Clinical effect of deep water running on non-specific low back pain: A randomised trial

ABSTRACT: Objectives: To evaluate clinical effect of deep water running (DWR) on non-specific low back pain. Outcome measures were pain, disability, general health and physical fitness. Materials and methods: Experimental, randomized, controlled trial involving 46 persons with CLBP over 15 weeks with two experimental processes, each three times a week. Evidence-based Program (EBP, personalized physical exercise program, manual therapy and health education) was the common process to which was added 20 minutes of personalized intensity DWR at the aerobic threshold. Measurements were made at the beginning and end of the study of pain, disability, general health and physical fitness. Results: The pain of CLBP were homogeneous at baseline. Significant changes between group were don’t found for pain in favour of the EBP+DWR group (p<0.3). The within-group differences were highly significant for all clinical and functional variables. The effect was clinically relevant for pain in the EBP+DWR group (0.70) and in the EBP group (0.58), and for disability degree it was also relevant in the EBP+DWR group (0.48) and relevant for the EBP group (0.36). Conclusion: Significant improvement was seen in CLBP when EBP was complemented with the high-intensity exercise of DWR.

KEYWORDS: DEEP WATER RUNNING, CLINICAL EFFECT, RANDOMISED TRIAL, EVIDENCE-BASED PHYSIOTHERAPY; AQUATICS; HYDROTHERAPY.

INTRODUCTION
The recent guidelines for the management of patients with CLBP recommend supervised exercise therapy as a first-line treatment for the reduction of pain and disability (Airaksinen et al., 2006). A potential exercise modality is water. Presently there is also sufficient evidence to suggest that therapeutic active aquatic exercise is potentially beneficial to patients suffering from chronic low back pain, compared to active dry land programs (Waddle et al. 2009). Deep water running is a feasible aerobic exercise for persons with physical impairments (Burns and Lauder, 2000).

The main indication for deep water running (DWR) in the treatment of chronic non-specific low back pain (CLBP) is based on the improvement of chronic pain by activation of the hypothalamus - pituitary - adrenal (HPA) axis, gradually increasing the plasma cortisol concentration levels above 60% of maximum oxygen consumption (Branderberger, 1985), although this depends on the duration of the exercise and the individual aerobic thresholds (AT) (Branderberger, 1985). A very recent study of high intensity aerobic exercise on CLBP reported a significant decrease compared with other forms of active physiotherapy due to the activation of the HPA axis (Chatzitheodrou et al. 2007).

The mechanical indication for DWR is based on the decompression of the lumbar spine, assessed with precise measurements of body height, when compared with the motor-driven treadmill and shallow water running, with significant differences in height in favor of DWR (Dowzer et al. 1998). It also affords a guarantee of predominantly aerobic exercise with changes in all functional parameters of mobility, strength and endurance, and cardiometabolic improvement, which all have a significant negative correlation with the degree of pain and physical disability (Reilly et al. 2003).

Deep water running has proved able to prolong the beneficial effect on functional ability after earlier stages of physical exercise on land (Quinn et al. 1994). In large military population samples, DWR was associated with a lower relapse rate in non-specific CLBP and other exercise-induced injuries compared with other programs based on land training (Burns AS, Lauder TD 2000). The effectiveness of DWR as an alternative to other aerobic workouts has also been demonstrated at different ages: among young persons and middle-aged (Nakanishi et al 1999) and older persons (Broman et al. 2006). Additionally, it is clinically effective in various musculoskeletal disorders with a mechanical impact, such as hip and knee osteoarthritis.

Correspondence to:
AI Cuesta-Vargas, PT, MSc, PhD, Department of Physical Therapy, School of Medicine, University of Málaga, 29080 Málaga, SPAIN, e-mail: acuesta@uma.es, Office phone: 0034 952137551, Cell phone: 0034 667455544
Manual therapy, specific training and education have all proved effective at increasing the functional capacity and symptomatic improvement in CLBP, either alone or in various combinations (Bentsen et al 1997, Cairns et al 2006, Frost et al 1998, Moseley L 2002, Niemisto et al 2003). The supplement to the EBP program of deep water running (DWR), an exercise modality with sufficient physiological inferences to improve the clinical success.

