Clinical Pilates versus General Exercise for Chronic Low Back Pain: Randomized Trial

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[1]DMA Physiotherapy and Clinical Pilates, South Yarra, Victoria, AUSTRALIA; [2]Back in Motion Health Group, Mulgrave, Victoria, AUSTRALIA; and [3]Centre for Health, Exercise and Sports Medicine, Department of Physiotherapy, School of Health Sciences, The University of Melbourne, Parkville, Victoria, AUSTRALIA

ABSTRACT

WAJSWELNER, H., B. METCALF, and K. BENNELL. Clinical Pilates versus General Exercise for Chronic Low Back Pain: Randomized Trial. *Med. Sci. Sports Exerc.*, Vol. 44, No. 7, pp. 1197–1205, 2012. **Purpose**: This single-assessor-blinded randomized controlled trial aimed to compare the efficacy of physiotherapy-delivered clinical Pilates and general exercise for chronic low back pain. **Methods**: Eighty-seven community volunteers with low back pain for ≥3 months and age 18–70 were randomized to either the Pilates (n = 44) or general exercise (n = 43) group. The primary outcome was pain/disability measured with the Quebec scale. Secondary outcomes included pain on a numeric rating scale, Patient-Specific Functional Scale, Pain Self-efficacy Questionnaire, quality of life, and global perceived effect of treatment. All participants attended 60-min exercise sessions twice weekly for 6 wk supervised by a physiotherapist and performed daily home exercises that were continued during the follow-up. Participants from the clinical Pilates group received an individualized direction-specific exercise program prescribed by the physiotherapist after a clinical examination. The general exercise group received a generic set of exercises that were multidirectional and nonspecific. Outcomes were assessed after 6 wk (primary time point) and at 12 and 24 wk. Differences in mean change were compared between groups using ANCOVA adjusted for baseline values of the outcome. **Results**: Eighty-three participants (96%) completed the 6-wk intervention and 60 (69%) completed the 24-wk follow-up. At 6 wk, no difference was found between groups for change in the Quebec scale (3.5, 95% confidence interval = −7.3 to 0.3, P = 0.07); both groups showed significant improvements. Similar results were found at the 12- and 24-wk follow-up and for the secondary outcome measures. **Conclusions**: An individualized clinical Pilates program produced similar beneficial effects on self-reported disability, pain, function and health-related quality of life as a general exercise program in community volunteers with chronic low back pain. **Key Words:** BACK PAIN, EXERCISE, CLINICAL TRIAL, PILATES

In a global context, chronic low back pain (CLBP) generates one of the highest costs in health spending and is a substantial source of morbidity and social impact (23). Exercise plays a role in the management of CLBP with recent systematic reviews showing that exercise is effective in improving pain and function and is more beneficial than passive therapies (1,14,15,19,36). However, the most effective type of exercise remains to be clarified.

Indeed, one of the main controversies in the CLBP and exercise literature is whether specific exercise is needed or whether general exercise is equally effective (14). Specific exercise refers to exercise that is individually prescribed by a health care practitioner based on a patient's clinical details such as direction of movement that aggravates or eases symptoms, history of injury, findings on examination, and response to clinical testing. General exercise, defined as any exercise that is not individually prescribed for patients based on clinical examination, may include exercise such as walking, swimming, cycling, strength training, and stretching. There is currently a lack of evidence supporting one type of exercise over another, and there are currently few studies that adequately compare general and specific exercise programs for CLBP.

Pilates is a method of exercise and movement reeducation based on interpretations of the work and teachings of Josef Pilates (22). Clinical Pilates is a further modification of this

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method adapted for therapeutic use by various health and fitness professionals and can be a form of specific exercise. It involves the use of specialized Pilates equipment to support and guide the movement for the exercises. Clinical Pilates can include exercises that focus on trunk flexion, trunk extension, abdominal and back strengthening, and motor control or stabilization. Despite its popularity, recent systematic reviews with meta-analyses have highlighted the paucity of well-designed clinical trials investigating the effects of clinical Pilates in CLBP (25,31). One review concluded that Pilates-based exercise was superior to minimal intervention for pain in CLBP but was unable to establish its superiority over other forms of exercise (25). However, another meta-analysis where studies with serious methodological flaws were excluded found that Pilates exercise did not improve functionality or pain compared with control and that Pilates exercise was not superior to lumbar stabilization exercise (31).

