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Randomized Controlled Trial of Specific Spinal Stabilization Exercises and Conventional Physiotherapy for Recurrent Low Back Pain

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Study Design. Pragmatic, multicentered randomized controlled trial, with 12-month follow-up.

Objective. To evaluate the effect of adding specific spinal stabilization exercises to conventional physiotherapy for patients with recurrent low back pain (LBP) in the United Kingdom.

Summary of Background Data. Spinal stabilization exercises are a popular form of physiotherapy management for LBP, and previous small-scale studies on specific LBP subgroups have identified improvement in outcomes as a result.

Methods. A total of 97 patients (18–60 years old) with recurrent LBP were recruited. Stratified randomization was undertaken into 2 groups: "conventional," physiotherapy consisting of general active exercise and manual therapy; and conventional physiotherapy plus specific spinal stabilization exercises. Stratifying variables used were laterality of symptoms, duration of symptoms, and Roland Morris Disability Questionnaire score at baseline. Both groups received *The Back Book,* by Roland *et al*. Back-specific functional disability (Roland Morris Disability Questionnaire) at 12 months was the primary outcome. Pain, quality of life, and psychologic measures were also collected at 6 and 12 months. Analysis was by intention to treat.

Results. A total of 68 patients (70%) provided 12-month follow-up data. Both groups showed improved physical functioning, reduced pain intensity, and an improvement in the physical component of quality of life. Mean change in physical functioning, measured by the Roland Morris Disability Questionnaire, was −5.1 (95% confidence interval −6.3 to −3.9) for the specific spinal stabilization exercises group and −5.4 (95% confidence interval −6.5 to −4.2) for the conventional physiotherapy group. No statistically significant differences between the 2 groups were shown for any of the outcomes measured, at any time.

Conclusions. Patients with LBP had improvement with both treatment packages to a similar degree. There was no additional benefit of adding specific spinal stabilization exercises to a conventional physiotherapy package for patients with recurrent LBP.

Key words: physiotherapy, stabilization exercise, randomized controlled trial, exercise, recurrent low back pain, manual therapy. **Spine 2006;31:E670–E681**

Back pain is a common, costly problem, often associated with high recurrence rates[1–4] and equivocal management efficacy. In the United Kingdom, an estimated 9% of patients with back pain per year visit physiotherapists,[5] with 37% of the £1632 million direct health care costs associated with low back pain (LBP) in the United Kingdom estimated to relate to physiotherapy and allied specialists.[6] Physiotherapy treatment of back pain may incorporate many approaches, but conventional treatment is normally individually tailored, and includes advice and education, manual therapy, and exercise.[7–9] Fitness programs[10–13] and general exercise for chronic back pain[14,15] have been effective, but evidence for the effectiveness of "specific" exercise is inconclusive.[14,15] Clinically, this is at odds with much current physiotherapy practice and management.[8,9]

An increasingly common approach used within the physical therapy management of LBP has been low load, high repetition training of the abdominal and trunk muscles (stabilization or muscle imbalance training),[16] developed partially in response to evidence indicating specific neuromuscular alterations in the control and activation of the back and abdominal muscles in the presence of back pain.[17–20] Clinical trials and experimental studies using these types of exercises have shown improved objective and subjective outcomes in specific subgroups of patients with LBP, such as those with radiologic evidence of instability, acute, first-episode LBP, and postpartum pelvic pain.[21–24] However, to our knowledge, the usefulness of these exercises as part of conventional physiotherapy treatment packages, mirroring current use within the United Kingdom, has not been investigated. This article reports the results of a randomized con-

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M.C.C., N.E.F., and C.W. developed the protocol and implemented the study. Carolyn Edwards acted as clinical advisor for the study. M.C.C. carried data collection and N.E.F. data checking. M.C.C. performed the statistical analyses in conjunction with C.W. M.C.C. wrote the original draft with reviewing and redrafting from N.E.F. and C.W. Donald Pennington advised on elements of study design and outcome measures.
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trolled trial (RCT), which tests the additional benefit of spinal stabilization exercises over and above conventional physiotherapy treatment.

■ Subjects and Methods

Design. The study was a multicenter, single-blind RCT, based in secondary care, with 12-month follow-up. The reporting is in accordance with the CONSORT recommendations.[25,26]

Procedure. Participants were recruited following normal referral from a General Practitioner, consultant, or physiotherapy led back pain clinic for routine physiotherapy. Patients attending for physiotherapy assessment were assessed for eligibility for the trial, including assessment of psychologic distress (combined scores of the Modified Zung and Modified Somatic Perception Questionnaire as the Distress Risk Assessment Method)[27] and back-related functional limitation (Roland Morris Disability Questionnaire).[28,29] Eligible patients were identified and invited to participate in the trial. Ethical approval for the study was gained from The University of Birmingham NHS Trust LREC, and all participants gave full informed, written consent. Inclusion criteria were patients with LBP, with or without radiating leg pain, aged between 18 and 60 years, who had had a minimum of 1 previous episode of LBP necessitating alteration in normal activities or for which medical care/intervention had been sought.[18,30] All patients had a Roland Morris Disability Questionnaire score of ≥5 and sufficient proficiency in English to complete the self-report questionnaires. Patients with evidence of distress were excluded because this has increased the risk of poor outcome with physical treatment alone.[27,31] These patients received treatment in the usual way and have previously been reported.[32] Other exclusion criteria are shown in Table 1.

There were 10 senior physiotherapists, with a minimum of 4 years since qualification and 3 years specialization in musculoskeletal care, that delivered both treatment packages. To achieve appropriate expertise,[33] all were experienced in stabilization training, having undertaken recognized postgraduate training courses, and 3 training days as part of the trial, including the use of diagnostic ultrasound to identify correct muscular activation patterns.