The aim of this study was to determine whether there were differences in pain, physical and mental health state, disability and functional ability following a combined EBP and DWR intervention, compared to EBP alone.

MATERIAL AND METHODS

Design: We undertook a randomized, controlled, prospective study with one group receiving evidence-based physiotherapy (EBP) and a second group with EBP plus DWR (EBP + DWR). The choice of an experimental design providing an intervention to the first experimental control group, but without DWR, was for the ethical requirement to provide the patients with the best physiotherapy service available, combining practical knowledge with the highest quality scientific evidence. The experimental group was given a supplement of aerobic exercise through DWR, based on physiological studies indicating its use. The study was authorized by the Ethics and Research Committee of the Faculty of Medicine at Malaga University. All the participants gave written informed consent and confidentiality and anonymity were preserved at all times. Two researches were blinded to the participants groups. The physiotherapists also were blinded because the intervention is a procedure implemented in a community-based physiotherapy program of National Health Service and the staff don’t know which participant and which not were recruitment to this trial.

Figure 2. Symbolized drawing of deep water running.

Figure 3. Deep water running technique.

Spine neutral
Simulate running
Line of shoulders
Shoulders flexed with elbows at 90%
Wrist at least 5 cm under the water
Fists closed
Cyclic movement of legs
Hip flexed 70°
Ankle relaxed
( adverse effect of running)
Trunk inclination <10°
(correlation with hip)
Subjects: The participants had all had non-specific CLBP, without radiating to the legs, for at least three months. Patients were excluded, during the health care recruitment interview, if they refused to participate in the study, or if they had low back pain as a result of specific spinal disease, infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder, radicular syndrome or caudal equine syndrome. Patients with cognitive worsening of whatever etiologic or exercise intolerance were also excluded. The recruitment system was between the subjects with eligibility criterion from primary or secondary health care. The final number of participants was 49 (figure 1). After providing written informed consent, these patients were randomly assigned to one of two groups, by the use of sealed envelopes, previously assigned to one group or another.

The clinical and physical procedures were selected for their reliability, relevance to the type of intervention and prior experience. Measurements were made before and after the intervention.

At the start of the study each participant completed various scales and questionnaires in order to measure the clinical outcomes. Disability was measured with the Roland Morris Disability Questionnaire (RMDQ), validated by Roland and Morris, using the Spanish version validated by Kovacs et al. (Kovacs et al 2002) which has a high reliability (0.87); pain was evaluated by the visual analogue scale (VAS) (Huskisson, 1974); and general health state by means of the Short Form 12 (SF-12) validated for back pain by Luo et al. (Luo et al 2003) with a good reliability of 0.70, and adapted from the larger SF-36 version.

To measure the physical results each patient underwent three tests measured impairments. The first was given in order to measure the maximum isometric strength of the lumbar and hip extensors (FIML test), using an extensionisometric mechanical dynamometer (it evaluates traction strength). The dynamometer was a specially calibrated spring (KERN and Sonh GMBH mod. 80100), fixed to the floor by solid rings with a chain to a handgrip. The procedure consisted of extending the trunk and thighs whilst standing from a trunk flexion of 45 degrees (inclinometer) from vertical, which requires calibration of the length of the chain to the height of the subject. The peak power was recorded in kilograms. The test was performed twice, with a rest of at least 2 minutes between tests (figure 2). The best measurement was recorded. The reliability and validity of this procedure has been correlated with surface electromyography in multifidus at L5, lumbar iliacostal mass at L3 and dorsal width at L1 (r=0.64-0.69) (Lariviére et al 2008).