Given the limited research, it is apparent that further randomized controlled trials are needed. Our primary hypothesis was that a 6-wk individualized clinical Pilates program would result in greater immediate improvements in disability, pain, and function compared with a more traditional general exercise program both delivered by physiotherapists for the management of CLBP.

METHODS

Study design. The design was a parallel single-assessor-blinded randomized controlled trial of a 6-wk intervention with a 1:1 allocation ratio and measurements taken at baseline and 6 wk (primary time point) as well as at 12 and 24 wk (secondary time points). The trial was prospectively registered with the Australia and New Zealand Clinical Trials Registry (ACTRN no. 12609000536268).

Participants. Participants were recruited from the community via local newspaper advertisements in two inner suburban areas of Melbourne, Australia, and via e-mail news items at the University of Melbourne between August 2009 and May 2010. Volunteers underwent telephone screening and clinical examination by a specialist physiotherapist to determine eligibility. The University of Melbourne Human Research Ethics Committee approved the study. All participants provided written informed consent.

Inclusion criteria were as follows: age between 18 and 70 yr, symptoms of pain or stiffness in the lower back with or without lower limb symptoms on most days of the week for more than 3 months (defined as chronic), average pain score in the past week at telephone screening ≥ 4 on an 11-point numeric rating scale (0 = no pain and 10 = worst pain possible), and good understanding of written and spoken English.

The exclusion criteria were as follows: spinal surgery; fever, infection, night sweats or rigors; unexplained weight loss or loss of appetite; history of cancer or malignancy; cauda equina lesion, loss of bladder or bowel control, or saddle paresthesia; pregnancy or the possibility of pregnancy in the next 6 months; spinal fractures or diagnosed osteoporosis; spinal inflammatory disease such as ankylosing spondylitis, rheumatoid arthritis; comorbidities that would prevent exercise; previous participation in a clinical Pilates program or other regular therapeutic back exercise program in the last 6 months; inability to comply with trial requirements; or compensable back pain.

Randomization and group allocation. After baseline assessment, participants were randomly allocated in permuted blocks of six and eight, stratified by age (18–35, 35–55, and 55–70 yr) and gender, to either the clinical Pilates group or the general exercise group. The randomization sequence was generated *a priori* using a computer program by an independent investigator. Allocation was sealed in opaque and consecutively numbered envelopes held centrally. An independent administrator opened the envelopes in sequence and then revealed the group allocation to the physiotherapist just before the participant presented for treatment.

Interventions. Five musculoskeletal physiotherapists located in two accredited private practices and with expertise in the exercise-based treatment of CLBP prescribed and supervised both treatments. The therapists had between 5 and 30 yr of clinical experience. All had completed advanced clinical Pilates training and one had also completed postgraduate research training. The physiotherapists attended an average of 4 h (ranging from 2 to 6 h) of training to familiarize themselves with the trial protocols.

Both interventions comprised an initial 1-h individual session with the physiotherapist whereby an exercise program was prescribed. The therapist could use up to two further 30-min individual sessions to ensure that the participant could perform all exercises safely and effectively. After this, the participant attended group exercise sessions (maximum number of four people) at one of the trial clinics twice a week (60 min) for the 6-wk duration of the program. All sessions were supervised by one of the project physiotherapists. Participants were also requested to perform a smaller number of daily home exercises and to continue with these during the follow-up period. Simple analgesia was permitted, but participants were requested to refrain from seeking other forms of treatment during the trial. Treatment in both groups was provided at no cost to the participant.

The clinical Pilates group received a tailor-made, direction-specific exercise program prescribed by a physiotherapist based on history, aggravating factors, and physical examination. The clinical Pilates exercise program was a series of exercises performed on the reformer and trapeze equipment. The equipment both supports the patient and guides the direction and type of movement required for the prescribed exercises. The exercises were designed to work the patient in a specific direction, for example, flexion, extension, neutral, or to the left or right side. Common to all exercises were concepts of finding and maintaining the spinal comfort range, exercise movement precision, breathing control, correct postural

alignment, central trunk stability, smoothness of movement, and complete range of motion. The clinical Pilates program consisted of 6 to 12 of the equipment-based exercises plus 1–4 home-based clinical Pilates exercises using the floor or simple props such as a chair or wall. Examples of the clinical Pilates exercises in a lumbar flexion direction are listed in Appendix 1 (see Supplemental Digital Content 1, http://links.lww.com/MSS/A151, Example of a clinical Pilates flexion program).