Randomization and Blinding. An adaptive stratified randomization procedure was used incorporating minimization,[34–36] using laterality of symptoms (Quebec Task Force for Spinal Diseases Classification categories 1–4),[37] total duration of symptoms (more than or less than 5 years), and Roland Morris Disability Questionnaire score (0–12 or ≥13). Participants' characteristics were assessed against these categories. If the specified category had uneven numbers in each treatment arm, allocation balanced the distribution. If the category was empty or had even numbers in each treatment arm, a coin flip by an independent observer determined patient allocation. Double blinding was not possible, so single blinding, with a credible alternate treatment,[15] was used. Patients were naive to allocation, and therapists had no influence over the randomization process and treatment allocation, and follow-up consisted of patient-completed measures only.

Interventions. Initial assessment lasted 60 minutes, and follow-up sessions lasted 30 minutes. Patients received a maximum of 12 treatment sessions over 12 weeks. No restriction was placed on prescribed or over-the-counter medication. The same physiotherapists delivered both interventions. Details of the content and number of sessions were recorded. Hydrotherapy, back school, or other group therapy was prohibited.

Both groups received standardized educational information based on the best available evidence regarding continuing normal activities and avoiding rest (*The Back Book*).[38] The 2 groups received manual and exercise treatments currently used within UK clinical practice.[39] The protocol allowed treatment to be adapted to individual patient needs, with therapists able to select from a range techniques.

Conventional Treatment Group. Exercises using low load, high repetition muscle activity, as detailed in the Appendix, were excluded. All participating departments had adopted an active approach to back pain management, with encouragement to remain active and the minimal use of more "passive" forms of treatment.[40,41]

Specific Spinal Stabilization Exercise Group. Endurance training for the deep abdominal and back extensor muscles[16] was the predominant component of this treatment group. An outline of the exercises used are detailed in Appendix Table A1. A treatment manual for clinicians outlined appropriate exercise progression, but treatment was individualized at the discretion of the clinician. A patient booklet was developed to emphasis the specific nature of the exercises, outlining anatomy and function of the muscles and the concept of endurance training (Appendix Table A2). Diagnostic ultrasound was available at the discretion of the treating clinician for patients in the stabilization groups if needed. See Appendix for indications for use.

Table 2 provides a summary of components used for both groups. The majority of patients received manual therapy, such as Maitland mobilizations, exercise and advice, with little use of electrotherapy or mechanical lumbar traction. Excluding the

Table 1. Exclusion Criteria

Red flags	Evidence of cauda equina compression
	Nonmechanical LBP
	Clinical presentations suggestive of acute objective motor radiculopathy or nerve root compression, with new or progressive neurologic loss
Surgical	Abdominal surgery within the last 12 months
	Any spinal surgery
Medical	Systemic illness
	Neurologic or muscular degenerative disorders
Other	Pregnancy or less than 1-year postpartum
	Psychologic distress (Distress Risk Assessment Method-Distressed Depressed or Distressed Somatic)

Table 2. Summary of Treatment Components Used in Each Group

No. of Patients Receiving (%)	Conventional Treatment (n = 50)	Stabilization Training (n = 47)
Manual therapy	38 (76)	32 (67)
Exercise*	50 (100)	45 (94)
Advice	41 (82)	40 (83)
Electrotherapy	3 (6)	3 (6)
Lumbar traction	6 (12)	8 (17)

*Exercise other than stability training.

specific stabilization training, the number and type of treatment approaches used were comparable across both groups.

Main Outcome Measures. Baseline demographic data, study variables, and history of current and previous back pain episodes were collected before randomization, immediately after the physical assessment. Standardized study variables consisting of validated, self-reported questionnaires[42,43] were completed before randomization, on completion of treatment (discharge), and by post at 6 and 12 months following discharge. The primary outcome measure was back-related functional disability (Roland Morris Disability Questionnaire) at 12-months, which is a self-report measure scored from 0, representing no back pain-related disability, to 24, representing maximum disability.[28,29]

The Roland Morris Disability Questionnaire is advocated as a "core" outcome measure in LBP trials,[42,44] has proven reliability and validity,[45,46] and known test-retest reliability in various settings.[44,46,47] Secondary outcomes included pain (Short-Form McGill Pain Questionnaire),[48] "usual" pain (11-point numerical rating scale), psychologic distress (Modified Zung[49] and Modified Somatic Perception Questionnaire combined to produce 1 of the 4 Distress Risk Assessment Method classifications[50]), and generic health (Short-Form 36 [SF-36]).[51] Measures such as return to work were not used because pilot work showed that the majority of patients remained at work during episodes.

Statistical Analysis

Sample Size. An a priori sample size was estimated based on the primary outcome measure (Roland Morris Disability Questionnaire) at 12-month follow-up, and assuming 90% power and 5% significance. To detect a clinically meaningful difference of 5 points on the Roland Morris Disability Questionnaire[52] between the group mean changes from baseline to 12-month follow-up, a total sample size of 92 was required. This total was based on a standard deviation (SD) of 6 points, identified from pilot work, and allowed 10% attrition at each follow-up point. Actual power achieved was more than 95%. Reports subsequent to the start of the trial[53] suggest that a change score of 3 points in the Roland Morris Disability Questionnaire should be used in sample size calculations. Based on this, the current study achieved 89% power to detect a 3-point difference between groups at 12 months.

Analysis. Following a random 20% check of the data for accuracy, both per-protocol and intention-to-treat analyses were undertaken. For the intention-to-treat analysis, data of patients who withdrew or failed to respond to follow-up were included until they withdrew, after which the group mean at the missing data point was imputed.[54] All analyses were undertaken using Analysis of Covariance to examine the difference in mean change score, adjusted for baseline values, at 12 months between the 2 groups. All analyses were performed using SPSS, version 13.0 (SPSS, Inc., Chicago, IL).

