



Centre for Clinical Effectiveness

Enhancing patient outcomes through clinical application of the best available evidence

EVIDENCE CENTRE
CRITICAL APPRAISAL
Series 2002: Therapy

Exercise therapy for the treatment of chronic low back pain

Nicki Jackson

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Southern Health

MONASH
UNIVERSITY

Centre for Clinical Effectiveness
Monash Institute of Health Services Research
Monash Medical Centre
Locked Bag 29
Clayton VIC 3168
Australia

Telephone: +61 3 9594 7505
Fax: +61 3 9594 7552
Email: cce@med.monash.edu.au (quote author of report)
URL: <http://www.med.monash.edu.au/healthservices/cce/>

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SUMMARY STATEMENT

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REQUEST

Is there any evidence to support a particular exercise or exercise regime for the treatment of chronic low back pain patients?

REQUESTED BY

Kim Jacoby, Physiotherapist, Physiotherapy (RASP), Hampton Rehabilitation Hospital, Hampton.

METHODOLOGY

Search Strategy

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias. We determine this according to pre-defined National Health and Medical Research Council (NHMRC, 2000) criteria (see Appendix 1).

First, we search for systematic reviews, evidence based clinical practice guidelines, health technology assessments and randomised controlled trials. If we identify sound, relevant material of this type, the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable or have other methodological difficulties. We include case-control and longitudinal cohort studies in our critical appraisal reports. While we cite observational and case series studies, and narrative reviews and consensus statements, in our reports we do not critically appraise them. Such studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

Details of Evidence Request

Patients (Subjects): Patients with chronic low back pain (activity intolerance due to lower back pain lasting 3 or more months)

Intervention: Exercise therapy

Comparisons: No exercise therapy

Outcomes: Pain, functional disability, range of motion, fitness, return to work, activities of daily living

Search terms

(see Appendix 2 for exact search strategy)

Patient (Subject): low back pain, lumbar pain

Intervention: exercise, exercise therapy

Comparison:

Outcome:

Resources Searched

We searched the following databases:

The Cochrane Library (CD-ROM) 2002 Issue 2

Medline (OVID)- 1996 to July Week 1 2002

CINAHL (OVID)- 1982 to June Week 4 2002

Current Contents (OVID)- 1993 Week 27 to 2002 Week 29

PREMEDLINE (OVID)- July 17th 2002

Australasian Medical Index- accessed 18th July 2002

PEdro – accessed 18th and 19th July 2002

Refinements, Searching & Reporting Constraints

We included items of evidence that were available to us on 18th and 19th July 2002. Initially, we only included articles published in the last 5 years. Critical appraisal was performed on the subset of studies published in English.

As muscle dysfunction is hypothesized to be important in the persistence of chronic low back pain, studies were included if the primary outcome was size of the trunk muscles after exercise therapy.

RESULTS

Our preliminary search resulted in the identification of a Cochrane Systematic Review, published in 2002 (van Tulder, 2002). This systematic review identified all randomised controlled trials up to April 1999 in the area of exercise and low back pain (both acute and chronic phases). Therefore, our search was limited to randomised controlled trials published after April 1999. From our sources we identified 27 potentially relevant articles. We obtained the full text of these articles to determine their relevance.

After examination of the 27 articles, the following were excluded as follows:

Reason for exclusion	Number
Combination of exercise and other therapy	3
Review articles / letter	3
Back pain was not of a chronic nature	4
Exercise therapy not compared with standard treatment	1
Patients were not randomised	2
Study was the initial results of a study that was included	1
Patients were only advised to stay active	1
Evidence-based clinical practice guidelines that identify some of the same randomised controlled trials as van Tulder (2002)	1
Systematic review published in journal article	1

Patients had back pain, or neck pain or shoulder pain	1
Total	18

Nine articles then remained for appraisal. These studies are classified as follows:

Study Design	Number included
Systematic reviews or meta-analyses	1
Evidence-based clinical practice guidelines	0
Randomised controlled trials	8
Total	9

Based on our refinements, searching and reporting constraints we are reasonably confident these articles represent the most relevant findings published to date. Three of the articles identified (Mannion 1999, Mannion 2001, and Kaser 2001) report different outcomes from one randomised controlled trial.

Summary of findings

The results of the 4 randomised controlled trials examining pain, disability and muscle fatigability are briefly outlined below:

- 1) A 3-month program of gym workouts was shown to reduce pain and improve spinal and muscle flexibility significantly more than a home exercise program
- 2) A 3-month program of muscle reconditioning using training devices was equally effective as physiotherapy or aerobics in reducing pain and decreasing disability
- 3) Both aerobic exercise and flexion exercise carried out for 3 months reduced the pain score significantly
- 4) Three-month trunk muscle function training was effective in reducing pain and disability and improving lumbar endurance compared to passive treatment consisting of thermal therapy and massage.

Therefore, it would appear that exercise is useful in the treatment of patients with chronic low back pain, but is only as effective as conventional physiotherapy. This supports the finding of the systematic review previously published (van Tulder, 2002).