Participants of the general exercise group were taught a standardized generic set of exercises traditionally used by physiotherapists for the management of CLBP. These exercises were chosen via consensus of seven musculoskeletal physiotherapists with expertise in exercise prescription as well as from previous studies of general exercise programs for CLBP (6,15,36). The exercises included stationary bike, leg stretches, upper body weights, theraband, Swiss ball, and floor exercises that were multidirectional and nonspecific in nature (see Appendix 2, Supplemental Digital Content 2, http://links.lww.com/MSS/A152, The general exercise program). Four daily home exercises were given to the general group participants (lumbar twists, lumbar flexion, bridging, and cobra).

Measures. Several self-report questionnaire measures were taken including those recommended in the European Guidelines on Chronic Low Back Pain (1). Baseline and 6-wk outcomes were collected at the research institution, whereas 12- and 24-wk follow-up questionnaires were completed at home and returned by post. Participants were also asked to rate their expectation of a beneficial effect of the intervention on an ordinal scale from 1 to 5 (1 = no effect at all, 2 = minimal improvement, 3 = moderate improvement, 4 = large improvement, 5 = complete recovery) after their first session to investigate whether there was any bias toward a particular exercise method.

The primary outcome measure was pain/disability measured with the Quebec scale (20). This disease-specific measure contains 20 questions about how back pain affects various activities of daily living. It has demonstrated reliability (4,20) and good responsiveness to change (4) and has been recommended for use in clinical trials of CLBP (30).

Several secondary outcomes were collected. Participant's overall assessment of average pain intensity during the previous week was measured with an 11-point numeric rating scale (0 = no pain and 10 = worst pain possible). The reliability and validity of this measure have been well investigated in musculoskeletal conditions (26).

The Patient-Specific Functional Scale was used to assess three main functional limitations as nominated by the participants themselves. It has been used extensively in CLBP research and displays excellent clinometric properties (40). It uses three 11-point numeric rating scales from 0 to 10, with the three scores summed to form a single score out of 30.

The Pain Self-efficacy Questionnaire was used to measure the person's confidence to cope with and manage his/her pain problem, and it has been shown to be reliable and valid for CLBP (28).

Participant-perceived global rating of change in pain and in function (since baseline) were recorded on separate 5-point Likert scales (1 = much worse, 2 = slightly worse, 3 = no change, 4 = slightly better, 5 = much better). This has been shown to be a reliable and valid measure of perceived change in chronic musculoskeletal disorders (18).

Generic health-related quality of life was measured using the Medical Outcomes Study 36-item Short Form (SF-36), which contains eight subscales scaled from 0 to 100, where a higher score represents better health (39). The clinometric properties of the SF-36 have been well established in persons with CLBP (38).

Participant adherence to the intervention was measured by recording the number of exercise class sessions attended (out of a maximum number of 12) as well as by completion of a daily logbook to record home exercise sessions during the 6-wk program (out of a maximum of 42). For the 12- and 24-wk follow-up, participants were asked to self-rate their

