

## Motor Control Exercise for Chronic Low Back Pain: A Randomized Placebo-Controlled Trial

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**Background.** The evidence that exercise intervention is effective for treatment of chronic low back pain comes from trials that are not placebo-controlled.

**Objective.** The purpose of this study was to investigate the efficacy of motor control exercise for people with chronic low back pain.

**Design.** This was a randomized, placebo-controlled trial.

**Setting.** The study was conducted in an outpatient physical therapy department in Australia.

**Patients.** The participants were 154 patients with chronic low back pain of more than 12 weeks' duration.

**Intervention.** Twelve sessions of motor control exercise (ie, exercises designed to improve function of specific muscles of the low back region and the control of posture and movement) or placebo (ie, detuned ultrasound therapy and detuned short-wave therapy) were conducted over 8 weeks.

**Measurements.** Primary outcomes were pain intensity, activity (measured by the Patient-Specific Functional Scale), and patient's global impression of recovery measured at 2 months. Secondary outcomes were pain; activity (measured by the Patient-Specific Functional Scale); patient's global impression of recovery measured at 6 and 12 months; activity limitation (measured by the Roland-Morris Disability Questionnaire) at 2, 6, and 12 months; and risk of persistent or recurrent pain at 12 months.

**Results.** The exercise intervention improved activity and patient's global impression of recovery but did not clearly reduce pain at 2 months. The mean effect of exercise on activity (measured by the Patient-Specific Functional Scale) was 1.1 points (95% confidence interval [CI]=0.3 to 1.8), the mean effect on global impression of recovery was 1.5 points (95% CI=0.4 to 2.5), and the mean effect on pain was 0.9 points (95% CI=-0.01 to 1.8), all measured on 11-point scales. Secondary outcomes also favored motor control exercise.

**Limitation.** Clinicians could not be blinded to the intervention they provided.

**Conclusions.** Motor control exercise produced short-term improvements in global impression of recovery and activity, but not pain, for people with chronic low back pain. Most of the effects observed in the short term were maintained at the 6- and 12-month follow-ups.

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## Motor Control Exercise for Chronic Low Back Pain

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Low back pain is a major health and socioeconomic problem and is associated with high costs in care, work absenteeism, and disability worldwide.<sup>1–3</sup> A recent inception cohort study demonstrated that 43% of patients with acute low back pain seen in primary care settings developed chronic low back pain and that nearly a third of them did not recover within 1 year.<sup>4</sup>

Exercise is endorsed as an effective treatment for chronic low back pain in most clinical practice guidelines.<sup>1–3</sup> However, at present, there are no placebo-controlled trials of exercise for chronic low back pain.<sup>5,6</sup> The positive recommendations in guidelines are derived instead from trials comparing exercise with usual care,<sup>7,8</sup> with a waiting list,<sup>9</sup> or with no treatment.<sup>10</sup> These trials do not control for placebo effects and potentially provide biased estimates of the effect of exercise because they do not control for changes in patient and assessor behavior caused by knowledge of treatment allocation.<sup>11,12</sup>

Motor control exercise (also known as *specific stabilization exercise*) was first considered as a treatment for low back pain about 13 years ago, when a group of researchers from The University of Queensland in Australia published the first article on this topic.<sup>13</sup> Since then the number of studies on this topic,<sup>14–16</sup> as well as its popularity and use in clinical practice, have increased.

The biological rationale for motor control exercise is fundamentally based on the idea that the stability and control of the spine are altered in people with low back pain.<sup>13</sup> Physiological studies have demonstrated that patients with low back pain may exhibit a delayed onset of activity of the deep trunk muscles (eg, transversus abdominis, multifidus) when the stability of the spine is

challenged in dynamic tasks.<sup>17,18</sup> Morphologically, a lower cross-sectional area<sup>19</sup> and a larger percentage of intramuscular fat in the multifidus muscle<sup>20</sup> were found in patients with low back pain compared with asymptomatic controls. Moreover, it was found that patients with low back pain tend to increase the spinal stiffness to compensate for the lack of stability from the deep muscles by increasing the activity of the superficial muscles.<sup>21</sup> Finally, it was demonstrated that patients who recovered from an episode of acute low back pain are more susceptible to recurrence and chronicity if these changes were not treated with motor control exercise.<sup>22</sup>

A large number of clinical trials on this topic have been performed, and 3 systematic reviews are now available.<sup>14–16</sup> The most recent systematic review was confined to clinical trials of motor control exercise for patients with chronic low back pain<sup>15</sup> and, as an advantage from the 2 previous systematic reviews,<sup>14,16</sup> a meta-analysis approach was used. This review identified 13 randomized controlled trials and 1 quasi-randomized controlled trial, all of which compared motor control exercise with other treatments (eg, spinal manipulative therapy, other exercise regimens, education, surgery) or with no treatment. Notably, no



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placebo-controlled trials were identified. In order to establish the efficacy of motor control exercise for chronic low back pain, we conducted the first placebo-controlled trial of this intervention.