Of interest, the well-designed randomised controlled trial conducted by Mannion et al (2001) showed that alterations in muscle performance (improved fatigability and strength) were not explainable on the basis of structural changes within the muscle. The authors note that these changes may appear to be due to changes in neural activation of the lumbar muscles and psychological changes concerning, for example, motivation or pain tolerance. This finding should be applied when considering the results of the studies conducted by Danneels (2001a, 2001b), which only assess the impact of exercise on muscle size.

EVIDENCE SUMMARIES

Format

Evidence summaries are presented as spreadsheets in the following section of this report. Each spreadsheet contains the article citation, details of the study design, patient description, scientific validity of the article, results, and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

<p>Evidence Summary Therapy/ Systematic review</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p>Exercise for the treatment of chronic low back pain</p> </div>	<p>Study 1 – Systematic Review</p> <p>Tulder MWv, Malmivaara A, Esmail R & Koes BW (2002). Exercise therapy for low back pain [Systematic Review]. <i>Cochrane Database of Systematic Reviews, Issue 2, 2002</i></p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p>Level I – Systematic Review</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Patients (Subjects): Subjects aged 18 to 65 years and treated for non-specific low back pain in a primary health care or occupational setting. Intervention: All types of exercise therapy Comparisons: Other active treatment, inactive or 'placebo' treatment Outcomes: Four primary outcome measures: 1) pain, 2) global measure (overall improvement, proportion of patients recovered, subjective improvement of symptoms), 3) back pain specific functional status, 4) return to work. Exclusion criteria: Randomised controlled trials (RCTs) that included subjects with low back pain caused by specific pathological entities such as infection, neoplasm, metastasis, osteoporosis, rheumatoid arthritis, or fractures were excluded. RCTs in which the exercise therapy was given as part of a back school or multidisciplinary treatment program were excluded. Inclusion criteria: Low back pain was defined as pain localised below the scapulae and above the cleft of the buttocks, with or without radiation to the lower extremities including patients with nerve root pain or sciatica. All types of exercise were included. Chronic low back pain (LBP) was defined as pain for more than 12 weeks.</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Focussed question: Yes Search strategy: MEDLINE 1966 to April 1999, EMBASE 1988 to September 1998, PsycLit 1984 to April 1999, references from review articles, Cochrane library Issue 1, 1999. Assessed validity: Methodological quality assessed by blinded reviewers. Clinical homogeneity was assessed. Nine validity items were used to assess the methodological quality of the studies. Consistent results: Studies were considered heterogeneous with regard to study populations, interventions and outcomes (no meta-analysis was therefore conducted). Appropriate analysis of results: No meta-analysis was conducted due to heterogeneity. Studies were separated into acute low LBP and chronic LBP.</p>
<p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>Twenty-three studies reported on chronic low back pain patients. 1) Exercise therapy versus other active treatment Nine RCTs in 1005 patients compared exercise therapy with another active conservative treatment i.e., usual care by a primary care physician (3 studies), conventional physiotherapy (3 studies), manual therapy (1 study), back school (1 study), behavioural therapy (1 study). The three studies (all high quality) comparing exercise with conventional physiotherapy did not show any significant differences with regard to pain intensity, functional status, overall improvement or return to work. <i>Therefore, there is strong evidence that exercise therapy and conventional physiotherapy are equally effective for chronic LBP.</i> Two high quality studies compared exercises with usual care by a general practitioner (GP) and reported better outcomes for return to work. This finding was supported by a lower quality study. <i>Therefore, there is strong evidence that exercise therapy is more effective than usual care by a general practitioner for chronic LBP.</i> There was limited evidence that exercises provided better outcomes on pain and functional status than back school education, early morning lumbar flexion or manual therapy. 2) Exercise therapy versus inactive or 'placebo' treatment Six studies compared exercise with some type of inactive treatment (hot packs and rest, semi-hot packs and sham traction, waiting list control, TENS or sham TENS, and detuned ultrasound and detuned shortwave diathermy). The two high quality studies found 1) larger decrease of pain for stretching and relaxation exercise than for no exercise, 2) no differences between strengthening exercises and semi-hot packs and sham</p>

	<p>traction. The results of the remaining four studies of lower quality also found conflicting results. <i>Therefore, there is conflicting evidence regarding the effectiveness of exercise therapy for chronic LBP.</i></p> <p>3) Effectiveness of Flexion and Extension Exercises No RCTs were identified comparing flexion or extension exercises with active or inactive treatments. Three small low quality studies compared extension to flexion exercises. Two studies reported no differences in pain intensity while one study reported better global improvement with flexion exercises. <i>Therefore, there is conflicting evidence about which type of exercise, extension or flexion, is more effective for chronic LBP.</i></p> <p>4) Effectiveness of strengthening exercises Nine studies included some type of strengthening exercises for chronic low back pain; four studies were of high quality. Three of the high quality studies reported no differences regarding pain or functional status between strengthening exercises alone or with conventional physical therapy. The other high quality study reported better outcomes regarding pain and functional status for an intensive, dynamic strengthening program than with mild exercises. <i>Therefore, there is conflicting evidence that strengthening exercises are more effective than inactive treatment for chronic LBP.</i></p>
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>"The evidence for chronic low back pain is less clear and less consistent. There is strong evidence that exercise therapy is more effective than usual care by GPs and that exercise therapy and conventional physiotherapy are equally effective. However, it is still unclear if exercise therapy is or is not more effective than inactive treatment for chronic low back pain, and it is still unclear if any specific type of exercise is more effective than another. Exercises may be useful in the treatment of chronic low back pain if they aim at improving return to normal daily activities and work."</p>
<p>OUR COMMENTS: Opportunity for bias, weakness and strength</p>	<p>Potential for bias: The methodology of a systematic review is designed to reduce bias. Strength/s: Assessed validity of the studies. Searched relevant databases and references of review articles. Clear inclusion and exclusion criteria.</p>