To address potential biases caused by incomplete follow-up, a sensitivity analysis was undertaken. A best-case scenario of "no-change," using the last available value carried forward, and a "worst-case" scenario of return to baseline value[55] was planned. However, because of the pattern of loss, this resulted in the same value being imputed in both scenarios in 11 cases in the conventional treatment group, which was believed not to be adequately robust. Therefore, the largest improvement and deterioration from baseline were calculated and used to impute data for missing values for the sensitivity analysis. For the "best-case" scenario, the largest group improvement was subtracted from baseline scores and imputed (reduced scores representing improvement). For the "worst case" scenario, the largest group deterioration was added to baseline scores and imputed for missing data (increased scored representing deterioration). The per-protocol analysis presents the results for patients with 12-month follow-up data.

To create a single score that captures all follow-up points and assist in the interpretation of the results, a summary measure was calculated using area under the curve (AUC),[56,57] and this was then used in the Analysis of Covariance. Completers' data were examined in terms of predetermined minimal clinically important differences (MCIDs).

■ Results

Study Population

A total of 221 patients were screened between May 1999 and October 2000, with 97 entering the study, and follow-up data collection completed by January 2002. The main reason for exclusion was evidence of psychologic distress,[27] and these results have been reported elsewhere.[32] Of the 97 patients, 47 were randomized to the specific stabilization group and 50 to the conventional treatment group. Figure 1 shows the progress through the trial. At 12 months, the loss to follow-up is 30% for each group and was within the calculated attrition rates. Patients who failed to respond to 12-month follow-up (nonresponders) were equally distributed between the 2 groups, with 14 (28%) in the specific stabilization group and 15 (32%) in the conventional treatment group, with comparability of baseline demographic and study variables across groups ($P < 0.05$).

Baseline Data

The clinical and demographic characteristics of the groups were well balanced at randomization (Table 3), except for total duration of symptoms, which was slightly longer in the specific stabilization than the conventional treatment group, although not statistically significant. The majority of patients were working (77/97, 79%), with 17/97 (18%) not working because of their back pain. In total, 12% of patients were off sick and 5% unemployed, spread evenly across both groups.

Of 97 patients, 9, evenly spread across both groups, did not complete a course of treatment. Treatment completers and noncompleters were comparable to their individual groups with the exception of the "total duration of symptoms," which was higher in the specific stabilization completers than noncompleters, but not statistically significant. Study variables at baseline across completers and noncompleters were comparable ($P < 0.05$).

Clinical Outcomes

For the primary outcome, both groups improved over time, showing within group changes in Roland Morris Disability Questionnaire of −5.1 (95% confidence interval [CI] −6.3 to −3.9) for the specific stabilization (n = 47) and −5.4 (95% CI −6.5 to −4.2) for the conven-

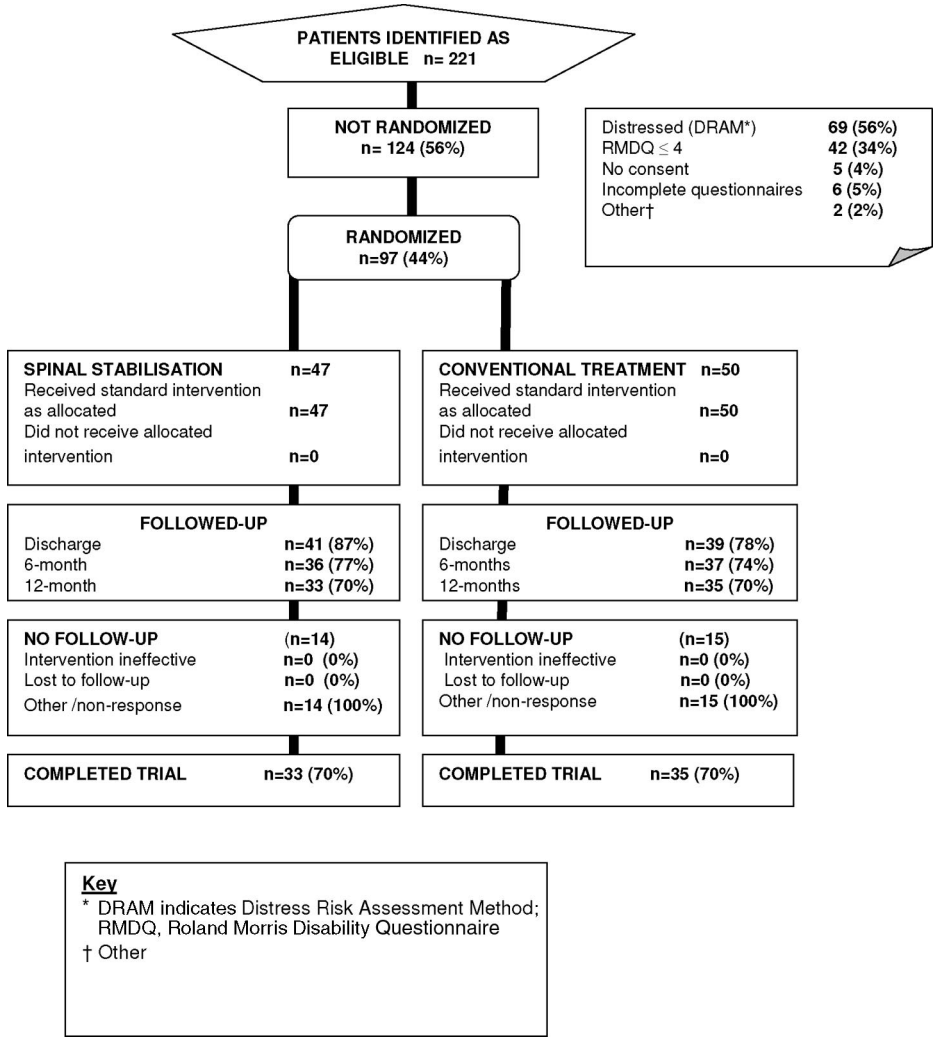

Figure 1. Flow of participants through the trial.