## Method

### Setting and Participants

This randomized, placebo-controlled trial was conducted in an outpatient physical therapy department of a university teaching hospital in Sydney, Australia. Consecutive patients seeking care for chronic low back pain were screened for eligibility. To be eligible for inclusion, participants had to have *nonspecific low back pain* (defined as pain and discomfort) localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain of at least 3 months' duration; be currently seeking care for low back pain; be aged between 18 and 80 years; comprehend English; and expect to continue residing in the study region for the study duration. In addition, potential participants underwent a simple trunk muscle test to determine that motor control exercise treatment was indicated.<sup>23,24</sup> Exclusion criteria were suspected or confirmed spinal pathology (eg, tumor, infection, fracture, inflammatory disease), pregnancy, nerve root compromise, previous spinal surgery, major surgery scheduled during treatment or follow-up period, and presence of any contraindication to exercise,<sup>25</sup> ultrasound, or shortwave therapy.

### Randomization and Interventions

The randomization sequence was computer-generated by one of the investigators who was not involved in recruitment of participants. The sequence was blocked (block sizes of 4, 6, and 8, in random order). Allocation was concealed in sequentially numbered, sealed, opaque envelopes. Eligible patients were allo-

cated to treatment groups by the physical therapist who opened the next-numbered envelope.

Participants in each group received 12 half-hour treatments over an 8-week period (2 sessions per week in the first month and 1 session per week in the second month). The placebo treatment was designed to be structurally equivalent<sup>26</sup> to the active intervention, providing similar contact time with the physical therapist. Both interventions were provided by 3 senior physical therapists who received training from experts in motor control exercise and placebo interventions. This training included a 1-day workshop prior to the commencement of the study and 3 half-day follow-up sessions during the trial period. Random audits and regular meetings provided by the same experts were conducted during the trial to monitor delivery of interventions. No deviations from the treatment protocol were observed during the audits.

The motor control exercise program was based on the treatment approach described in previous publications.<sup>7,8,27,28</sup> At the first session, participants were comprehensively assessed by the physical therapist, who prescribed exercises that were individualized based on the participant's presentation. The exercises were designed to improve function of specific muscles of the low back region and control of posture and movement.

The motor control exercise program involved 2 stages. Each participant was progressed through the stages according to specific criteria that should be met in each stage.<sup>23</sup> The 2 stages and their main objectives were:

- Stage 1. Train coordinated activity of the trunk muscles, including independent activation of the deeper

muscles (including transversus abdominis and multifidus) and reduce overactivity of specific superficial muscles in an individualized manner.

- Stage 2. Implement precision of the desired coordination and train these skills in static tasks and incorporate them into dynamic tasks and functional positions.

Stage 1 of the exercise program involved retraining of the multifidus and transversus abdominis muscles. These exercises were supplemented with exercises for the pelvic-floor muscles, breathing control, and control of spinal posture and movement. The specific muscles that were trained depended on the initial assessment. Participants were taught how to contract these muscles independently from the superficial trunk muscles.<sup>27,29</sup> Physical therapists used real-time ultrasound biofeedback to enhance learning of the tasks. The exercises were progressed until the patient was able to maintain isolated contractions of the target muscles for 10 repetitions of 10 seconds each while maintaining normal respiration.<sup>27</sup> When this level of competence was achieved, patients were considered ready to progress to stage 2.

Stage 2 of the exercise program involved increasing the complexity of the exercise by progressing through a range of functional tasks and exercises targeting coordination of trunk and limb movement, maintenance of optimal trunk stability, and improvement of posture and movement patterns. Participants required the ongoing support of a trained physical therapist to ensure correct performance of the exercises. The participants were instructed to perform a daily set of home exercises. These exercises were performed at the same level and in the same position as those demonstrated during the treatment session. Session 12 was a

discharge session in which the patient's progress was reviewed and exercises were prescribed to be continued at home. A more comprehensive description of the motor control intervention is presented online at [www.ptjournal.org](http://www.ptjournal.org).

The placebo intervention consisted of 20 minutes of detuned shortwave diathermy and 5 minutes of detuned ultrasound for 12 sessions over an 8-week period. This form of placebo was used because the detuned machines do not provide a specific treatment effect, but it has been established in previous trials<sup>30-32</sup> that participants view this intervention as credible. To ensure the perceived credibility of the placebo intervention, physical therapists followed the usual clinical routine for the delivery of the active form of these 2 treatments (ie, by checking for contraindications, monitoring changes in symptoms, adjusting the detuned devices, and appearing to progress the treatment). Each placebo treatment session lasted 30 minutes to match the duration of active treatment sessions.

A careful explanation was provided to patients to ensure they remained blinded to treatment allocation. We used the following description for the patients: "In this trial, normal physical therapy treatment and placebo physical therapy treatment will be provided. A placebo treatment is a harmless treatment delivered at less than the effective dose. We will not tell you which type of treatment you will receive, and it is unlikely that you could distinguish them." The trial staff described the placebo intervention as "pulsed ultrasound and pulsed shortwave" and explained to patients that they probably would not feel any sensation during treatment. The active forms of these treatments delivered in pulsed mode do not produce heat; thus, previous experience with the treat-

ments would not unblind participants. The sham machines were identical to active machines (eg, the on and off lights illuminated, the output dial moved), except that they did not provide output. The nature of the interventions precluded blinding of the treatment provider.