The second test measured lumbosacral mobility in flexion in the sagittal plane (LSMflex), by means of a dual inclinometer (DUALER Jtech) according to the protocol of Waddel et al (1992). With the subject upright, the primary inclinometer was placed on the T12-L1 interspinous space and the secondary inclinometer on S1. The patient was then requested to perform maximum flexion of the trunk with the hands together, arms extended and keeping the knees extended while the DUALER recorded the whole range of motion. The repeatability of the inclinometer is ±1 degree. The test was performed twice and the best value recorded. The inter-test reliability for the dual inclinometer in lumbar flexion has a Pearson correlation of 0.96 to 0.99 (Saur et al 1996).

The third test measured the muscular endurance of the lumbar and hip extensors by means of the Sorensen test (Burns et al 2000). The latest systematic review on the use of the Sorensen test found that the study by Biering-Sorensen in 928 persons demonstrated that good isometric resistance of the lumbar and hip extensors is a first-line preventive measure for mechanical conflicts of the spine. In persons with non-specific mechanical lower back pain it has high indices of reliability, with an interclass correlation (ICC) of 0.88, 0.83 in healthy persons and 0.77 in patients who have recovered from non-specific mechanical low back pain (Latimer et al 1999).

EBP: The EBP intervention consisted of the following:

An individual evaluation with a general clinical interview, which forms part of our procedure with the ASETER 2.0 computer program (12). Concentrating on functional ability, this initial evaluation was centered on defining the functional deficit to determine the prescription of more effective exercise enhanced in physical impairments found. During the clinical interview the patient was given a ten-point leaflet on lower back pain and encouraged to adopt an active role in the program, as well as making a “contract” concerning therapeutic adherence and program compliance.

An individual program of therapeutic physical exercise three times per week for fifteen weeks (INDIVIDUAL PHYSIOTHERAPEUTIC EXERCISE PROGRAM), based on a common structure of objectives to improve physical ability according to the initial individual evaluation, to be undertaken as a group. Each 60-minute session comprised 15 minutes dedicated to improving mobility, 15 minutes to the motor control of lumbar-pelvic stabilization and 30 minutes to resistance and muscle strengthening. The physiotherapists carried out the supervision the program of EBP in the group and adjust the individual workload of physical exercises and practice the manual therapy and education in the same time of patients development the exercise program.

INDIVIDUAL PHYSIOTHERAPEUTIC EXERCISE PROGRAM

Improvement of Mobility. Here, manual therapy is involved, normalising angular joint movements and translation of hypomobile findings as well as proprioceptive neuromuscular facilitation of the myotendinous barriers till the patients finds a position of myofascial elongation. First the physiotherapy achieve manually and after the patient self-stretching is repeated systematically. The method consists of holding muscular elongation continuously on one side of the body for 3 series of 30 seconds each, with a rest between series of 30 seconds. The patient always starts on the right side with stretching of the extensor muscles of the hip and the flexor muscles of the knee, stretching the pelvic and trochanteric muscles and stretching the iliolumbar muscles.
The method for the improvement of motor control of the local system of lumbar stabilisation is based on activation of the local system for 10 seconds by trial and error. The aim is to hold a neutral spinal lumbar position, with the help of air pressure feedback or the manual control of the physiotherapist and/or the patient. The patient should try to hold the position at least 10 seconds over 2 series each exercise in four stages of difficulty, Figure 5. In the exercise protocol the patient is taught to recruit the deep muscles of the local segmental system of the spine and to gradually reduce the undesired excessive activity of the overall system.

The method to improve isometric muscle resistance is based on proprioceptive exercises with an individually sized Swiss ball (diameter according to the shoulder-wrist distance). The method consists of three exercises of 30 seconds each repeated three times with a rest of 30 seconds between exercises.