<p style="text-align: center;">Evidence Summary Therapy/Intervention</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p style="text-align: center;">Exercise for the treatment of chronic low back pain</p> </div>	<p style="text-align: center;">Study 2</p> <p style="text-align: center;">Danneels LA, Cools AM, Vanderstraeten GG, Cambier DC, Witvrouw EE, Bourgois J & de CHJ (2001a). The effects of three different training modalities on the cross-sectional area of the paravertebral muscles. <i>Scandinavian Journal of Medicine & Science in Sports</i> 11: 335-341.</p>	<p style="text-align: center;">Study 3</p> <p style="text-align: center;">Danneels LA, Vanderstraeten GG, Cambier DC, Witvrouw EE, Bourgois J, Dankaerts W & De Cuyper HJ (2001b). Effects of three different training modalities on the cross sectional area of the lumbar multifidus muscle in patients with chronic low back pain. <i>British Journal of Sports Medicine</i> 35: 186-191.</p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p>Level II – Randomised Controlled Trial</p>	<p>Level II – Randomised Controlled Trial</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Patients (subjects): 59 chronic LBP patients (>3 months) Intervention: Group 2, 20 patients) stabilization training combined with dynamic resistance/strengthening training, Group 3, 20 patients) stabilization training combined with dynamic-state resistance/strengthening training Comparisons: Group 1, 19 patients) Stabilisation training, 10-week intervention period for all treatments, sessions were 3/week. Outcomes: Cross-sectional area (CSA) of the paravertebral muscles (PA), assessed by computerised tomography Incl & Excl Criteria: Exclusion criteria were previous lumbar surgery, the presence of spondylolysis or spondylolisthesis, a lumbar scoliosis exceeding 10°, neuromuscular or joint disease, evidence of systemic disease, carcinoma or organ diseases. Patients involved in sports or fitness training for low back pain muscles during the previous 3 months were also excluded.</p>	<p>Patients (subjects): 59 chronic LBP patients (>3 months) Intervention: 1) stabilization training combined with dynamic resistance/strengthening training (20 patients, Group 2), 2) stabilization training combined with dynamic-state resistance/strengthening training (20 patients, Group 3) Comparisons: Stabilisation training (19 patients, Group 1), 10-week intervention period for all treatments, sessions were 3/week. Outcomes: Cross-sectional area (CSA) of the lumbar multifidus muscle assessed by computerised tomography Incl & Excl Criteria: Exclusion criteria were previous lumbar surgery, the presence of spondylolysis or spondylolisthesis, a lumbar scoliosis exceeding 10°, neuromuscular or joint disease, evidence of systemic disease, carcinoma or organ diseases. Patients involved in sports or fitness training for low back pain muscles during the previous 3 months were also excluded.</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Randomisation: Method of randomisation not specified. All patients accounted for: Number of patients excluded or who dropped-out was not specified. Similar groups: There were no statistical differences between the groups on entry to the trial.</p>	<p>Randomisation: Method of randomisation not specified. All patients accounted for: Number of patients excluded or who dropped-out was not specified. Similar groups: There were no statistical differences between the groups on entry to the trial.</p>
<p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>Analysis of differences within each group at the end of the intervention period showed significant differences in group 2 and group 3. In group 1, there were no significant differences between before and after therapy for these back muscles. The differences between the effects of the 3 modes of treatment on the CSA of the PA were significant at the 3 levels (level I p=0.002, level II p=0.008, level III p=0.008). Also, between groups 1 and 3 significant differences were found at the 3 levels (p=0.001, p=0.008, p=0.035) for level I, II, and III respectively.</p>	<p>Stabilisation training and stabilisation training combined with progressive dynamic resistance had no significant effect on the size of the multifidus muscle. Analysis of differences within group 3 showed significant differences at three levels (p=0.014, 0.008, and 0.002 for levels I, II, and III).</p>
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>"Controlled application of progressive and intensive overload is necessary to cause a volume growing effect in the treatment of LBP patients with atrophied back muscles. However, differences between dynamic and combined dynamic-state</p>	<p>"The static holding component between the concentric and eccentric phase was found to be critical in inducing muscle hypertrophy during the first 10 weeks. A treatment routine consisting of stabilisation training combined with</p>

	training were not found, suggesting that an isometric holding component is not critical in inducing muscle hypertrophy during the first 10 weeks.”	dynamic-static workload for the paravertebral muscles seems to be the most appropriate method for reversing atrophy of the multifidus muscle.”
OUR COMMENTS: Opportunity for bias, weakness and strength	<p>Potential for bias: A well-designed study.</p> <p>Weakness/es: The authors note that the contribution to muscle strength was not considered in the present study.</p> <p>Strength/s: Radiologist was blinded to the treatment status of the patient.</p>	<p>Potential for bias: A well-designed study.</p> <p>Weakness/es: The authors note that the contribution to muscle strength was not considered in the present study.</p> <p>Strength/s: Radiologist was blinded to the treatment status of the patient.</p>