### Outcomes and Follow-up

Measurements of outcomes were obtained at baseline and at follow-up appointments 2, 6, and 12 months after randomization. Primary outcomes were nominated in the trial protocol.<sup>24</sup> The primary outcomes were pain intensity over the previous week (measured with a 0-10 numeric rating scale [NRS]),<sup>33</sup> activity (measured with the 0-10 Patient-Specific Functional Scale [PSFS]),<sup>34</sup> and global impression of recovery (measured with the -5 to +5 Global Perceived Effect Scale [GPE]) at 2 months.<sup>35</sup> Secondary outcomes were pain intensity over the previous week, activity (measured with the PSFS), patient's global impression of recovery measured at 6 and 12 months, and activity limitation (measured with the 0-24 Roland-Morris Disability Questionnaire [RMDQ])<sup>36</sup> at 2, 6, and 12 months. Table 1 presents the description of each of these outcome measures. Participants reported their outcomes by telephone interview to an investigator who was blinded to the treatment allocation. Patients were asked not to discuss any aspect of their treatment with the assessor.

We also measured recovery and recurrence at 12 months. Patients were considered to have recovered if they reported that they had become pain-free and this pain-free period lasted for at least 1 month.<sup>37</sup> Recurrences could only occur in patients who had recovered. *Recurrence* was defined as a new episode of low back pain that persisted for more than 24 hours.<sup>37,38</sup>

Baseline data were collected prior to randomization. The baseline data included all outcome measurements and the participant's characteristics (age, sex, ethnicity, religion, weight, height, level of education, and employment status). In addition, we collected information about depressive symptoms (measured with the Depression Anxiety Stress Scales [DASS-21])<sup>39,40</sup> to test whether the effect of the exercise intervention on primary outcomes was influenced by the DASS-21 depression score. We chose to investigate depression as a possible effect modifier, first because depression is common in patients with low back pain<sup>41</sup> and second because there is evidence from cohort studies that depression is associated with poor outcomes in patients with low back pain.<sup>42</sup>

Participants rated treatment credibility (measured with the 0-24 Treatment Credibility Scale)<sup>43</sup> after the first treatment session. They were asked about side effects at 2 months using open-ended questions.<sup>44</sup> At 12 months, patients were asked about treatment satisfaction, measured with a 4-item scale with questions about the therapist (ie, how helpful, friendly, and understanding the physical therapist was) and about the treatment helpfulness in general. At 12 months, patients were asked "Which treatment did you receive? Real physical therapy treatment? Or a sham or pretend treatment?" to check participant blinding.

### Data Analysis

A sample size of 154 participants was nominated in the trial protocol.<sup>24</sup> We allowed for 15% nonadherence to treatment and 15% loss to follow-up, and assumed a correlation of .5 between baseline scores and outcomes. This sample size provides 80% power to detect an effect of exercise of 1 unit on the pain intensity scale (estimated SD=2.0), 1 unit on the PSFS (estimated SD=1.8), 1

**Table 1.**  
Outcome Measures

Measure	Construct	Description
Roland-Morris Disability Questionnaire (RMDQ) <sup>57</sup>	Activity limitation	The RMDQ is a 24-item questionnaire related to normal activities of daily living. Patients are asked to tick the items that they perceive as difficult to perform due to low back pain. Each answer is scaled either 0 (no difficulty) or 1 (difficulty), thus leaving a range of scores from 0 to 24, with a higher score indicating higher levels of activity limitation. This well-known questionnaire has proven to be reliable, <sup>58</sup> valid, <sup>59</sup> and responsive <sup>35</sup> in patients with low back pain.
Patient-Specific Functional Scale (PSFS) <sup>34</sup>	Activity	In the PSFS, patients are asked to identify up to 3 important activities that they are having difficulties with or are unable to perform due to their condition (eg, low back pain). In addition, the patients are asked to rate on an 11-point scale (ranging from 0 ["unable to perform activity"] to 10 ["able to perform activity at preinjury level"]) their current level of ability associated with each activity, with a higher score indicating higher functional ability. This scale has levels of reliability, validity, and responsiveness similar to those of the RMDQ. <sup>35,59</sup>
Pain numerical rating scale (NRS) <sup>60</sup>	Pain intensity	The pain NRS involves asking patients to rate their pain intensity levels over the previous week on an 11-point scale (ranging from 0 ["no pain"] to 10 ["pain as bad as could be"]). The number that the patient states represents his or her pain intensity score. This scale has good measurement properties. <sup>59</sup>
Global Perceived Effect Scale (GPE) <sup>61</sup>	Overall measure of change	The GPE is an 11-point scale that ranges from -5 ("vastly worse") to 0 ("no change") to +5 ("completely recovered"). For all measures of global perceived effect (at baseline and all follow-ups), participants were asked, "Compared to when this episode first started, how would you describe your back these days?" A higher score indicates greater recovery from the condition. This scale has good measurement properties. <sup>62</sup>

unit on the GPE (estimated SD=1.7), and 4 units on the RMDQ (estimated SD=4.9) when the alpha level is set at .05.

Data were double-entered. The statistical analysis was performed on an intention-to-treat basis. The statistician was given coded data and thus was blinded to which group received the exercise intervention.