The method to improve strength is based on specific weight-training with the apparatus pre-set to the most relevant functional movements. During the strengthening exercise the patient was instructed to concentrate on local motor control of the neutral lumbar-pelvic position. Leg and back extensions were chosen because they are components of the specific muscle chains involved in sitting, standing up, bending, and going up and down stairs, and arm-pulls were used as they are involved in the muscle chain used for pushing and pulling. The workload was estimated taking 50% of one maximum repetition. This load was used for the first 15 weeks. For the first and second weeks, the participants attempted to perform 10-15 repetitions, and with effect from the third week 15 - 20 repetitions. If at any time the participant reached the maximum number of repetitions 2.5 kg were added. This system of strengthening was repeated for two series each exercise, with a two-minute rest between each exercise.

**EBP+DWR Group:** This group undertook both 1 and 2 above, as well as the following:

Aerobic exercise with DWR aided by a special flotation belt for 20 minutes in AT. Starting from individualized workloads based on the initial test, the intensity was increased by 2 to 4 millimoles (mmol) of lactatemia (LACT) over 15 weeks, using the heart rate to control the exercise intensity.

The initial test before the DWR was carried out on a different day to the rest of the functional evaluation. The subject undertook DWR whilst wearing a flotation belt tethered by an elastic band to the edge of the pool (figure 3). The temperature of pool was 28°C and every participant in experimental group was familiarizing with DWR in one individual session before the test and training. The DWR technique was supervised the whole time (Cuesta-Vargas and Guillen Romero 2005) as per figure 4. The only variable to increase was cadence, marked by an increasing rhythm of 10 beats per minute each two minutes provided by a programmed audio tape. The data were recorded by two observers at the end of each 2-minute stint without interrupting the increasing process of the test. This was done by puncturing the ear lobe to measure the LACT and by a precordial heart rate transmitter attached by an elastic band to the chest and a wrist receiver to measure the heart rate (HR). This procedure was used to calculate the individual prescription for the aerobic workload in DWR. This initial test was used to establish the individual correlation between the HR and LACT for the AT. For weeks 1 to 5 this workload corresponded to the HR at 2 mmol of LACT, for weeks 6 to 10 at 3 mmol of LACT, and for weeks 10 to 15 at 4 mmol of LACT. These figures were...
based on previous studies concluding that 2 to 4 mmol of LACT is the AT in water exercise (31).

The total time per DWR session was 20 minutes consecutively. A physiotherapist supervised both the technique (figure 3) and the intensity according to the HR, not the running speed or the distance covered.

Sample size. A minimum of 23 patients per group was necessary for the trial to have sufficient statistical power (80%), using the t test for independent data (alpha=0.05) and to detect differences between groups after the intervention of 2.0 on the visual analog scale (VAS) for pain (Moseley L 2002). The sample size was calculated using software EPIDAT 3.1

Statistical analysis. A database was used to collect the information provided by the participating therapists and the self-administered questionnaires. The analysis was designed to seek significant differences between the variables of disability, pain and general state of health. A descriptive analysis was also carried out, with measurements of central trend and dispersion of the study variables. An inferential analysis was made between the main study variables and the result. The changes were established for the primary outcome measures by examining and comparing improvement scores, as the difference between groups and standard deviation. The effect size was measured for the main result variables by relative risk reduction (RRR; % of 1-quotient two groups), absolute risk (AR= means difference) and number needed to treat (NNT= quotient of AR) (Laupacis et al, 1998). In Health Science in general and in CLBP in particular, a very relevant effect size for pain is >0.5, a relevant effect >0.2, and irrelevant <0.2 (Keller et al 2007). These analyses were done with software SPSS 15.0.

RESULTS
Initially, 64 patients were recruited for the study, of whom 49 fulfilled all the inclusion criteria. Three of these 49 were lost, two unable to complete the program and one with increased pain (Figure 1). Table 1 shows the sample characteristics. No significant differences were found between the descriptive variables at the start of the study. The results of the inferential analysis are shown in Table 2.

Table 1. Comparison between groups at the start of the test.