tional treatment group (n = 50) (Figure 2). These changes represent a clinically significant change because they exceed the a priori MCID set for the trial. Table 4 shows mean changes in outcome measures over time and between group differences for the intention-to-treat analysis and Table 5 for the per-protocol analysis. The between group difference for the Roland Morris Disability Questionnaire was small at −0.4 (range −2.0 to 1.3) and was not statistically or clinically significant. The sensitivity analysis undertaken using best and worst case scenarios also showed no statistical significance.

The SF-36 summary score for physical functioning mirrored the improved level of function shown by the Roland Morris Disability Questionnaire and Oswestry Disability Index. Baseline physical functioning scores were consistent with other LBP cohorts,[58,59] with change scores (8.8 and 8.5 specific stabilization and conventional treatment groups, respectively) representing a clinically relevant improvement in self-reporting physical functioning, including bodily pain and general health. However, again, no significant between group differences were seen.

Broadly, the findings from the 12-month follow-up were similar to those seen at discharge and 6 months. Final follow-up results for pain indicated a reduction in both groups for "current" (visual analog scale [VAS]) and "usual" (numerical rating scale) levels, with both groups exceeding the predetermined MCID of 1–1.8-cm change for the VAS[60,61] and 2 points for the numerical rating scale.[62–65] No between group differences were shown for either the VAS or numerical rating scale. Neither treatment package showed clear effects on the psychologic outcomes measured, with a small deterioration in self-reported mental health component of the SF-36, which is unlikely to be clinically meaningful. Distress Risk Assessment Method classifications showed fewer patients "At risk" and more reporting "no distress" at 12 months compared to baseline. However, some patients (4/97) were classified as being distressed at 12 months who had previously been "at risk." Examination of mean Roland Morris Disability Questionnaire at 12 months for these patients showed no change from baseline and a high degree of individual variation, possibly as a result of continuing pain.

Table 6 shows the number of patients, with complete follow-up, in each group having predetermined minimal clinically important changes for the 2 functional measures (Roland Morris Disability Questionnaire and Os-

Table 3. Baseline Characteristics of Patients With Recurrent LBP Included in the Study

Variable	Stabilization (n = 47)	Conventional (n = 50)	*P*
Age	37.5 ys (9.5)	39.9 ys (11.3)	0.26
Height	169.0 cm (10.5)	170.4 cm (10.7)	0.54
Weight	75.4 kg (15.2)	78.3 kg (15.2)	0.36
Current duration of episode	9.6 mos (8.5)	7.9 mos (7.6)	0.10
Total duration	118.2 mos (86.3)	82.0 mos (69.0)	0.06
No. females (%)	25 (53)	25 (50)	0.76
No. pregnancy ≥1 (%)	23 (49)	21 (42)	0.51
No. cesarean sections (%)	6 (13)	1 (2)	0.91
No. not working because of back pain (%)*	10 (21)	7 (14)	0.80
No. smokers (%)	16 (34)	17 (34)	0.99
Roland and Morris Disability questionnaire [0–24]	10.4 (4.3)	10.3 (4.1)	0.96
Oswestry Disability Index [0% to 100%]	24.81 (9.4)	24.64 (9.7)	0.86
Short Form McGill Pain Questionnaire components			
Total [0–45]	11.2 (6.8)	10.6 (7.1)	0.67
Sensory [0–33]	9.0 (5.0)	8.8 (5.3)	0.82
Affective [0–12]	2.2 (2.5)	2.0 (2.5)	0.72
Visual analog scale [0–10]	4.2 (2.00)	4.22 (2.3)	0.93
Present pain intensity [0–3]	2.0 (0.8)	2.2 (1.0)	0.51
Numerical rating scale [0–10]	5.7 (1.8)	5.3 (2.3)	0.37
SF-36 physical component summary [0–50]	31.2 (9.5)	32.2 (9.2)	0.38
SF-36 mental component summary [0–50]	55.5 (6.5)	55.0 (7.7)	0.74
Modified Zung [0–69]	19 (8)	17 (8)	0.21
Modified Somatic Perception Questionnaire [0–33]	4.3 (2.8)	4.5 (4.3)	0.83
Distress Risk Assessment Method classifications			
No. normal (%)	19 (40)	23 (46)	N/A
No. at risk (%)	28 (60)	25 (50)	N/A
No. distressed (%)†	0 (0)	2(4)†	N/A

Values are unadjusted means (SDs) unless stated otherwise. No statistically significant differences between groups were shown between any variables at baseline. Square brackets [ ] represent range of available scores for each outcome.
*Includes those patients employed as well as those not working, and those unemployed because of LBP.
†Includes 2 distressed depressed patients, constituting a protocol violation.
N/A indicates not applicable.

westry Disability Index) and 1 of the pain measure (VAS). For this number, previously reported MCIDs have been used.[52,53,60,61] Baseline and mean change scores are shown for patients with varying symptom duration.