The mean effects of intervention on pain intensity, activity (measured by the PSFS and RMDQ), and global impression of recovery were calculated using linear mixed models (random intercepts and fixed coefficients), which incorporated terms for treatment, time, and the treatment × time interactions. The effect of time was nonlinear, so time was dummy coded and analyzed as a categorical variable (ie, 3 dummy variables were created for the categories 2, 6, and 12 months). The coefficients of the

treatment × time interactions provided estimates of the effects of the exercise intervention.

To determine whether baseline depression scores modified the effect of exercise, a secondary analysis was conducted in which a higher-level interaction term (baseline DASS-21 depression score × group × time) was added to each of the regression models.<sup>45</sup>

As very few patients recovered, according to our definition of being pain-free for 30 days during the study period, only a small subset of participants could experience a recurrence. To provide a measure relevant to all participants, we created a new outcome called "persistent or recurrent pain," which was coded as "no" for participants who recovered and did not have a recurrent episode within 12 months and "yes" for all other participants. This outcome

was tested in a *post-hoc* analysis and, therefore, was considered as secondary. We calculated confidence intervals (CIs) for the risk difference using the method described by Newcombe based on Wilson's score method, without continuity correction.<sup>46</sup>

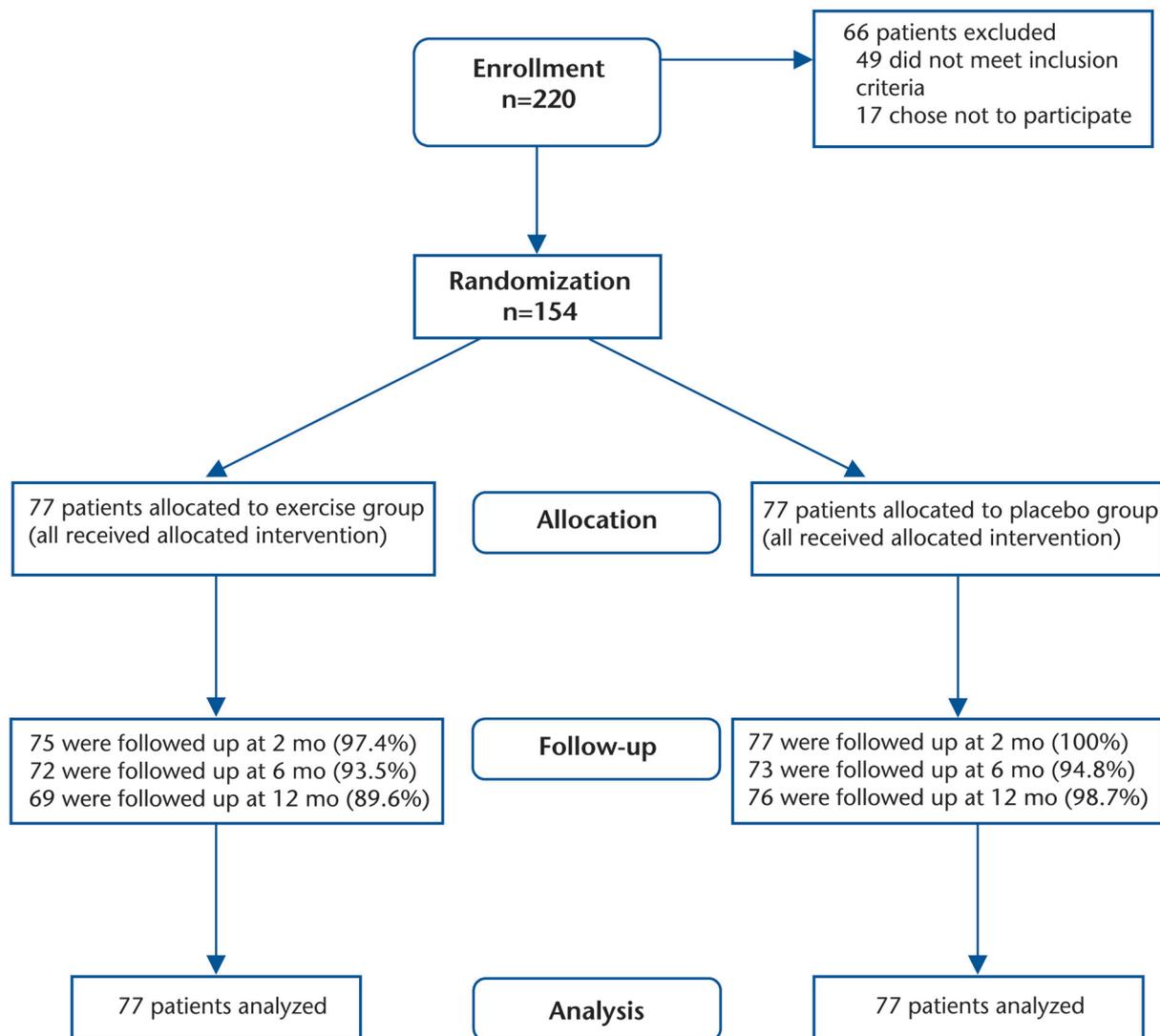
Mixed-models analyses were performed with Stata 9.\* Other analyses were performed with SPSS version 16.0 for Windows.†

**Role of Funding Sources**

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\* StataCorp LP, 4905 Lakeway Dr, College Station, TX 77845.

† SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.