<table>
<thead>
<tr>
<th></th>
<th>EBP + DWR</th>
<th>EBP</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>39.88±11.21</td>
<td>37.65±13.21</td>
<td>0.563</td>
</tr>
<tr>
<td>Body mass index</td>
<td>26.22±3.95</td>
<td>25.21±4.53</td>
<td>0.798</td>
</tr>
<tr>
<td>Duration of symptoms, weeks</td>
<td>14.3±9.4</td>
<td>16.9±9.5</td>
<td>0.235</td>
</tr>
<tr>
<td>Pain, (100 mm, VAS)</td>
<td>52.53±20.02</td>
<td>57.62±14.19</td>
<td>0.249</td>
</tr>
</tbody>
</table>

Table 2. Score according to group and time and changes within-group and between group.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post-Intervention (15 weeks)</th>
<th>Within-group</th>
<th>Between-group</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>EBP + DWR</td>
<td>EBP + DWR</td>
<td>EBP</td>
<td>EBP + DWR</td>
</tr>
<tr>
<td>Pain (100 mm, VAS)</td>
<td>52.53±20.02</td>
<td>57.62±14.19</td>
<td>36.06±25.11***</td>
<td>34.18±26.05b***</td>
</tr>
<tr>
<td>Disability, (24-RMDQ)</td>
<td>6.12±3.28</td>
<td>5.25±2.93</td>
<td>3.56±2.47</td>
<td>3.00±4.85b**</td>
</tr>
<tr>
<td>PHS (0-100, SF-12)</td>
<td>41.29±11.74</td>
<td>37.80±8.10</td>
<td>46.73±9.17</td>
<td>-10.59±12.99b***</td>
</tr>
<tr>
<td>MHS (0-100, SF-12)</td>
<td>44.16±12.20</td>
<td>45.64±10.01</td>
<td>47.42±9.79</td>
<td>-6.44±14.52a</td>
</tr>
<tr>
<td>LP-ROMflex, degrees</td>
<td>46.31±20.56</td>
<td>47.60±18.84</td>
<td>60.76±15.26</td>
<td>-12.69±24.46b*</td>
</tr>
<tr>
<td>FIML test, kg</td>
<td>54.25±16.97</td>
<td>58.40±16.10</td>
<td>75.26±21.78</td>
<td>-12.86±19.10b***</td>
</tr>
<tr>
<td>Sorensen test, seconds</td>
<td>25.80±13.60</td>
<td>24.28±12.48</td>
<td>45.28±13.09</td>
<td>-37.27±15.04b***</td>
</tr>
</tbody>
</table>

PHS: Physical health state
MHS: Mental health state

a Non-significant differences with the t test for independent samples.
b Significant differences with the t test for paired samples.
b *0.05
b ** 0.01
b ***0.001
The effect for pain of the intervention on CLBP was 0.70 in the EBP+DWR experimental group, 0.59 in the EBP control group, and 0.32 between the two groups. The size effect of our intervention for the degree of disability in CLBP was 0.48 in the EBP+DWR experimental group, 0.32 in the EBP control group, and 0.12 between the two groups.

The effect of the intervention on the physical health state was 0.20 in the EBP+DWR experimental group, 0.19 in the EBP control group, and 0.1 between the two groups; this latter at the limit of clinical relevance. The effect of the intervention on the mental health state was 0.12 in the EBP+DWR experimental group, and irrelevant for the EBP control group (0.03) and the difference between the two groups (0.06).

The results of this study were determined according to the NNT, following the current recommendations to express the clinical relevance of the findings of a randomized control trial (Reilly et al. 2003). For EBP + DWR, the NNT was 3 for pain, 8 for the degree of disability, and 9 for the physical health state. For EBP without DWR, the NNT was 3 for pain, 14 for the degree of disability, and 11 for the physical health state. It is estimated that for chronic pain, a NNT of 2 or 3 is indicative of an effective intervention (Keller et al. 2007).