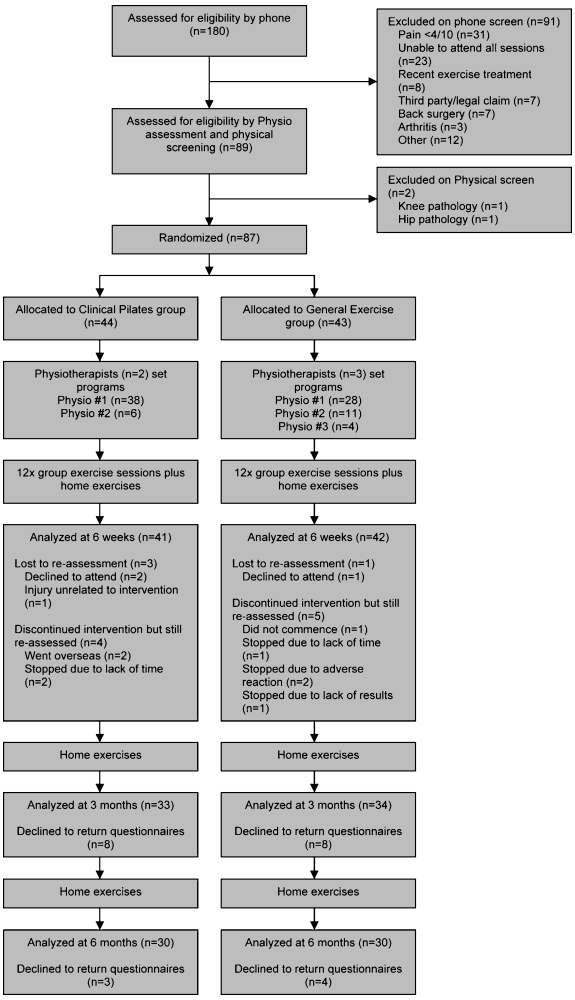

FIGURE 1—Trial flowchart.

TABLE 1. Baseline characteristics of participants.

Characteristics	Pilates (n = 44)	General (n = 43)	P
Age, mean ± SD (yr)	49.3 ± 14.1	48.9 ± 16.4	0.90
Females, n (%)	25 (57)	23 (53)	0.75
Height, mean ± SD (cm)	169.3 ± 8.9	169.0 ± 9.5	0.86
Weight, mean ± SD (kg)	76.3 ± 13.7	75.6 ± 13.9	0.82
Body mass index, mean ± SD (kg·m^{-2})	26.5 ± 4.1	26.4 ± 3.9	0.85
Duration of LBP, mean ± SD (yr)	13.6 ± 14.2	14.2 ± 12.7	0.83
Leg symptoms, n (%)	26 (59)	20 (46)	0.24
Neurological symptoms, n (%)	13 (29)	10 (23)	0.51
Taking medication, n (%)	13 (29)	14 (33)	0.76
Days between baseline and follow-up, mean ± SD	70.1 ± 17.4	63.5 ± 14.9	0.07

home exercise adherence on a scale of 0–10, with a score of 10 indicating full adherence to the prescribed exercise program. Adverse events and the use of cointervention in both groups were recorded in a logbook during the intervention phase.

Power calculation and statistical analysis. The sample size was calculated based on the ability to detect a minimal clinically important difference in change in Quebec Back Pain Scale of 14 points between the two groups with a conservative SD of change of 22 points (4) at the 6-wk time point. This gave an effect size of $d = 0.63$. Based on a two-tailed test with a 5% significance level, power of 80%, and an anticipated 10% dropout rate, 38 participants per group were required.

The primary analysis was by intention-to-treat and was performed in a blinded manner using the Statistical Package for the Social Sciences (SPSS; Norusis/SPSS, Inc., Chicago, IL). A per-protocol analysis was also performed including only those participants who were deemed to be adherent to the exercise program, arbitrarily defined as completing 80% or more of the required exercise days. $P < 0.05$ was considered significant. Comparison of demographic, clinical characteristics, and participant expectation of treatment outcome between groups was performed using independent t-tests or χ^2 analysis as appropriate. All primary and secondary outcomes (except for global rating of change in pain and function) were measured using an essentially continuous scale. For the efficacy analysis of these continuous measures, the change (follow-up minus baseline) at each time point was calculated for each participant. The mean change at each time point (6, 12, and 24 wk) was then compared between groups using separate one-way ANCOVA adjusted for baseline values of the outcome. Results for these are presented as estimated mean differences with 95% confidence intervals (CI). For the global rating of change in pain and function, separate χ^2 analysis was used to compare responses between groups at each follow-up time point. The numbers of exercise classes attended and home exercise sessions performed as well as self-rated adherence were compared between groups using Mann–Whitney U tests. The proportion of participants considered adherent to the exercise program was compared between groups using χ^2 analysis.

RESULTS

Of the 180 respondents to advertising, 87 (48%) were enrolled in the study. Eighty-three participants (96%) completed the 6-wk intervention, 67 (77%) completed the 12-wk follow-up, and 60 (69%) completed the 24-wk follow-up, leaving a total of 30 (68%) of 44 participants in the clinical Pilates group and 30 (70%) of 43 participants in the general exercise group. Figure 1 illustrates the flow of participants through the trial.

TABLE 2. Mean ± SD of groups at baseline and follow-up.