**Figure 1.**  
Study flow diagram.

design, data collection, data analysis, interpretation of data, or writing of the trial report. The investigators had final responsibility in the decision to submit the report for publication. The study was prospectively registered with the Australian Clinical Trials Registry (ACTRN01260500026-2606), and the protocol was published.<sup>24</sup>

**Results**

In total, 220 participants seeking care for low back pain were screened for eligibility between Oc-

tober 2005 and December 2007 (Fig. 1). Seventeen patients chose not to participate, and 49 patients were considered ineligible. The reasons for ineligibility were nerve root compromise (n=9), previous spinal surgery (n=8), serious spinal pathology (n=6), non-English speaker (n=6), scheduled for major treatment or surgery during the follow-up period (n=5), low back pain of less than 12 weeks' duration (n=7), aged older than 80 years (n=1), contraindication to exercise (n=1), unable to commit to attend the treatment ses-

sions due to distance (n=1), and advice from the trial therapists that the patient was not suitable for motor control exercise treatment due to comorbidities (n=5) (for reasons of bilateral knee replacement, substance abuse, recent epilepsy collapse, vascular claudication, or Erdheim-Chester disease). Results of the simple trunk muscle task indicated that motor control exercise was suitable for all tested individuals, and thus no participants were excluded based upon this criterion. Of the 154 participants who were randomly as-

**Table 2.**  
Baseline Characteristics

Characteristic	Exercise Group (n=77)	Placebo Group (n=77)
Age (y), mean (SD)	54.6 (13.0)	52.8 (12.7)
Female, n (%)	45 (58)	48 (62)
Low back pain duration (wk), mean (SD)	334.8 (392.3)	328.2 (395.1)
Height (m), mean (SD)	1.65 (0.09)	1.64 (0.10)
Weight (kg), mean (SD)	74.5 (17.5)	75.9 (15.3)
Smoker, n (%)	21 (27)	19 (25)
Taking analgesics, n (%)	61 (79)	58 (75)
Participating in moderate exercise, n (%) <sup>a</sup>	41 (53)	51 (66)
Work status, n (%)		
Working full-time	6 (8)	13 (17)
Working part-time	5 (7)	3 (4)
Not working	20 (26)	12 (16)
Not seeking employment	46 (60)	49 (64)
Education, n (%)		
School certificate	19 (25)	17 (22)
High school certificate	19 (25)	18 (23)
Trade certificate, diploma, or advanced diploma	9 (11)	15 (20)
Bachelor's degree or higher	15 (19)	12 (15)
Other (lower than school certificate)	15 (20)	15 (20)
General health status, n (%)		
Excellent	3 (4)	8 (10)
Very good	18 (23)	12 (16)
Good	38 (49)	44 (57)
Fair	14 (18)	7 (9)
Poor	4 (5)	6 (8)
Depression Anxiety Stress Scales, mean (SD)		
Depression <sup>b</sup>	11.4 (12.9)	11.2 (13.4)
Anxiety <sup>c</sup>	11.9 (11.1)	11.8 (12.2)
Stress <sup>d</sup>	14.1 (11.8)	14.4 (12.5)
Primary outcome scores, mean (SD)		
Pain intensity <sup>e</sup>	6.8 (2.1)	6.6 (2.0)
Global impression of recovery <sup>f</sup>	-1.9 (2.5)	-2.1 (2.4)
Activity (Patient-Specific Functional Scale) <sup>g</sup>	3.3 (1.7)	3.3 (1.8)
Secondary outcome scores, mean (SD)		
Activity limitation (Roland-Morris Disability Questionnaire) <sup>h</sup>	13.1 (5.0)	13.4 (4.9)

<sup>a</sup> Moderate exercise was any type of exercise of moderate intensity with a duration greater than 30 minutes at least 3 times per week.

<sup>b</sup> Scores range from 0 ("no depression") to 42 ("high depression").

<sup>c</sup> Scores range from 0 ("no anxiety") to 42 ("high anxiety").

<sup>d</sup> Scores range from 0 ("no stress") to 42 ("high stress").

<sup>e</sup> Scores range from 0 ("no pain") to 10 ("worst pain possible").

<sup>f</sup> Scores range from -5 ("vastly worse") to 5 ("completely recovered), with 0 being "unchanged."

<sup>g</sup> Scores range from 0 ("cannot perform activity") to 10 ("can perform activity at preinjury level").

<sup>h</sup> Scores range from 0 ("no disability") to 24 ("high disability").

**Table 3.**  
Credibility and Treatment Evaluation Comparisons

Characteristic	Exercise Group (n=77)	Placebo Group (n=77)
Median credibility scale (IQR <sup>a</sup> )		
How confident do you feel that this treatment can help relieve your pain? <sup>b</sup>	5 (2)	4 (2)
How confident do you feel that this treatment will help you manage your pain? <sup>b</sup>	5 (2)	4 (3)
How confident would you be in recommending this treatment to a friend who suffered from similar complaints? <sup>b</sup>	5 (2)	4 (3)
How logical does this treatment seem to you? <sup>c</sup>	5 (2)	4 (3)
Median treatment evaluation (IQR)		
Therapist helpfulness <sup>d</sup>	5 (2)	5 (2)
Therapist understanding <sup>e</sup>	6 (1)	6 (1)
Therapist friendliness <sup>f</sup>	6 (0)	6 (0)
Treatment helpfulness <sup>d</sup>	4 (2)	4 (3)

<sup>a</sup> IQR=interquartile range.