The mean number of treatment sessions was 5.9 (SD 2.3) for the conventional treatment group and 7.5 (SD 2.5) for the specific stabilization group. The mean time period for treatment was 8 weeks (SD 3.6) for the con-

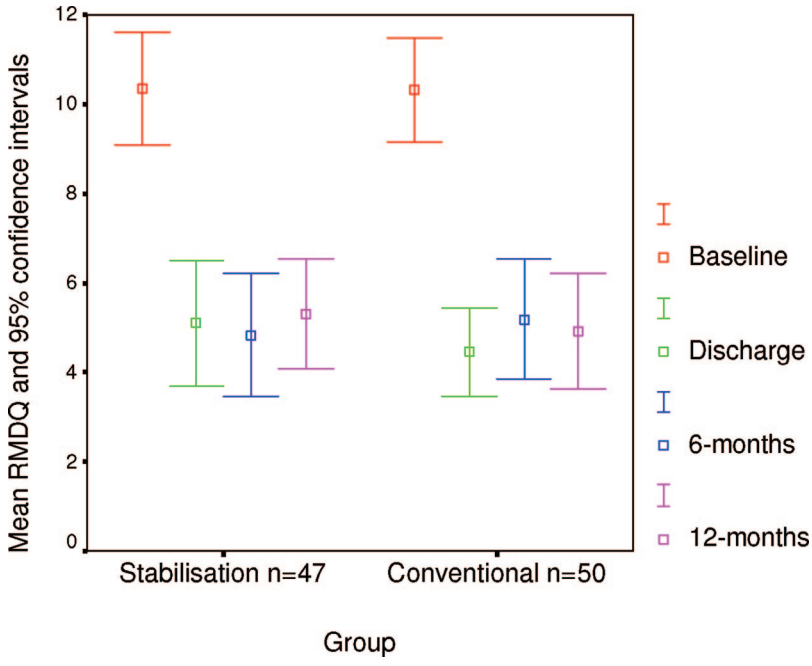

Figure 2. Mean Roland Morris Disability Questionnaire (95% CIs) scores at baseline, discharge, and 6 and 12 months.

Table 4. Mean Change (SD) in Disease-Specific and Generic Outcomes at 12 Months for the Stabilization and Conventional Treatment Groups–Intentional-to-Treat Analysis

	Mean Difference* in Score and 95% CI†			
Primary Outcome Measure	Stabilization Treatment (n = 47)	Conventional Treatment (n = 50)	Difference (95% CI)	*P*
Roland and Morris Disability Questionnaire	−5.1 (−6.3 to −3.9)	−5.4 (−6.5 to −4.2)	−0.4 (−2.0 to 1.3)	0.67
	Mean Difference* in Score and 99% CI†			
Secondary Outcome Measures	Stabilization Treatment (n = 47)	Conventional Treatment (n = 50)	Difference (99% CI)	*P*
Functional Disability				
Roland and Morris Disability Questionnaire AUC‡	−4.9 (−6.2 to −3.6)	−5.3 (−6.6 to −4.1)	−0.5 (−2.3 to 1.4)	0.51
Oswestry Disability Index	−6.1 (−10.2 to −2.0)	−7.0 (−10.9 to −3.0)	0.9 (−6.5 to 4.8)	0.69
Distress/psychologic				
Modified Zung	−2.7 (−5.5 to 0.2)	−3.2 (−6.0 to −0.5)	−0.5 (−4.5 to 3.4)	0.72
Modified Somatic Perception Questionnaire	0.6 (−0.7 to 1.9)	0.7 (−0.6 to 1.9)	0.4 (−1.8 to 1.9)	0.95
	Stabilization Treatment (n = 47)		Conventional Treatment (n = 50)	
Distress Risk Assessment Method	Baseline	12-Months	Baseline	12-Months
Normal (%)	19 (40)	32 (68)	23 (46)	38 (76)
At risk (%)	28 (60)	11 (23)	25 (2)	9 (18)
Distressed depressed (%)	0 (0)	2 (4)	2 (4)§	2 (4)
Distressed somatic (%)	0 (0)	1 (4)	0 (0)	1 (2)
	Mean Difference* in Score and 99% CI†			
	Stabilization Treatment (n = 47)	Conventional Treatment (n = 50)	Difference (99% CI)	*P*
Pain				
Short form McGill Pain Questionnaire				
Total	−1.4 (−3.7 to 0.9)	−3.1 (−5.3 to −0.8)	−1.7 (−4.9 to 1.6)	0.18
Sensory	−1.1 (−2.9 to 0.7)	−2.4 (−4.2 to −0.6)	−1.3 (−3.8 to 1.2)	0.18
Affective	−0.4 (−1.0 to 0.2)	−1.0 (−1.5 to 0.3)	−0.5 (−1.4 to −0.3)	0.10
Visual analog scale	−1.5 (−2.1 to −0.9)	−1.9 (−2.5 to −1.3)	0.4 (−1.2 to 0.5)	0.28
Numerical rating scale	−2.1 (−2.9 to −1.4)	−2.2 (−3.0 to −1.5)	−0.9 (−1.2 to 1.0)	0.83
Quality of life				
SF-36‖ physical component summary	8.8 (4.9–12.7)	8.5 (4.7–12.3)	−0.2 (−5.7 to 5.2)	0.90
SF-36 mental component summary	−3.7 (−6.4 to −1.1)	−3.4 (−6.0 to −0.8)	0.4 (−3.4 to 4.1)	0.78

For all measures except the UK SF-36, negative scores indicate a reduction in the dimension measured (*e.g.*, reduced levels of disability or pain).
*Mean difference adjusted for baseline score.
†Primary outcome analyzed using a 5% α -level and 95% CI are quoted. Secondary outcomes and AUC analyzed using a 1% α -level and 99% CI are quoted.
‡Summary measure of functional level of the previous 12 months.
§Protocol violation.
‖UK SF-36 positive figures represent an improvement in reported health status.

ventional treatment group and 11 weeks (SD 3.6) for the specific stabilization group. These differences were not statistically significant. Overall, after adjustment for baseline scores, no statistical or clinical difference between the 2 treatment groups was seen in any outcome. The results are consistent with no additional benefit of stabilization training to conventional physiotherapy and an advice booklet.