	Groups, Mean ± SD							
	Week 0		Week 6		Week 12		Week 24	
Outcome	Pilates	General	Pilates	General	Pilates	General	Pilates	General
Quebec score (100)	28.1 ± 11.4	23.9 ± 14.0	15.3 ± 9.1*	17.1 ± 13.4*	14.8 ± 10.4*	14.0 ± 15.3*	14.1 ± 10.4*	13.0 ± 11.4*
Pain Score NRS (10)	4.9 ± 1.6	4.6 ± 1.8	2.8 ± 1.6*	3.2 ± 2.1*	3.0 ± 2.3*	2.4 ± 1.7*	2.5 ± 1.8*	2.2 ± 1.7*
Function (PSFS) (30)	11.6 ± 4.4	13.1 ± 5.0	19. ± 6.2*,**	18.9 ± 5.9*	20.4 ± 5.8*	20.0 ± 7.1*	19.2 ± 8.2*	22.8 ± 8.0*
Pain Self-efficacy Questionnaire (60)	43.1 ± 10.6	46.3 ± 9.3	51.2 ± 10.4*	50.7 ± 8.0*	51.7 ± 10.5*	51.5 ± 11.9	50.1 ± 9.2*	52.4 ± 7.6**
SF-36: Physical Function (100)	64.2 ± 16.3	72.1 ± 15.1	74.6 ± 25.0*	77.4 ± 18.1**	80.6 ± 13.0*	79.6 ± 20.0**	75.6 ± 21.1**	83.3 ± 14.1*
SF-36: Role Physical (100)	65.0 ± 21.2	71.9 ± 19.2	77.9 ± 26.7**	79.9 ± 20.6**	81.8 ± 23.0**	83.9 ± 22.8*	82.0 ± 18.1*	87.5 ± 17.0*
SF-36: Bodily Pain (100)	54.5 ± 14.3	61.3 ± 16.4	68.5 ± 22.3*	71.9 ± 18.9*	70.5 ± 22.4*	77.6 ± 19.4*	73.5 ± 18.9*	80.7 ± 15.6*
SF-36: General Health (100)	68.2 ± 21.4	70.1 ± 17.0	71.6 ± 24.4	75.7 ± 14.5**	71.4 ± 20.2	74.4 ± 15.1	74.6 ± 20.2	75.7 ± 15.7
SF-36: Vitality (100)	55.2 ± 20.2	56.8 ± 19.1	61.9 ± 19.9**	62.6 ± 14.8**	63.5 ± 18.4	61.8 ± 17.3	62.7 ± 18.4**	62.1 ± 19.4
SF-36: Social Functioning (100)	73.0 ± 23.7	79.7 ± 16.7	86. ± 24.9*	90.8 ± 15.1*	89.1 ± 16.2*	87.0 ± 18.5	88.8 ± 18.1*	86.3 ± 20.1
SF-36: Role Emotion (100)	84.3 ± 21.9	83.0 ± 19.2	89.6 ± 22.5	91.9 ± 13.1*	91.3 ± 10.8	92.0 ± 13.0**	84.8 ± 20.4	88.9 ± 15.8
SF-36: Mental Health (100)	72.0 ± 17.0	75.7 ± 14.1	76.3 ± 21.8	82.6 ± 8.3*	81.5 ± 9.6**	83.7 ± 7.4**	79.5 ± 13.2	82.0 ± 12.1**

Note that the primary end point is at the 6-wk follow-up.
[a] Means have been adjusted for baseline scores.
* Significant difference at $P < 0.01$ from baseline.
* * Significant difference at $P < 0.05$ from baseline.
PSFS, Patient-Specific Functional Scale; NRS, numeric rating scale.

The groups were similar at baseline for demographic and clinical characteristics (Table 1). The mean age of the cohort was in the late 40s, with an even number of men and women. In general, participants tended to be slightly overweight, as indicated by their body mass index, and have a long duration of back pain. About one-third of participants in the cohort were taking regular medication for their back problem. The participant expectation of treatment outcomes was similar between groups ($P = 0.52$), with 43 (50%) of 86 participants expecting a large or complete beneficial effect. Characteristics of the 27 participants lost to follow-up were similar to those completing the study (data not shown), except that those remaining in the study at the 24-wk time point were significantly older than those who withdrew. Mean ± SD age for those who remained was 51.3 ± 15.0 yr versus 44.3 ± 14.9 yr for those who withdrew ($P = 0.048$).