**DISCUSSION**

The EBP intervention supplemented with 20 minutes of DWR at the individual AT was not more effective for pain than without the DWR. The changes between two active treatments did not present significance difference in any outcomes. We have found no studies of DWR at the AT in CLBP. However, interventions involving part of the exercise program in water have shown significant changes in pain and disability scores when compared with controls or inefficient interventions (McIlveen and Robertson 1998). Significant improvement has also been found when the changes were evaluated from baseline (McIlveen and Robertson, 1998; Yozbatiran et al. 2004). Comparison of water-based exercises with land-based exercises showed no significant differences for pain (Yozbatiran et al. 2004).

However, unlike our study, these other studies involved non-individualized low-intensity exercises in water, without the integration of other effective land-based techniques, manual therapy or health education.

The results also coincide with other studies involving similar interventions, which showed mean intra-group changes in pain of 19 mm (95% CI, 2.5-1.3) (Frost et al. 1998), 15 mm (95% CI, 2.3-0.7) (Bendix et al. 2003). More specific trials with similar interventions to those here found similar results for the reduction in the disability score by 3.5 (95% CI, 1.3-6.2) (Niemisto et al. 2003), 3.9 (95% CI, 2.0-5.8) (Niemisto et al. 2003), 5.2 (95% CI, 3.6-6.7) (Cairns et al. 2006), and 1.8 (95% CI, 0.9-2.7) (Frost et al. 1998). These treatments, like the present study, are based on exercise programs with the integration of health education techniques and manual therapy.

The results of this study and evidence from earlier studies suggest that the increase in effect size may be favored by exercise based on the motor control of the local system of trunk stability (Ferreira et al. 2006), due to the intensity of active training (Liddle et al. 2004), the incorporation of educational aspects and the combination of the various effective modes of physiotherapy in CLBP (Moseley, 2002).

Our results showed a positive response in both groups, not only statistically but also clinically. A 20% reduction in pain score is considered to be a clinically relevant improvement (Van der Roer et al. 2006). The effect size of the intervention on CLBP was 0.70 in the EBP+DWR experimental group, 0.59 in the EBP control group. This enabled us to evaluate the addition of DWR as an added value to the procedure regarding pain reduction, suggesting that physiotherapeutic treatment can be enriched with a predominantly aerobic exercise for CLBP, as is DWR.

Unlike pain, however, a reduction of just 10% in the disability scale is considered a clinically relevant improvement (Van der Roer et al. 2006). Significant differences were found in both groups when compared with baseline values, and these were clinically relevant in the experimental group.

The effect of the intervention in disability in CLBP was 0.48 in the EBP+DWR group, 0.32 in the EBP group. The inter-group effect was not relevant, though both groups experienced a relevant effect as compared with the baseline values. Of note, too, was the effect size of 0.48 in the experimental group, very close to being clinically very relevant for reduction in disability. These results are similar to those reported for the clinical relevance of non-surgical treatment of low back pain, where the effect size of the treatment with physical exercise was 0.22 for disability (Keller et al. 2007).

Following the recommendations of Deyo et al. (Deyo and Jarvik 2003), the present study incorporated the evaluation of the general state of physical health in the physiotherapeutic interventions of CLBP. As with the disability score, clinically relevant improvement is considered to be a 10% increase in the general state of health (Keller et al. 2007). The effect size in physical health state was clinically relevant compared to baseline values, with an effect of 0.20 in the EBP+DWR experimental group and 0.19 in the EBP control group. The effect size in mental health state was clinically relevant for the EBP+DWR experimental group (0.12), and irrelevant for the EBP control group (0.03).

The intragroup results for the physical health state are in agreement with those of other studies, showing a effect size in the EBP+DWR experimental group of 10.59 points (95% CI, 17.46-3.72) and in the EBP control group of 8.93 points (95% CI, 3.26-1.97) on the SF-12, versus the results of Cairns et al. (2006) of 8.5 (95% CI, 4.7-12.3). The intragroup mental health state showed no significant differences, like the study by Cairns et al. (2006).