<p style="text-align: center;">Evidence Summary Therapy/Intervention</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p style="text-align: center;">Exercise for the treatment of chronic low back pain</p> </div>	<p style="text-align: center;">Study 4</p> <p>Mannion AF, Taimela S, Muntener M & Dvorak J (2001). Active therapy for chronic low back pain Part 1. Effects on back muscle activation, fatigability, and strength. <i>Spine</i> 26: 897-908.</p>	<p style="text-align: center;">Study 5</p> <p>Kaser L, Mannion AF, Rhyner A, Weber E, Dvorak J & Muntener M (2001). Active therapy for chronic low back pain Part 2. Effects on paraspinal muscle cross-sectional area, fiber type size, and distribution. <i>Spine</i> 26: 909-919.</p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p>Level II – Randomised Controlled Trial</p>	<p>Level II – Randomised Controlled Trial</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Patients (subjects): 148 patients with chronic low back pain Intervention: 1) Modern active physiotherapy, 2) muscle reconditioning on training devices, 3) low-impact aerobics. All patients were required to attend therapy twice per week for a total of 3 months. 1) Modern active physiotherapy This involved ½ hour individual therapy sessions focused on improving the functional capacity of the patient and giving instruction on ergonomic principles. Also included isometric exercises, and general strength training. 2) Muscle reconditioning on training devices The David Back Clinic program was utilised (effectiveness previously shown). The exercises applied isoinertial loading to the lumbar spine in the sagittal, frontal, and horizontal planes, in accordance with the strength-generating capacity of the trunk muscles. 3) Aerobics One-hour program that included stretching and aerobic and muscle-toning exercises. Thirty minutes of the one hour program was directed predominantly at the trunk and leg muscles. Outcomes: Erector spinae muscle activity during forward flexion movements, isometric fatigue test, maximal isometric strength of the trunk muscles, dynamic fatigue test. Assessment on entry to the study and after the 3-month treatment. Inclusion Criteria: <65 years, >3 months of continual or recurrent episodes of LBP, with or without referred pain, serious enough to cause absence from work, or solicitation of medical attention, ability and willingness to travel independently to the hospital, ability to perform a preinclusion test. Exclusion criteria: constant or persistent severe pain, nonmechanical LBP, pregnancy, previous spinal surgery, current nerve root entrapment accompanied by neurologic deficit, spinal cord compression, tumours, severe structural deformity, severe instability, severe osteoporosis, fresh fracture, inflammatory disease of the spine, spinal infection, severe cardiovascular or metabolic disease, other corresponding disorders preventing active rehabilitation,</p>	<p>Patients (subjects): 148 patients with chronic low back pain. Only 45 patients were assessed for the outcomes described below. These patients volunteered for MRI/muscle biopsy. Intervention: 1) Modern active physiotherapy, 2) muscle reconditioning on training devices, 3) low-impact aerobics. All patients were required to attend therapy twice per week for a total of 3 months. 1) Modern active physiotherapy This involved ½ hour individual therapy sessions focused on improving the functional capacity of the patient and giving instruction on ergonomic principles. Also included isometric exercises, and general strength training. 2) Muscle reconditioning on training devices The David Back Clinic program was utilised (effectiveness previously shown). The exercises applied isoinertial loading to the lumbar spine in the sagittal, frontal, and horizontal planes, in accordance with the strength-generating capacity of the trunk muscles. 3) Aerobics One-hour program that included stretching and aerobic and muscle-toning exercises. Thirty minutes of the one-hour program was directed predominantly at the trunk and leg muscles. Outcomes: Assessments of trunk muscle cross-sectional area, erector spinae fibre size/type distribution and pathology, and muscle function (assessed previously). Assessments were made before and after the 3 months of therapy. Inclusion Criteria: <65 years, >3 months of continual or recurrent episodes of LBP, with or without referred pain, serious enough to cause absence from work, or solicitation of medical attention, ability and willingness to travel independently to the hospital, ability to perform a preinclusion test. Exclusion criteria: constant or persistent severe pain, nonmechanical LBP, pregnancy, previous spinal surgery, current nerve root entrapment accompanied by neurologic deficit, spinal cord compression, tumours, severe structural deformity, severe instability, severe osteoporosis, fresh fracture, inflammatory disease of the spine, spinal infection, severe cardiovascular or</p>