<sup>b</sup> Scores range from 0 ("not at all confident") to 6 ("absolutely confident").

<sup>c</sup> Scores range from 0 ("not at all logical") to 6 ("very logical").

<sup>d</sup> Scores range from 0 ("not at all helpful") to 6 ("extremely helpful").

<sup>e</sup> Scores range from 0 ("not at all understanding") to 6 ("extremely understanding").

<sup>f</sup> Scores range from 0 ("not at all friendly") to 6 ("extremely friendly").

signed to groups, 152 attended the 2-month follow-up (98.7%) and 145 attended both 6- and 12-month follow-ups (94.2%). No differences were detected between the participants who were lost to follow-up and the patients who were followed up. The characteristics of the participants in the 2 groups were similar at baseline (Tab. 2).

Out of 12 planned treatment sessions, the participants in the exercise group attended a mean of 8.8 sessions (SD=3.5) compared with 9.6 sessions (SD=3.0) for patients allocated to the placebo group. Most of the participants believed that they were allocated to a "real or active" intervention (85% of patients from the exercise group versus 84% of patients from the placebo group). The ratings of treatment satisfaction were similar in both groups, with the medians ranging from 4 to 6 points (on a 0-6 scale) (Tab. 3).

Five patients (2 from the placebo group and 3 from the exercise group) reported mild adverse effects of the interventions. All adverse ef-

fects were temporary exacerbations of pain. None of the patients withdrew from the trial due to adverse effects. Ten patients from the exercise group and 14 patients from the placebo group reported use of interventions during the study period.

The exercise intervention improved activity and the patient's global impressions of recovery (Tab. 4 and Fig. 2). At 2 months, exercise improved activity by a mean of 1.1 points (95% CI=1.8 to 0.3) on the PSFS and improved patient's global impression of recovery by 1.5 points (95% CI=2.5 to 0.4). There was not a clear effect of exercise on pain intensity at 2 months (-0.9 points, 95% CI=-1.8 to 0.0, *P*=.053) or 6 months (-0.5 points, 95% CI=-1.4 to 0.5, *P*=.335), but there was a statistically significant effect at 12 months (-1.0 point, 95% CI=-1.9 to -0.1, *P*=.030) in favor of the exercise group. During the study period, few patients had become pain-free (recovered): 22% of the patients in the exercise group and 9% in the placebo group recovered. Ten percent of the exercise group and 7% of

the placebo group recovered but then experienced a recurrence within 12 months. Consequently, 88% of the exercise group and 98% of the placebo group were categorized at 12 months as having persistent or recurrent pain (absolute risk reduction=10%, 95% CI=1% to 19%, number needed to treat=10).

Exercise improved activity limitation (measured by the RMDQ) at 2 months (-2.7 points, 95% CI=-4.4 to -0.9) and 6 months (-2.2 points, 95% CI=-4.0 to -0.5), but the differences were smaller and no longer significant at 12 months (difference=1.0 point, 95% CI=-2.8 to 0.8). Finally, there was no evidence that depression was a predictor of response to treatment at 2 months for pain intensity ( $\beta$ =-.03, 95% CI=-0.10 to 0.04), global impression of recovery ( $\beta$ =-.05, 95% CI=-0.23 to 0.13), or activity ( $\beta$ =.10, 95% CI=-0.07 to 0.27).

### Discussion

This is the first randomized, placebo-controlled trial of motor control exercise for chronic low back pain. We

**Table 4.**  
Effects of Exercise Versus Placebo<sup>a</sup>

Variable	Unadjusted Mean Outcome (SD)		Exercise Group Versus Placebo Group	
	Exercise Group	Placebo Group	Adjusted Treatment Effect (95% CI)	P
Pain <sup>b</sup>				
2 mo	4.6 (2.8)	5.6 (2.6)	-0.9 (-1.8 to 0.0)	.053
6 mo	5.0 (2.9)	5.6 (2.5)	-0.5 (-1.4 to 0.5)	.335
12 mo	5.0 (2.9)	6.3 (2.3)	-1.0 (-1.9 to -0.1)	.030
Global impression of recovery <sup>c</sup>				
2 mo	1.3 (3.2)	0.0 (3.1)	1.5 (0.4 to 2.5)	.005
6 mo	1.5 (2.6)	0.3 (3.0)	1.4 (0.3 to 2.4)	.010
12 mo	1.2 (2.7)	-0.3 (2.9)	1.6 (0.6 to 2.6)	.003
Activity <sup>d</sup>				
2 mo	5.2 (2.4)	4.1 (2.3)	1.1 (0.3 to 1.8)	.004
6 mo	5.3 (2.7)	4.3 (2.6)	1.0 (0.3 to 1.8)	.007
12 mo	5.5 (2.6)	4.0 (2.6)	1.5 (0.7 to 2.2)	<.001
Activity limitation <sup>e</sup>				
2 mo	9.6 (6.5)	11.9 (5.9)	-2.7 (-4.4 to -0.9)	.003
6 mo	10.3 (7.0)	12.2 (6.7)	-2.2 (-4.0 to -0.5)	.014
12 mo	11.4 (7.8)	12.3 (6.4)	-1.0 (-2.8 to 0.8)	.271