■ Discussion

The current findings, from both the intention-to-treat and per-protocol analysis, indicate that specific spinal stabilization exercises provide no additional benefit, in terms of physical functioning, pain, psychologic distress, and quality of life, over a package of care consisting of advice and conventional physiotherapy (mainly exercise and manual therapy). Both groups had a clinically meaningful improvement in function and reduction in pain over time, but no statistical difference between groups was shown.

In terms of individual patient improvement, overall, a higher percentage of patients in the conventional physiotherapy group had improvement than in the stabilization group and received less treatments over a shorter period. For patients with complete follow-up and where improvement is taken as a change of ≥ 5 on the Roland Morris Disability Questionnaire, more patients who received conventional physiotherapy had improvement compared to those who received stability training: 20/35 (57%) and 16/33 (48%), respectively. Using a 3-point change, the results are similar, with 29/35 (82%) of the

Table 5. Mean Change (SD) in Disease-Specific and Generic Outcomes at 12 Months for the Stabilization and Conventional Treatment Groups-Per-Protocol Analysis

	Mean Difference* in Score and 95% CI†			
Primary Outcome Measure	Stabilization Treatment (n = 33)	Conventional Treatment (n = 35)	Difference (95% CI)	*P*
Roland Morris Disability Questionnaire	−4.5 (−6.2 to −2.9)	−5.2 (−6.7 to −3.6)	0.6 (−2.9 to 1.7)	0.60
	Mean Difference* in Score and 99% CI†			
Functional Disability Outcome Measure	Stabilization Treatment (n = 33)	Conventional Treatment (n = 35)	Difference (99% CI)	*P*
Roland and Morris Disability Questionnaire AUC‡	−4.6 (−6.3 to −3.5)	−5.4 (−6.7 to −4.0)	0.9 (−2.5 to 1.5)	0.61
Oswestry Disability Index	−6.0 (−11.9 to −0.2)	−7.1 (−12.8 to −1.5)	−1.1 (−9.17 to 7.1)	0.73
Distress/psychologic				
Modified Zung	−2.4 (−6.0 to 1.7)	−2.2 (−6.2 to 1.8)	0.1 (−5.37 to 5.9)	0.96
Modified Somatic Perception Questionnaire	0.4 (−1.4 to 2.3)	0.6 (−1.2 to 2.4)	−0.2 (−2.4 to 2.75)	0.87
Distress risk assessment method	Baseline	12-Months	Baseline	12-Months
Normal (%)	14 (42)	18 (55)	18 (51)	23 (66)
At risk (%)	19 (58)	11 (33)	15 (43)	9 (26)
Distressed depressed (%)	0 (0)	2 (6)	2 (6)§	2 (6)
Distressed somatic (%)	0 (0)	2 (6)	0 (0)	1 (3)
	Mean Difference* in Score and CI†			
Pain Outcome Measures	Stabilization Treatment (n = 33)	Conventional Treatment (n = 35)	Difference (95% CI)	*P*
Short Form McGill Questionnaire				
Total	−1.1 (−4.3 to 2.2)	−2.9 (−6.0 to 0.2)	−1.8 (−6.35 to 2.68)	0.29
Sensory	−0.7 (−3.3 to 1.8)	−2.5 (−5.0 to 0.01)	−1.7 (−5.29 to 1.80)	0.20
Affective	−0.35 (−1.2 to 0.5)	−0.84 (−1.7 to 1.1)	−0.5 (−1.72 to 0.73)	0.29
Visual analog scale	−1.2 (−2.1 to −0.4)	−1.8 (−2.6 to −0.9)	−0.5 (−1.75 to 0.72)	0.27
Numerical rating scale	−2.2 (−3.3 to −1.0)	−2.0 (−3.1 to −1.0)	0.1 (−1.45 to 1.68)	0.84
Quality of life				
SF-36‖ Physical Component Summary	8.5 (4.2–12.7)	8.6 (4.4–12.8)	−0.1 (−8.08 to 7.87)	0.97
SF-36 Mental Component Summary	−2.8 (−5.7 to 0.01)	−3.5 (−6.3 to 0.7)	0.7 (−4.66 to 6.07)	0.73

For all measures except the UK SF-36, negative scores indicate a reduction in the dimension measured (*e.g.*, reduced levels of disability or pain).
*Mean difference adjusted for baseline score.
†Primary outcome analyzed using a 5% α -level and 95% CI are quoted. Secondary outcomes and AUC analyzed using a 1% α -level and 99% CI are quoted.
‡Summary measure of functional level of the previous 12 months.
§Protocol violation.
‖UK SF-36 positive figures represent an improvement in reported health status.

conventional management group and 21/33 (63%) of the stabilization group having a 3-point change (Table 6). The number and amount of treatment were recorded for each group and indicated that the conventional treatment group had fewer sessions over a shorter period, although this was not statistically significant. This result potentially has associated cost implications, however, resources prohibited a formal cost analysis, and this should be planned for future trials.