	acute infection, lack of co-operation.	metabolic disease, other corresponding disorders preventing active rehabilitation, acute infection, lack of co-operation.
VALIDITY: Methodology, rigour, selection	Randomisation: Patients stratified by age and gender and then randomised by using random number tables. All patients accounted for: Yes. Intention-to-treat analysis. Similar groups: There were no significant differences among the 3 groups for any of the variables at baseline. The 16 patients who dropped out were not significantly different to the 132 patients who completed the program.	Randomisation: Patients in the whole group were stratified by age and gender and then randomised by using random number tables. All patients accounted for: Six patients dropped out of the study during therapy, leaving 53 patients. Of these 53 patients 4 did not undergo MRI and 4 patients did not undergo muscle biopsy a second time. Thus, MRI and muscle biopsy data was available for 45 patients both before and after therapy. Similar groups: There were no significant differences among the 3 groups for any of the variables at baseline. There were also no significant differences between the subgroup who volunteered for the biopsy and the whole cohort from which they were drawn.
RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate	Trunk muscle maximal strength: Significant increases in isometric strength in each of the 4 movement directions (extension (p=0.0008), flexion (p=0.0001), lateral bending (p=0.0001), axial rotation (p=0.0001)). The devices group showed significantly greater improvements for all movements except extension, compared to the aerobics and physiotherapy groups. Erector spinae activation duration maximal and submaximal isometric contractions: Significant increases in activation were observed post-therapy, without differences among the therapy groups. Isometric back muscle fatigability: Endurance time for performance of the Biering-Sorensen test showed an 18% increase, from 123±57 seconds to 145±72 seconds (p=0.0001). There were no significant differences among the three therapy groups in the extent of the change. Dynamic Back muscle fatigability: A significant increase in the rate of decline in the EMG median frequency (i.e. muscle fatigability) was observed at 3 of the 4 recording sites post-therapy, with the changes being most prominent in the devices group. Muscle activation during flexion movements: Pretherapy 55% of the subjects showed no relaxation of the back muscles at L5 when in fully relaxed position; no changes were observed in any group post-therapy.	Trunk muscle size: The cross-sectional area of the erector spinae muscles was approximately 5% greater at L3/4 than at L4/5 (p=0.0001) and slightly larger on the left than on the right side of the spine. In the case of psoas, the muscle was 26% smaller at L3/4 than at L4/5 (p=0.0001). Changes following therapy: There were no significant changes in either erector spinae or psoas muscle size pre- and post-therapy. Both erector spinae and psoas showed a small decrease in the devices group, while in the 2 other groups a slight increase in the size of each muscle was observed. The effects were most marked at the L4,5 vertebral level. Architecture of muscle fibres: There were no major changes in fibre type proportion or fibre size in any group following therapy. Correlation with muscle strength and muscle fatigability: At baseline, significant correlations were observed between the size of the paraspinal muscles and isometric back extension strength (p=0.0001), and between the proportional area of the muscle occupied by each fibre type and the fatigability of the muscle (p=0.012). Following therapy, changes in erector spinae size correlated only weakly and nonsignificantly with changes in back extension strength.
AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research	"We are aware that the sample size and power of the study may not have been adequate to allow for absolute statistical certainty in reporting that these differences were not real. Because pain and disability were considered to be the key outcome measures, we based our power calculation on these variables."	"Three months active therapy is not sufficient to reverse the typical "glycolytic" profile of the muscles of chronic LBP patients or to effect major changes in back muscle size. The alterations in muscle performance were not explainable on the basis of structural changes within the muscle."
OUR COMMENTS: Opportunity for bias, weakness and strength	Potential for bias: A well-designed trial. However, because participants were volunteers who responded to a media advertisement, they may not be	Potential for bias: A well-designed study. Weakness/es: Participants may not be representative of all patients with chronic