<sup>a</sup> Primary outcomes are highlighted. CI=confidence interval.  
<sup>b</sup> Measured with a numerical rating scale, with scores ranging from 0 ("no pain") to 10 ("worst pain possible").  
<sup>c</sup> Scores ranged from -5 ("vastly worse") to 5 ("completely recovered"), with 0 being "unchanged."  
<sup>d</sup> Measured with Patient-Specific Functional Scale, with participant selecting 3 activities and rating his or her ability to perform the activity on from 0 ("cannot perform activity") to 10 ("can perform activity at preinjury level"). Summary score is the mean of the 3 activities.  
<sup>e</sup> Measured with Roland-Morris Disability Questionnaire, with scores ranging from 0 ("no disability") to 24 ("high disability").

found evidence of a beneficial, but small, effect of motor control exercise on global impression of recovery, activity, and activity limitation (measured by the PSFS and RDMQ, respectively) at 2 months and on "persistent or recurrent pain" at 12 months, but not pain intensity at 2 and 6 months and activity limitation (measured by the RMDQ) at 12 months. Most of the effects observed at short-term follow-up were maintained 12 months after randomization. We also found that the effect of motor control exercise was not influenced by the level of depressive symptoms.

Our interpretation of the trial results is that exercise produces small clin-

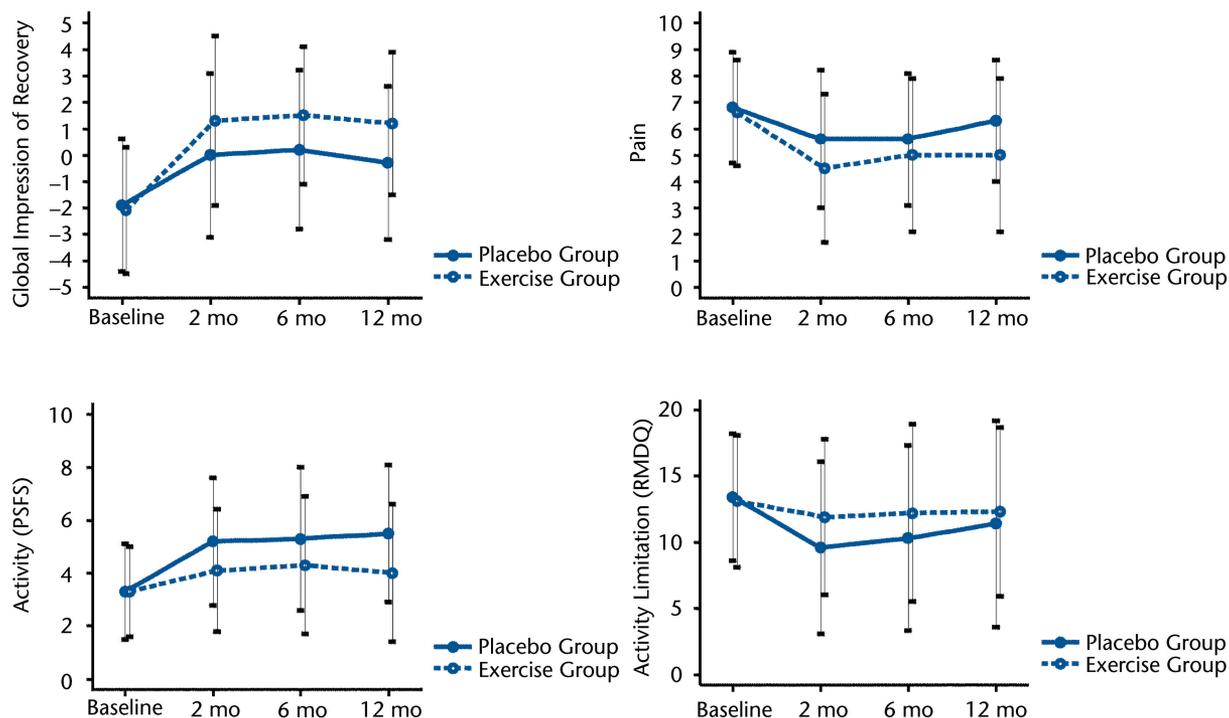
ical improvements, but complete recovery is unlikely in this nonspecific population. Some patients and clinicians may not consider these effects clinically worthwhile. The effects are smaller than benchmarks for clinically important effects suggested by expert researchers in the low back pain field<sup>47,48</sup> and in recent clinical practice guidelines.<sup>2</sup> However, we acknowledge that consensus has not been reached on this issue among back pain researchers, and one study of patients with low back pain<sup>49</sup> revealed an even wider range of views on how big an improvement in outcomes needs to be before it is considered worthwhile. Given this diversity of views, clinicians may need to spend some time with patients

considering motor control exercise treatment, outlining the likely outcomes, and assisting them to decide whether they want to pursue the treatment.