While allowing for individual variation in patient care, pragmatic trial designs are representative of current physiotherapeutic management of LBP and the use of packages of care[8,9] but preclude evaluation of individual components. Although no difference is necessarily synonymous with equivalence, examination of the elements delivered indicated that stabilization training was the main difference between the 2 groups. Little electrotherapy or lumbar traction was used in either group, and therapists were well trained and practiced in incorporating spinal stabilization training in the management of back pain. The exercises used were based on those that have been widely advocated and publicized to promote spinal stability.[66–69] The availability of diagnostic ultrasound for feedback purposes if clinicians believed patients were not progressing adequately ensured that the stabilization group was achieving what was required. As such, we are confident in these findings that concur with those from previous trials that stabilization training in recurrent, nonspecific back pain[70] and chronic LBP[71] is no more effective than either general exercise or a group exercise class involving aerobic exercise, stabilization exercise, and manual therapy, respectively.

Considering the mechanism behind the results of this trial, a number of factors should be regarded. Because, to our knowledge, a valid, reliable measure of core strength is not currently available, this specific construct could

Table 6. Analysis of Clinically Important Improvement for Patients With Complete Data at 12 Months by Group and Chronicity[27,53,54,61,62]

	Stabilization Treatment (n = 33)	Conventional Treatment (n = 35)
Roland and Morris disability questionnaire		
No. using MICD of 5-point change (%)[52]	16 (48)	20 (57)
No. using MCID of 3-point change (%)[53]	21 (63)	29 (82)
Oswestry disability index		
No. using 2–3-point (4% to 6%) change[60]	21	21
VAS (current pain)		
No. using 1.8-cm change[60,61]	14	13

	Stabilization Treatment (n = 33)		Conventional Treatment (n = 35)	
Duration of symptoms for current episode	Baseline (SD) RMDQ	Mean Change (SD) RMDQ	Baseline (SD) RMDQ	Mean change (SD) RMDQ*
<3/12	(n = 5)		(n = 8)	
	12.0 (5.1)	−1.4 (5.3)	8.8 (4.7)	−6.6 (4.2)
≥3/12	(n = 28)		(n = 27)	
	9.4 (4.0)	−5.0 (4.6)	10.6 (3.6)	−4.8 (5.2)

not be measured. As such, it is impossible to attribute directly any observed changes, in either group, to changes in core stability. A number of possibilities may be considered in relation to this point. First, that no change in the core stability occurred in the stabilization group and that the observed improvement has some other etiology. Second, that the core stability improved in both groups and accounts for the observed changes. Third, that the positive results in both groups may simply be attributable to generalized increased activity,[72] rather than any specific changes in core stability. Clinically, improvement was seen in both groups, however, the etiology of that change is unknown and remains a subject of speculation.

The issue of compliance is important in any trial examining the effects of an exercise-based intervention but one that is not without controversy. Although measured informally, which is representative of much clinical practice, it is a limitation of the study that compliance was not formally measured and, therefore, not possible to evaluate fully the effect of compliance on outcome. The use of additional advice (*The Back Book*[38]) may have influenced outcome, but because this was standardized in both groups, any influence should have been consistent across groups.

Traditionally, a "nontreatment" or placebo group is included within RCT design to counteract the effects of natural history. This would have been difficult to implement for ethical and practical reasons, and the use of a credible alternative treatment has been advocated in back pain trials[15] and, therefore, was adopted. Although this must be considered when assessing these results, the magnitude of the group mean changes and small CIs support the likelihood of true change. While all clinicians, in all units, adopted a biopsychosocial approach to patient management, distressed patients were not recruited because of the increased risks of poor outcome.[27] This procedure will affect the generalizability of the results because levels of distress in back pain populations are known to be high[32] and may account for the absence of improvement in the psychologic variables.

Overall, the results from the current study do not support the use of stabilization training in managing patients with recurrent back pain who have no clear evidence of psychologic distress. In contrast, a number of previous studies have shown positive results[20,22,23,73] following stabilization training. A key feature of these studies is well defined, specific subgroups of patients with back pain, such as those with radiologic evidence of spondylolisthesis,[21] immediate postpartum pelvic pain,[22,24] and acute first-episode LBP.[17] However, the clinical reality is that the majority of back pain is not well defined, therefore limiting the extrapolation of findings from such studies. Trials, including "groups" of back pain most frequently encountered clinically, such as subacute, chronic, or recurrent back pain, have generally shown more equivocal results. Often, trials investigating the effects of stability training do not consider, or report, basic information key to interpreting the results of RCTs, such as details of a priori power analyses.[23,73] Only small numbers of participants are often included, and, consequently, such studies are likely to suffer from inadequate power. Attrition, which is almost inevitable from RCTs, is often not considered and incorporated within sample sizes[17,73] with high rates of attrition,[73] which will affect both the validity and reliability of the reported results.

Although trial protocols are increasingly incorporating longer term follow-up,[74] results from trials reporting only immediate posttreatment[75] and short-term follow-ups should be interpreted with care.[70] Positive results from well-designed and appropriately powered trials have been reported.[71,76] Niemistö *et al*[76] examined the effects of manipulation and stabilization training within a package of treatment for chronic LBP compared to physician consultation, including instruction to keep mobile and 3–4 exercises that could conclude muscle stability based on individual assessment. Both groups

also received an educational booklet. Lewis *et al*[71] studied manual therapy and stabilization training on a one-to-one basis compared to an exercise class. Niemistö *et al*[76] showed significant improvement in the manipulation group, including stability training, over the consultation only group, and Lewis *et al*[71] reported significant improvements in both groups but no between group differences in the main outcome (functioning). However, as in the current trial, the effects of any specific element (manipulation, stabilizing, or information, or individual or group treatment) cannot be specified.