	<p>representative of all patients with chronic LBP who often seek help in the tertiary care setting.</p> <p>Weakness/es: The authors note that the greater improvement in movement in the devices group could be interpreted as being, in part, the result of simple practice effect. The authors add that the sample size may not have been adequate to detect significant differences.</p>	<p>LBP due to volunteering to take part in the study.</p>
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<p style="text-align: center;">Evidence Summary Therapy/Intervention</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: fit-content;"> <p>Exercise for the treatment of chronic low back pain</p> </div>	<p style="text-align: center;">Study 6</p> <p style="text-align: center;">Tritilanunt T & Wajanavisit W (2001). The efficacy of an aerobic exercise and health education program for treatment of chronic low back pain. <i>Journal of the Medical Association of Thailand</i> 84: S528-533.</p>	<p style="text-align: center;">Study 7</p> <p style="text-align: center;">Kankaanpaa M, Taimela S, Airaksinen O & Hanninen O (1999). The efficacy of active rehabilitation in chronic low back pain. Effect on pain intensity, self-experienced disability, and lumbar fatigability. <i>Spine</i> 24: 1034-1042..</p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p>Level II – Randomised Controlled Trial</p>	<p>Level II – Randomised Controlled Trial</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Patients (subjects): 72 patients who had suffered low back pain for more than 3 months. All patients were aged between 30 and 50 years. Intervention group: Aerobic exercise program, which incorporated a series of 3 health education sessions (33 patients). Comparisons: Flexion exercise program, which included regular health education, postural and behavioural instruction and a lumbar flexion exercise training program (35 patients). Outcomes: Back pain (visual analogue scale, 0 no pain –10 severe pain), resting pulse, blood pressure, height, body weight, high density lipoprotein (HDL) cholesterol. Twelve-week intervention. Incl & Excl Criteria: Smokers were excluded from the study.</p>	<p>Patients (subjects): 54 patients with chronic back pain (>3 months) and moderate functional disability. Intervention: Active rehabilitation for 3 months. This incorporated 24 exercise sessions during the 3-month program. The treatment also included behavioural support and ergonomic advice. Four specifically designed training units (lumbar flexion, lumbar extension, lateral flexion, and rotation) were used specifically to train trunk muscle function and co-ordination. Comparisons: Passive treatment. Patients received thermal therapy and massages once a week for 1 month, in the final 4 weeks of treatment of the active rehabilitation group. Outcomes: Measurements were performed before and after the interventions, and at 6-month and 1-year follow-up visits. Back pain and disability (pain and disability index (PDI)), isonertial back extension endurance, and mean power frequency were the outcomes measured. Inclusion Criteria: Patients with nerve root compression or disc prolapse, severe scoliosis, spondyloarthritis, previous back surgery, and other specific and serious causes of back pain were excluded. Exclusion criteria: Patients who had low back longer than 3 months and did not have radicular symptoms (radiating pain below knee, loss of sensation, muscle dysfunction, or loss of reflexes).</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Randomisation: Block randomisation. A card was withdrawn from an envelope which indicated either aerobic exercise or flexion back exercise. All patients accounted for: A total of 72 patients were randomised. 68 patients completed the study. Similar groups: The two treatment groups were similar in age, gender, body mass index, pulse rate and HDL-cholesterol.</p>	<p>Randomisation: Patient names were drawn out of two containers that had been previously separated according to sex, shuffled and placed into one of two containers. All patients accounted for: Following randomisation of 59 patients, 8 patients withdrew during the 1-year follow-up (reasons specified) and 2 were excluded before the intervention began due to requirement for surgery. Therefore, 49 patients completed the study through the 1-year follow-up. Similar groups: The two groups were similar in age, body mass index, and time since the first episode of low back pain. The men in the active group were significantly heavier than the men in the passive group (p<0.05). In addition, low back pain intensity and lumbar paraspinal</p>

		muscle endurance were similar in the two groups.
<p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p><u>Pain score:</u> The mean pain score on the visual analogue scale improved from 5.6 to 2.3 in the intervention group and from a mean of 5.4 to 4.0 in the control group. The difference between the two groups was significant ($p<0.001$), and also within both treatment groups, from baseline to 12-week follow-up ($p<0.001$).</p> <p><u>Resting pulse:</u> The pulse rate in the intervention group reduced significantly more ($p<0.01$) than the control group (70.1/min to 66.8/min in the intervention group, 71.5/min to 70.2/min in the control group). The improvement within the intervention group was significant ($p<0.001$).</p> <p><u>HDL-cholesterol:</u> The intervention group significantly improved their HDL level more than the control group ($p<0.05$). The control group significantly reduced their HDL level ($p<0.05$) whereas the intervention significantly increased their HDL level after the treatment period.</p>	<p>Back pain intensity and functional disability decreased significantly more in the active rehabilitation group than in the passive control group in a follow-up at 1 year ($p<0.05$). Low back pain intensity and functional disability decreased during the 12 weeks of active rehabilitation ($p<0.05$).</p> <p>The lumbar endurance improved significantly ($p=0.000$) during the active rehabilitation but not during the passive treatment at 1-year follow-up. The changes in lumbar endurance were significantly greater in the active group than in the passive group at the 6-month follow-up but not at the 1-year follow-up.</p>
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>"The results of the study demonstrated that aerobic exercise and a health education program are useful in the treatment of chronic low back pain, particularly in pain relief".</p>	<p>"The active progressive treatment program was more successful in reducing pain and self-experienced disability and also improving lumbar endurance than was the passive control group".</p>
<p>OUR COMMENTS: Opportunity for bias, weakness and strength</p>	<p>Potential for bias: The participants were volunteers from an outpatient clinic; they may not be representative of all patients with chronic low back pain.</p> <p>Weakness/es: Flexion exercise and aerobic exercise are not described. It is not possible to determine how appropriate the flexion exercise program was for the treatment of low back pain, or what information was provided in the two different education programs. The visual analogue scale to measure back pain was a subjective assessment. Patients may have reported pain in a non-comparable manner. No data reported on blinding of investigators.</p>	<p>Potential for bias: Those assessing the patients and the measurements were not blinded to group at the follow-up visit.</p> <p>Strength/s: Validated lumbar muscle endurance assessment.</p>

