4) with a p-value of 0.025 (p-value<0.05) demonstrates heterogeneity. An easier representation of the data is outlined in Table 1 and Figure 2.

Study Characteristics

Both studies selected were randomized control trials (6 and 18) utilized 40 or more patients and offered clear eligibility criteria for the age being 13-40.\textsuperscript{6,18} In both studies, symptoms were similar with an onset time of greater than 6 weeks and were provoked during functional activities such as running, jumping, squatting, and stair ascent/descent. Lastly, all studies gave clear exclusion criteria
including previous physical therapy within the last 3 months, previous trauma/surgery of the knee, previous use of orthotics and use of pharmaceuticals.

Each study included patients that participated in a physical therapy program and received orthotics as an additional treatment. One study\(^\text{18}\) included patients whom were given prefabricated orthoses and the control group received no treatment (wait and see policy). Collins et al.\(^\text{6}\) included clients whom participated in a PT program with flat inserts (sham orthotics), custom orthotic prescription alone, PT and CMO, and a group that received PT plus OTC.

Both studies (100%) used the VAS as a primary outcome measure and employed the global improvement scale (GIS). Next, Mills et al.\(^\text{18}\) used 2 other outcome measures: the Patient Specific Functional Scale (PSFS), and the Kujala Patellofemoral Score (KPS) and took measurements for a baseline and at 6 weeks post treatment. Whereas Collins et al\(^\text{6}\) utilized the anterior knee pain scale, and functional index questionnaire and took measurements during 6, 12, and 52 weeks of treatment. Since both studies utilized 2 different outcome measures for function, results for this factor were unable to be synthesized. Refer to Table 2 for a more detailed view of the studies characteristics.

**Risk of Bias**

Risk of bias was calculated with the with the PEDro scale (Table 3). The purpose of the Pedro scale is to aid researchers in quickly identifying which of the randomized clinical trials (i.e. Randomized Control Trials [RCTs] or Clinical Control Trials [CCTs]) used are internally and externally valid, and therefore, demonstrate sufficient statistical information to make their results understandable.\(^\text{19}\) Both studies received an 8/10 on the PEDro scale demonstrating a high degree of comparability, and a low risk of bias.
DISCUSSION

The review of literature found that there are 2 theoretical treatment options for patients with PF pain. Both involve controlling femoral internal rotation and adduction, as well as, the degree of tibial abduction during static and dynamic positions. On one side there is PT, and on the other hand, Orthotics. This study attempted to bridge the gap in order to discover if a combination of the 2 would provide evidence to a better outcome in terms of pain and function. Production of results demonstrated that CMO with PT has a greater effect size on pain when compared to prefabricated orthotics and PT, and orthotic use and PT are more effective than no treatment. However, heterogeneity of the study by Mills et al suggests high variability and inconsistencies with outcomes indicating inconclusive results compared to the homogeneity of the study by Collins et al. As previously mentioned differences presented on these trials could have adverse effects on the bias of this study.

Limitations included a paucity of high quality clinical trials combining the 2 treatments for PFPS, as well as, a lack of objective findings for the diagnosis. In fact, only 2 RCTs were discovered to abide by the inclusion/exclusion criteria. For each study reviewed, neither provided information of orthopedic special tests, manual muscle tests, knee alignment or foot and ankle measurements as a means of diagnosing the patients with PFPS. This may lead one to believe that the diagnosis of PFPS is not specific enough. Furthermore, the lack of objective measures required the author to place strict subjective criteria on the search to decrease the likelihood of error across the comparisons. Eng et al and Sultive et al reported on studies looking at combining PT and orthotics, however, patients were allowed in their studies with bilateral knee pain which may suggest possible
systemic or autoimmune origin of pain rather than musculoskeletal. Munuera et al\(^1\) implemented a study looking at the additional effect of CMO on PT in patients with PF pain, however failed to apply a control group, and therefore made the results incomparable to other studies. To complicate things further, there is a lack of standardization in orthotics.

Both studies selected utilized prefabricated orthoses constructed by ethylene-vinyl acetate making the comparison of greater significance. Furthermore, both studies used a standardized exercise program by a PT, yet failed to include what it consisted of. Collins et al\(^6\) used standard orthotics with no modifications, and the same inserts with a degree of customization that included heat molding and forefoot and rear foot postings. Mills et al\(^{18}\) included a no treatment group with a group prescribed 4 different OTC orthotics on the basis of best fit protocol used in an RCT\(^{26}\) ensuring that the medial longitudinal arch of the orthoses did not impede motion of the first metatarsal head. Mills et al\(^{18}\) implemented 4 new variables to the study of OTC which may have caused the high variability and inconsistencies of data causing the heterogeneity. Even if one could limit variability through standardization, there is a major thing that has not been researched.