The mean effects of exercise treatment were smaller than has been reported in some trials<sup>5,11</sup>; however, these trials included features associated with exaggerated treatment effects, such as lack of patient blinding and absence of controlling for placebo effects. Our use of a placebo-controlled design provides control of potentially important sources of bias, so the effects of treatment that we observed are less likely to be exaggerated than the effects observed in non-placebo-controlled trials.<sup>11</sup>

The exact biological basis for the efficacy of motor control exercise in patients with low back pain is still unclear,<sup>50</sup> but if subjects can be taught to control their trunk muscles while performing functional activities, then this may explain the improvements seen in activity, activity limitation, and global impression of recovery.<sup>19,22</sup> There is some evidence that this training can change trunk muscle behavior during functional tasks.<sup>51,52</sup> A range of mechanisms have been proposed to explain the effect of motor control training on pain. These mechanisms include reduced load and improved quality of movement<sup>53</sup> as a result of improved coordination of trunk muscles. Such changes in control may be mediated by plastic changes at the motor cortex or elsewhere in the motor system.<sup>54</sup>

Our study demonstrated that motor control exercise produced a small reduction in the risk for persistent pain at 12 months. This finding is supported by earlier work<sup>22</sup> suggesting that patients who have continuing impairment of the deep trunk muscles experience more recurrent low back pain episodes. This earlier



**Figure 2.**

Outcomes in the 2 treatment groups. Values shown are unadjusted means (SDs). Measurements were obtained at baseline and at 2, 6, and 12 months, but the data are slightly offset in the figure for clarity. Higher scores represent better outcomes for global impression of recovery and disability, and lower scores represent better outcomes for pain and function. PSFS=Patient-Specific Functional Scale, RMDQ=Roland-Morris Disability Questionnaire.

work<sup>22</sup> provides a rationale for why those in the exercise group, who re-trained the deep trunk muscles, experienced less resistant or recurrent pain than those in the placebo group, who had no such training.

This study was performed in an outpatient physical therapy department of a public hospital, and the results of this study should be generalizable to groups of patients with similar characteristics (ie, patients with chronic low back pain for a long time, seeking care for their low back pain problems, with moderate levels of depression and not working). In terms of the intervention, we believe that the motor control exercise intervention implemented in our study was well defined (as described in the Data Supplement), and we are confident that physical therapists with ap-

propriate training would be able to perform this intervention similarly.

Although systematic reviews of the efficacy of exercise for chronic low back pain<sup>5</sup> have generally concluded that exercise is effective, most reviews also signal some uncertainty in their conclusions because of methodological concerns in the available trials. Our trial avoided the main methodological problems of previous trials by using a placebo control and blinding patients and assessors. In addition, the trial was prospectively registered and the trial protocol was published.<sup>24</sup> Lastly, we took steps to ensure treatment quality by using experienced clinicians who were trained to deliver the treatments according to the protocol, and we monitored treatment delivery.

The main limitation of our study was that the trial therapists were not blinded to the treatment allocation. We are unaware of a method to blind therapists in trials of exercise. We tried to minimize the effect of unblinding by training the trial therapists to provide a credible placebo treatment and by auditing placebo treatment sessions. We believe that these steps were effective because scores on credibility and treatment satisfaction were similar in both treatment groups. Nevertheless, we cannot exclude the possibility that the lack of therapist blinding introduced some degree of bias into our results. Another potential limitation of this study was that we were not able to monitor adherence to the home exercise program for the patients allocated to the motor control exercise intervention.

Although it could be argued that our choice of placebo was not perfect, we believe that this choice was the best possible. We do not know of a “placebo exercise” that is both credible and inert. This problem is not unique to the study of exercise, and similar problems with developing an appropriate placebo were found in trials of complex nonpharmaceutical interventions such as spinal manipulative therapy<sup>32,55</sup> and acupuncture.<sup>56</sup> Our selection of sham electrotherapy as a placebo was primarily based upon the knowledge that these machines do not share the same specific components of the exercise intervention and that they have been used successfully in previous randomized controlled trials.<sup>30,32</sup>

Our study provides evidence that motor control exercise was better than placebo in patients with chronic low back pain. Most of the effects observed in the short term were maintained at 6- and 12-month follow-ups, but the magnitude of the effects was small in this population, who have aspects associated with poor outcome. Our results suggest that this intervention should be considered for patients with chronic low back pain in order to improve activity and global impression of recovery and to improve pain intensity in the long term but not the short term.

Dr Costa, Dr Maher, Dr Latimer, Dr Hodges, Dr Refshauge, and Dr McAuley provided concept/idea/research design. Dr Costa, Dr Maher, Dr Latimer, Dr Hodges, Dr Herbert, and Dr McAuley provided writing. Dr Costa, Dr Maher, and Dr Hodges provided data collection. Dr Costa, Dr Maher, Dr Hodges, and Dr Herbert provided data analysis. Dr Costa, Dr Maher, Dr Latimer, Dr Refshauge, Dr McAuley, and Mr Jennings provided project management. Dr Costa, Dr Maher, Dr Latimer, and Dr Refshauge provided fund procurement. Dr Maher and Mr Jennings provided participants. Dr Maher, Dr Refshauge, Dr McAuley, and Mr Jennings provided facilities/equipment. Dr Maher, Dr McAuley, and Mr Jennings provided institu-

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The study protocol was approved by The University of Sydney Human Research Ethics Committee.

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The study was prospectively registered with the Australian Clinical Trials Registry (ACTRN012605000262606), and the protocol was published.<sup>24</sup>

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