Efficacy analysis. At 6 wk, both groups showed significant improvements in the primary outcome measure of pain/disability measured with the Quebec scale compared with their baseline scores (Table 2). The difference in change between the groups of 3.5 units (95% CI = −7.3 to 0.3, $F = 3.33$, $P = 0.07$) was not statistically significant but indicated a trend toward greater improvement in the clinical Pilates group compared with the general exercise group. A similar number of participants in the clinical Pilates group, 14 (32%) of 44 participants, improved by a clinically relevant amount (≥14 points on the Quebec scale) as in the general exercise group, 9 (21%) of 43 participants ($P = 0.20$).

For both groups, these significant improvements from baseline for pain/disability were maintained at 12 and 24 wk (Fig. 2). However, there was no significant difference between the two exercise groups when comparing the amount of change from baseline at 12 or 24 wk.

Regarding the secondary outcome measures (Table 2), the general exercise group showed significant improvement in all measures immediately after the intervention, whereas the clinical Pilates groups improved in all measures except the General Health, Emotional Health, and Mental Health domains of the SF-36 scores. There were no significant differences found between the groups in the amount of change after the intervention for the secondary outcomes at the 6-wk time point.

Several of the SF-36 domains were not significantly different from baseline at the 12- and 24-wk time points in either or both of the exercise groups (Table 2). There was no difference between groups comparing the amount of change from baseline at either 12 or 24 wk for any of the secondary outcomes.

There was no significant difference in participant-perceived global change in pain or in function scores comparing groups immediately after the intervention. For the clinical Pilates group, both pain and function were reported to be "slightly better" or "much better" by 32 (73%) of 44 participants. These compared with 32 (74%) of 43 participants for pain and 31 (72%) of 43 participants for function in the general exercise group (pain, $P = 0.38$; function, $P = 0.81$). These scores were also similar between groups at the 12- and 24-wk time points (data not shown).

Adherence to intervention. Thirteen participants (seven from the clinical Pilates group and six from the general exercise group) failed to complete all 12 exercise class sessions. The mean ± SD number of completed exercise class sessions was the same for both groups at 11 ± 3 sessions ($P = 0.90$). The mean ± SD number of days exercises were performed at home was similar in the two groups: 38 ± 6 in the clinical Pilates group and 35 ± 10 in the general exercise group ($P = 0.15$). Satisfactory adherence (completion of ≥80% of the required exercise days) was achieved by 24 (55%) of 44 participants in the clinical Pilates group, which was similar to that in the general exercise group, 21 (49%) of 43 participants ($P = 0.31$).

Table 2. Continued.