Our study is in consonance with recent other studies on the classification of CLBP concerning the magnitude of the clinical relevance, given the variability of each individual in the different strategies of physiotherapeutic intervention. This variability is considered to be inter-subject, which explains the need for the initial individual evaluation as a base upon which to decide the physiotherapeutic strategy for each person.
There is also an intra-subject variability, associated with the changes produced in the different functional capacities at various times (O’Sullivan P and Beales D 2007). Our aim was to evaluate, as others have suggested in earlier studies, the implantation of manual interventions at the start (Assendelft et al 2004), the progression in motor learning of the motor control of the local system of trunk stability (Ferreira 2006), the progression of loads in resistance and muscle strength, and the progressive adaptation in AT during DWR in the experimental group, as the choice way of increasing the clinical effect from baseline.

In both groups, the results of all the functional variables (mobility, strength, resistance and motor control) showed significant improvement as compared with baseline values. The differences were highly significant for both groups regarding the improvement in muscle resistance, for strength in the EBP+DWR experimental group, and for improvement of mobility and strength in the EBP control group. These findings were to be expected after the controlled and supervised individual exercise program (Liddle et al 2004). However, the merit of the intervention centers on the mean individual differences between the values at baseline and those after the exercise program, as this way the progress of each individual person can be analyzed.

The results are influenced by the intervention variables. Strengthening assumes great importance, especially that of the lumbar and hip extensors (Vuori, 2001). Abdominal strengthening, particularly the deep system (transverse and internal oblique), has often been considered to facilitate stabilization of the trunk, with a recent systematic review concluding that, as compared with general medical practice, it improves pain and disability in patients with CLBP (Ferreira et al, 2006). However, the clinical relevance of this method of isolated strengthening has a effect of 0.4, compared with the baseline pain (Cairns et al. (2006) versus the 0.7 found in our study, thanks to the combination of the different strategies.

Our results are in consonance with those of a randomized clinical trial on CLBP that incorporated any system to improve mobility, for example, by manual therapy, joint mobilization, or stretching, and integrating them under different names like conventional physiotherapy (Cairns et al 2006), functional restoration (Bendix et al 2000), or generically, under the headings of manual therapy or therapeutic exercise (UK BEAM Trial Team 2004). In one way or another, they all use a similar combination to that used here, where educational strategies were also included.

Our results are greater than those of other studies that compared isolated procedures with a predominance of one system of physical therapy. One clinical trial that compared three active options of therapeutic exercise (active physiotherapy, muscle reconditioning on training devices, and low-impact aerobic exercise) showed no significant differences between the three groups (Cairns et al 2006, Moseley L 2002, Niemisto et al 2003).

**STUDY LIMITATIONS**

- Future studies should involve larger samples and undertake a long-term follow-up.
- Future studies should to determine differences in the efficacy of the two interventions described in this study in participants with acute low back pain.
- The variability between participants indicates the need to establish different strategies for each intervention. Future studies should therefore include valid, reliable and precise functional evaluations for decisions to be taken when treating CLBP.
- The different times to assimilate the response to the intervention for each modality used in this study indicates the need to include clinical and functional evaluations during the experimental stage.
- The relative contribution to the clinical results of the various components of the intervention provides more information on the degree of contribution of each component in the intervention used in this study.
- Cost-effectiveness analyses should be included, due to the variable costs to achieve similar results in persons with CLBP.

- Outcome variables should be included that evaluate motivation, compliance, lifestyle, return to work and the use of the term “malaise” instead of “pain” in patients who experience a relapse.

**CONCLUSIONS**

A complement to EBP of DWR at an intensity of the AT don’t produces a significant improvement in pain, general health state and disability in patients with CLBP over EBP alone.

The present procedure of EBP with an approach that combines the three strategies of physiotherapy produces a very relevant effect size for pain and a relevant effect for disability and general physical health in patients with CLBP.

Due to the variability between persons with CLBP, better results are achieved with an individualized plan of strategies according to the initial situation and the evolution of each patient.

The neuro-endocrine modulation of CLBP may be favored by aerobic exercise at the AT.

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