The current study was methodologically robust. The sample was adequate for statistical power, randomization was appropriate and successful, and attrition was within anticipated ranges. Statistical analysis was thorough, robust, and included both an intention-to-treat and sensitivity analysis, which all showed consistent results. Although a high level of change was sought in this trial, it was considered justified because the change sought represented one that was clinically significant rather than solely statistically significant. Various levels of change such as 2–3 points,[28,77,78] 2.5–5 for individual patients,[60] and 4.4 in patients with acute LBP have been suggested,[79] but even when these are considered, the power of the current study to detect smaller differences, such as 3 points, remains high (89%).

Laboratory based work has shown clear evidence regarding dysfunction in the core stabilizing system of the spine in the presence of both naturally occurring[80–83] and experimentally induced pain,[84] attention-demanding stressful activities,[19] and even the anticipation of back pain.[85] The theory that addressing that dysfunction should improve function and reduce pain is certainly very plausible, has been shown in a number of subgroups, and is clinically evident in practice.[21–24] However, the translation into positive outcomes from clinically based studies has not been universal. A number of factors will potentially have influenced this, not least the lack of a universally recognized and accepted classification system for LBP.

Historically, within the United Kingdom, but also in many other countries, guidelines discouraged the use of specific diagnoses or classifications of back pain and encouraged the use of terms, such as nonspecific back pain.[40,41] Accordingly, trialists incorporated these terms within trial designs. The consensus opinion now is that there is an urgent need to develop a universal classification system for back pain that will certainly assist in future RCT designs.[86,87] Basically, there is a need to identify which patients do well (or not) with which treatments and which baseline variable might be predicative of response to treatment, such as has been identified with regard to spinal manipulation.[88,89] Extending this procedure to stabilization training may provide useful data. The recent development and publication of a classification system for motor control impairment,[90] which shows good levels of reliability, both between experts and nonexperts is encouraging.[91] This process may be useful to incorporate into future studies examining stabilization training along with any development in multidisciplinary endorsed classifications that are developed.

■ Conclusions

This trial shows that for patients with nonspecific, recurrent LBP, without evidence of psychologic distress, no additional benefit is gained from spinal stabilization exercises over a package of advice, general active exercise, and manual therapy. If it is the case that some groups of patients do benefit from specific spinal stabilization exercises, over and above general active exercises, as recommended in international guidelines,[92] then the challenge remains to identify those patients most likely to benefit.

■ Key Points

- There are strong theoretical arguments and an increasing amount of laboratory based research to support the incorporation of specific spinal exercises into the physiotherapy treatment for patients with LBP.
- There are few good quality RCTs of spinal stabilization exercises as used in routine physiotherapy.
- This study shows there is no added benefit to using specific spinal stabilization exercises for patients with nonspecific, recurrent LBP, over and above a package of conventional treatment that consisted of evidence-based advice (*The Back Book*[38]), general active exercise, and manual therapy.

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■ APPENDIX

Table A1. Specific Spinal Stabilization Regime

General	Outline of plan of treatment. Anatomy and function of transversus and multifidus explained with appropriate visual aids. The need for active participation stressed and the nature of the cognitive motor relearning skill
Position	Choice of starting position is dependent on individual patients
	Four-point kneeling
	Crook side lying
	Crook supine
Basic exercises	Development of a relatively isolated specific contraction TrA and LM
	Repetition of co-contraction of TrA and LM
	Control of lumbo-pelvic neutral
	Control of lumbo-pelvic neutral with increasing load
	Control of lumbo-pelvic neutral with aggravating movement
	Maintaining lumbar spine stability during increasingly complex activities
Facilitation techniques	Pelvic floor contraction
	Visualization
	Palpation
	Identify any substitution techniques (*e.g.,* pelvic tilt)
	Refer for ultrasound feedback if necessary
Progression	Position in which TrA is activated progressed from a supine through sitting and standing and functional activities, depending on individual response
	Incorporation of functional and provocative positions started once good activation and endurance is achieved
	An arbitrary 10 × 10 goal can be used (*i.e.,* 10 repetition of 10-second holds)
Home exercises and compliance	Patient must be 100% sure of what he/she is doing
	In patient booklet write:
	Position
	Order of contraction
	Duration of hold
	Repetitions
	No. contractions per day

Based on [16,42].
LM indicates lumbar multifidus; TrA, transversus abdominis.

Table A2. Summary of Information Presented in the Stabilization Patient Information Booklet

Pages 1 and 2	General introduction and brief description of anatomy and function of the superficial trunk muscles (movement control), and the deep, local muscles attaching directly to the spine and providing core support
Pages 3 and 4	Detailed anatomy and function of TrA and LM, including diagrams, and outline of research to date (*e.g.*, anticipatory, feedforward activation of TrA)
Page 5	The core exercises: TrA and LM contractions introduced
Pages 6 and 7	Abdominal drawing in: description and diagram
Pages 8–10	Notes: space for individual instructions to be written to include position, holds, repetitions, number of exercises per day, and order of contraction
Page 11	Multifidus: description of activation
Pages 12 and 13	Notes: space for individual instructions to be written to include position, holds, repetitions, number of exercises per day, and order of contraction
Page 14	Notes on respiration during activation and progression
Page 15	Co-contraction of TrA and LM: description and diagram
Page 16	"How long will it take?" Information about timings for undertaking exercises and time for improvement
Page 17	Prevention of LBP and suggestion for continuation of stability training longer term
Pages 18 and 19	Spinal anatomy: diagrams
Page 20	Correct sitting posture: diagram
Page 21	General advice (*e.g.*, avoiding sustained postures and lifting)

LBP indicates lower back pain; LM, lumbar multifidus; TrA, transversus abdominis.

Indications for ultrasound: if by second session the patient has not, in the clinician's judgment, understood the basics concept of the position, anatomy and function of transversus abdominis and lumbar multifidus; able to activate transversus in an antigravity position but unable to progress; good transversus activation but unable to achieve multifidus activation.