<p style="text-align: center;">Evidence Summary Therapy/Intervention</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: fit-content;"> <p>Exercise for the treatment of chronic low back pain</p> </div>	<p style="text-align: center;">Study 8</p>	<p style="text-align: center;">Study 9</p>
<p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p>	<p>Level II – Randomised Controlled Trial</p>	<p>Level III – Pseudo-randomised controlled trial</p>
<p>DESCRIPTION: Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p>	<p>Patients (subjects): 148 patients with chronic low back pain Intervention: 1) Modern active physiotherapy, 2) muscle reconditioning on training devices, 3) low-impact aerobics. All patients were required to attend therapy twice per week for a total of 3 months. 1) Modern active physiotherapy This involved ½ hour individual therapy sessions focused on improving the functional capacity of the patient and giving instruction on ergonomic principles. Also included isometric exercises, and general strength training. 2) Muscle reconditioning on training devices The David Back Clinic program was utilised (effectiveness previously shown). The exercises applied isoinertial loading to the lumbar spine in the sagittal, frontal, and horizontal planes, in accordance with the strength-generating capacity of the trunk muscles. 3) Aerobics One hour program that included stretching and aerobic and muscle-toning exercises. Thirty minutes of the one hour program was directed predominantly at the trunk and leg muscles. Outcomes: Objective lumbar mobility, self-rated pain and disability, and psychosocial factors. Inclusion Criteria: <65 years, >3 months of continual or recurrent episodes of LBP, with or without referred pain, serious enough to cause absence from work, or solicitation of medical attention, ability and willingness to travel independently to the hospital, ability to perform a preinclusion test. Exclusion criteria: constant or persistent severe pain, nonmechanical LBP, pregnancy, previous spinal surgery, current nerve root entrapment accompanied by neurologic deficit, spinal cord compression, tumours, severe structural deformity, severe instability, severe osteoporosis, fresh fracture, inflammatory disease of the spine, spinal infection, severe cardiovascular or metabolic disease, other corresponding disorders preventing active rehabilitation, acute infection, lack of co-operation.</p>	<p>Patients (subjects): Eighty-six patients with chronic low back pain Intervention: 1) Intensive training group, 2) home exercise group. The intervention lasted 3 months. Patients in the intensive training and home exercise programs included 7 exercises for different parts of the body, and training was carried out in either the gymnasium using pulleys, barbells, pillows and plinths or at home without extra equipment. The intensive training group had their gym workout 3 times a week (supervised by a physiotherapist) and on other days were advised to exercise at home. The home exercise group were advised to exercise every day. Comparisons: Control group; no alteration to physical activity levels Outcomes: Back pain intensity, spinal and muscle flexibility Incl & Excl Criteria: Subjects with a history of surgery or signs of sciatica were excluded. The low back disorders of the subjects were non-specific and 62% had a low back episode of more than 3 months' duration.</p>
<p>VALIDITY: Methodology, rigour, selection</p>	<p>Randomisation: Patients stratified by age and gender and then randomised by using random number tables. All patients accounted for: Yes. Intention-to-treat analysis. Similar groups: There were no</p>	<p>Randomisation: Due to the slow rate of obtaining subject numbers, the first 29 patients were placed in the intensive training group. The remaining 57 were matched according to age, gender and level of activity and then randomised into</p>

	<p>significant differences among the 3 groups for any of the variables at baseline.</p> <p>The 16 patients who dropped out were not significantly different to the 132 patients who completed the program.</p>	<p>the home exercise or control group.</p> <p>All patients accounted for: The total drop-out rate was 18%. Reasons for drop-out did not relate to any specific exercise programs. The rate of dropout did not differ between groups.</p> <p>Similar groups: There were no statistically significant differences in the outcome variables between the groups at baseline, except for erector spinae flexibility (intensive training group had significantly better flexibility).</p>
<p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>137 of the 148 data sets were available for the pretherapy, posttherapy, and 6 month after therapy analysis.</p> <p><u>Pain score:</u> There was a significant ($p=0.0001$) reduction in all 3 groups in the greatest and the average pain recorded after therapy, as compared with pretherapy values. There were no significant differences found among the 3 groups. The improvement was maintained at 6 months.</p> <p><u>Pain frequency:</u> Before therapy, 52% of the patients declared that they experienced LBP "continuously", 38% "often", and 10% "sporadically". After treatment there was a significant reduction in the regularity of pain (35% continuously, 36% often, 25% sporadically, 4% totally pain-free). A further, slight improvement was noted at 6 months. There was no significant group differences.</p> <p><u>Disability (Roland and Morris scale):</u> Self-rated disability showed a significant ($p=0.0001$) decrease from pre to post-therapy. There were no significant group differences. A slight improvement in scores was noted at 6 months.</p> <p><u>Objective lumbar spinal mobility:</u> There was a small but significant increase in the range of motion in the sagittal plane (flexion and extension) with no differences among the 3 groups. The ranges of lateral bending and axial rotation showed the greatest improvements in the aerobics and devices group. The difference between the extent of change in the aerobics and devices group compared with the physiotherapy group was significant ($p=0.04$ lateral bending, $p=0.02$ axial rotation).</p> <p><u>Psychosocial variables:</u> There was a highly significant reduction in fear-avoidance beliefs about physical activity in all 3 groups after treatment. Two of the cognitive coping strategies, praying and hoping and catastrophizing, were used to a significantly ($p=0.0001$) lesser extent after therapy.</p>	<p>The mean number of sessions of exercise for the intensive training group was 5, and 3.5 for the home exercise group.</p> <p><u>Lumbar flexion:</u> Immediately after the training period there was a significant difference in the degree of lumbar flexion between the intensive training group compared to the control group ($p<0.05$). This improvement was not maintained at 6 or 12 months. At 12 months lumbar extension was not different from the baseline measures for all study groups.</p> <p><u>Lumbar extension:</u> Six months after the intervention the intensive training group had significant better lumbar extension in comparison to the control group ($p<0.05$). At 12 months lumbar extension was not different from the baseline measures for all study groups.</p> <p><u>Spinal rotation:</u> Immediately after the training period there was a significant difference in spinal rotation between the intensive training group and the control group ($p<0.05$). However, at 12 months, spinal rotation had decreased significantly ($p<0.05$) among all 3 groups from baseline.</p> <p><u>Erector spinae:</u> Flexibility improved in the intensive training group from baseline to 12-month follow-up ($p<0.05$).</p> <p><u>Hamstring flexibility:</u> Flexibility improved in both the intensive and home exercise groups from pre to post-training. This improvement was not maintained at follow-up.</p> <p>The Oswestry Index and back pain intensity decreased significantly in all groups during the 3-month training period. There was no correlation between flexibility, the Oswestry Index or back pain intensity. There was no significant difference between the 3 groups at any time point.</p>
<p>AUTHOR(S) CONCLUSIONS: Limitations, implications for practice and research</p>	<p>"This confirms, experimentally, the conclusion reached by van Tulder et al, after a systematic review of randomised controlled trials assessing common interventions for chronic LBP, that there is strong evidence to substantiate exercise therapy as one of the leading treatments, but that it is not possible to advocate one specific exercise method over another."</p>	<p>"The baseline values of the Oswestry Index and back pain intensity were very low. Therefore, it is unlikely that clinically significant gains would have been possible. So, it is presumed that subjects in this sample had sufficient flexibility to perform their activities of daily living and to cope with their low back pain. On the basis of this study it is not possible to provide any specific, practical rules for</p>