During the review of literature, there was a fact discovered that would make one reconsider utilizing foot orthotics for the treatment of PFPS with orthotics. Sultive et al\(^8\) found no studies testing the validity of rear-foot alignment in subtalar joint neutral (STJN), navicular drop, relaxed calcaneal stance, and Q-angle applied to the population with PFPS. Only after reports validating a measurement tool of the foot and ankle complex can a clear definition or protocol be assimilated for CMO for patients with PF pain. However, a recent systematic review and meta-analysis\(^{22}\) validated isometric manual muscle testing of the hip in reference to
patients with PFPS. It linked the given population with weakness in hip abductors, extensors, and external rotators. This may be the reason that patients with PF pain respond well to PT as these findings would be detected during the assessment and incorporated into the patient’s plan of care.\textsuperscript{39}

This study demonstrated the requirement for more high quality RCT testing the efficacy of orthotics combined with PT before a clear decision can be made. Next, there is an absolute necessity for a meta-analysis comparing PT alone to the sole use of orthotics in the treatment of PFPS. This would test the conclusion of one of the RTCs\textsuperscript{6} used in this study that stated no significant difference in effectiveness between PT interventions and the use of orthotics alone in the treatment of PF pain. Lastly, a cost benefit analysis is required to investigate PT and orthotic use as the study\textsuperscript{6} states—without evidence—orthotics being a cheaper alternative to PT interventions ($174 for 3 CMO and $495 for 6 sessions of PT).

Clinicians should continue to assess the hip and ankle foot complex when a patient presents with knee pain, however, are cautioned with using objective measurements of the foot and ankle as there is no research validating their worth as far as treatment is concerned in patients with PFPS.

**Conclusion**

Patients with PFPS demonstrate a higher effect in terms of pain per the VAS when treated with CMO versus OTC when used as an adjunct to PT interventions. Furthermore, a greater effect was demonstrated with all forms of treatment when compared to the patients receiving no treatment at all. This conclusion is based on a meta-analysis with heterogeneity and therefore clinicians are advised to continue to use their clinical judgment to create a proper plan of
care for patients with PF pain. Future research on this topic is a requirement with a basis on long-term prevalence, functional disability and cost of treatment.
REFERENCES


39. Guide to PT practice


Table 1. Forest Plot Comparison Data

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<th>OTC</th>
<th>Description</th>
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<th>Y</th>
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<td>vs CMO Collins 2009</td>
<td>ES</td>
<td>0.46</td>
<td>4</td>
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<tr>
<td></td>
<td>CI Lower</td>
<td>0.04</td>
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</tr>
<tr>
<td></td>
<td>CI Upper</td>
<td>0.88</td>
<td>4</td>
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<tr>
<td>vs PT Collins 2009</td>
<td>ES</td>
<td>0.69</td>
<td>3</td>
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<tr>
<td></td>
<td>CI Lower</td>
<td>0.27</td>
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<td></td>
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<tr>
<td>vs no treatment Mill</td>
<td>ES</td>
<td>-0.34</td>
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<td></td>
<td>CI Lower</td>
<td>-0.97</td>
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Table 2. Participant Characteristics

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<td>46</td>
<td>45</td>
<td>20</td>
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<tr>
<td>Age (years)</td>
<td>29(6)</td>
<td>27.0(5.3)</td>
<td>30.9(5.8)</td>
<td>30.04(5.47)</td>
<td>28.5(5.89)</td>
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<td>No (%) of women</td>
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<td>25(54.3)</td>
<td>29(64.4)</td>
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<td>Weight (kg)</td>
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<td>23.9(3.5)</td>
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<td>Duration of knee pain (months)</td>
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<td>42</td>
<td>37</td>
<td>36</td>
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<td>Usual pain at 6 weeks</td>
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<td>25.4(17.4)</td>
<td>21.2(17.3)</td>
<td>22.1(13.1)</td>
<td>28.07(20.8)</td>
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Table 3. Quality Ratings Using the PEDro Scale of Reviewed Studies

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<td>no</td>
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<td>yes</td>
<td>yes</td>
<td>8</td>
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<tr>
<td>Mills 2012</td>
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<td>no</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
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<td>yes</td>
<td>yes</td>
<td>no</td>
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FIGURES
Figure 1. Flow chart of process with rationale for study selection
Figure 2. Standardized mean differences for pain following interventions with physical therapy and orthotics after 6 weeks. OTC = over-the-counter orthotics; CMO = custom made orthotics; PT = physical therapy.
APPENDIX: PEDro SCALE
**PEDro scale**

1. eligibility criteria were specified

2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)

3. allocation was concealed

4. the groups were similar at baseline regarding the most important prognostic indicators

5. there was blinding of all subjects

6. there was blinding of all therapists who administered the therapy

7. there was blinding of all assessors who measured at least one key outcome

8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups

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: no ☐ yes ☐ where:

   no ☐ yes ☐ where:

   no ☐ yes ☐ where: no ☐ yes ☐ where: no ☐ yes ☐ where:

   no ☐ yes ☐ where:

   no ☐ yes ☐ where: 10. the results of between-group statistical comparisons are reported for at least one key outcome

   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
Criterion 1 Criterion 2
Criterion 3
Criterion 4
Criteria 4, 7-11
Criterion 5-7
Criterion 8
Criterion 9
Criterion 10
Criterion 11

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.

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.

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.

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”.

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.

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.
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 (e.g., visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.

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.

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.

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.

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.
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**June 1, 2015**

Date