		what constitutes appropriate training dosage, duration or optimal timing.”
<p>OUR COMMENTS: Opportunity for bias, weakness and strength</p>	<p>Potential for bias: A well-designed trial. However, because participants were volunteers who responded to a media advertisement, they may not be representative of all patients with chronic LBP.</p> <p>Strength/s: The self-rating assessment was initially pilot tested. Adequate randomisation method. Sample size was determined statistically. Intention-to-treat analysis. Well-defined inclusion and exclusion criteria. Compliance rates for therapy were above 80%, and similar in all 3 groups.</p>	<p>Potential for bias: Patients were not truly randomised to the treatment groups. Physiotherapists who conducted the flexibility measurements were not blinded to the treatment regime of the subject. Patients may differ in their subjective assessment of back pain.</p> <p>Weakness/es: Application of these results to patients with more severe pain or limitations should be undertaken with caution. Randomisation method not specified.</p>

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APPENDIX 1

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Levels Of Evidence

Based on "How to use the evidence: assessment and application of scientific evidence" (National Health & Medical Research Council, Canberra, 2000):

- | | |
|-----------|--|
| Level I | Evidence obtained from a systematic review (or meta-analysis) of all relevant randomised controlled trials. |
| Level II | Evidence obtained from at least one randomised controlled trial. |
| Level III | -1 Evidence obtained from pseudo-randomised controlled trials (alternate allocation or some other method).
-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group.
-3 Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group. |
| Level IV | Evidence obtained from case series, either post-test or pretest/post-test. |

APPENDIX 2

Search strategy

	Search terms for MEDLINE, CINAHL, PREMEDLINE, Current Contents
1	Randomized controlled trial.pt.
2	Controlled clinical trial.pt.
3	Randomized controlled trials.sh.
4	Random allocation.sh.
5	Double blind method.sh.
6	Single-blind method.sh.
7	or/1-6
8	(animal not human).sh.
9	7 not 8
10	Clinical trial.pt.
11	Exp clinical trials/
12	(clin\$ adj25 trial\$).ti,ab.
13	((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
14	Placebos.sh.
15	Placebo\$.ti,ab.
16	Random\$.ti,ab.
17	Research design.sh.
18	or/10-17
19	18 not 8
20	19 not 9
21	Comparative study.sh.
22	Exp evaluation studies/
23	Follow up studies.sh.
24	Prospective studies.sh.
25	(control\$ or prospective\$ or volunteer\$).ti,ab.
26	or/21-25
27	26 not 8
28	27 not (9 or 20)
29	9 or 20 or 28
30	Low back pain/
31	(low adj back adj pain).mp.
32	(lumbar adj pain).mp.

33	or/30-32
34	EXERCISE/ or EXERCISE THERAPY/ or exercise.mp.
35	29 and 33 and 34
36	Limit 35 to (English language and yr=1999-2002)

ABBREVIATIONS

CSA	Cross-sectional area
HDL	High-density lipoprotein
LBP	Low back pain
PA	Paravertebral muscles
PDI	Pain and Disability Index
RCT	Randomised Controlled Trial