Difference Within Groups, Adjusted Mean[a] ± SE						Difference Between Groups, Adjusted Mean[a] (95% CI)		
Week 6 − Week 0		Week 12 − Week 0		Week 24 − Week 0		Week 6 − Week 0	Week 12 − Week 0	Week 24 − Week 0
Pilates	General	Pilates	General	Pilates	General	Pilates − General	Pilates − General	Pilates − General
−11.2 ± 1.4	−7.7 ± 1.3	−9.1 ± 1.9	−8.2 ± 1.9	−11.2 ± 1.8	−9.3 ± 1.8	−3.5 (−7.3 to 0.3)	−0.91 (−6.4 to 4.5)	−2.0 (−7.0 to 3.1)
−1.9 ± 0.3	−1.4 ± 0.3	−1.8 ± 0.3	−2.1 ± 0.3	−2.1 ± 0.3	−2.5 ± 0.3	−0.5 (−1.3 to 0.3)	0.3 (−0.7 to 1.2)	0.3 (−0.6 to 1.2)
7.2 ± 0.9	6.2 ± 0.9	7.5 ± 1.1	6.7 ± 1.1	8.0 ± 1.6	9.1 ± 1.6	1.0 (−1.5 to 3.5)	0.8 (−2.3 to 3.9)	−1.0 (−5.5 to 3.5)
7.0 ± 1.1	4.9 ± 1.0	6.2 ± 1.8	4.2 ± 1.7	6.7 ± 1.9	5.4 ± 1.9	2.1 (−0.8 to 5.1)	1.9 (−3.1 to 6.9)	1.3 (−4.2 to 6.8)
8.5 ± 3.0	6.8 ± 3.0	13.4 ± 2.8	7.5 ± 2.7	8.1 ± 3.0	11.0 ± 3.0	1.7 (−6.9 to 10.4)	5.9 (−2.1 to 13.9)	−2.9 (−11.4 to 5.6)
9.9 ± 3.6	10.2 ± 3.6	12.7 ± 4.1	13.5 ± 4.0	12.4 ± 3.2	16.7 ± 3.2	−0.2 (−10.3 to 9.9)	−0.8 (−12.2 to 10.6)	−4.3 (−13.4 to 4.8)
12.2 ± 3.1	13.0 ± 3.1	11.6 ± 3.7	16.2 ± 3.6	15.9 ± 3.0	19.4 ± 3.0	−0.8 (−9.6 to 8.1)	−4.7 (−15.0 to 5.7)	−3.4 (−12.0 to 5.2)
3.6 ± 2.8	5.9 ± 2.8	1.8 ± 2.7	2.8 ± 2.6	1.2 ± 2.6	2.7 ± 2.6	−2.2 (−10.1 to 5.7)	−1.0 (−8.5 to 6.5)	−1.5 (−8.8 to 5.9)
6.5 ± 2.5	6.8 ± 2.5	6.3 ± 3.3	5.0 ± 3.2	7.2 ± 3.0	5.7 ± 3.0	−0.2 (−7.2 to 6.7)	−1.4 (−7.8 to 10.6)	1.6 (−6.9 to 10.1)
10.0 ± 3.1	13.5 ± 3.1	10.1 ± 3.2	7.6 ± 3.1	12.5 ± 3.3	8.2 ± 3.3	−3.4 (−12.3 to 5.4)	2.5 (−6.6 to 11.5)	4.2 (−5.3 to 13.7)
5.3 ± 2.7	8.3 ± 2.7	7.5 ± 3.0	3.6 ± 2.9	−1.3 ± 3.2	4.3 ± 3.2	−3.0 (−10.6 to 4.7)	3.9 (−4.5 to 12.3)	−5.7 (−14.8 to 3.5)
2.4 ± 2.5	8.1 ± 2.5	6.1 ± 2.8	4.3 ± 2.7	2.1 ± 2.8	6.6 ± 2.8	−5.7 (−12.7 to 1.3)	1.8 (−5.9 to 9.6)	−4.5 (−12.5 to 3.6)

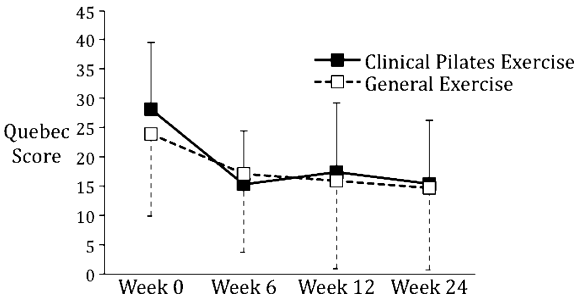

FIGURE 2—Mean ± SD baseline and follow-up scores for the clinical Pilates and general exercise groups on the Quebec scale. Both groups showed significant differences at each time point compared with week 0, but there was no difference between groups.

Reanalysis of the results on the primary outcome measure (Quebec score) including only these adherent participants (per protocol analysis) still showed no significant difference between the two exercise groups at the 6-wk time point ($F = 0.44$, $P = 0.51$). There was also no correlation between the number of days exercised and the change in Quebec score in the cohort as a whole (Spearman ρ, $r = 0.04$, $P = 0.71$), in the clinical Pilates group ($r = -0.11$, $P = 0.49$), or the general exercise group ($r = -0.02$, $P = 0.91$) separately.

Self-rated home exercise adherence during the follow-up period was relatively low but did not differ between groups. At 12 wk, the mean ± SD adherence for the clinical Pilates group was 4 ± 3 versus 5 ± 3 for general exercise ($P = 0.43$). At 24 wk, clinical Pilates adherence was 4 ± 3 versus 5 ± 3 for general exercise ($P = 0.68$).

Cointerventions and medication use. There were few reported cointerventions. One participant in the clinical Pilates group received shoulder treatment, whereas another received treatment to her thoracic spine. One participant in the general group visited her general practitioner to obtain stronger pain medication. Seven participants (16%) in the clinical Pilates group and five (12%) in the general exercise group reported a temporary increase in their usual pain medication during part of the intervention.

Adverse events. In the clinical Pilates group, two participants reported minor shoulder pain and ceased the exercise program for 3–4 d before resuming. One participant experienced knee pain but continued. In the general exercise group, two participants reported worsening back pain causing them to cease the intervention. Two more experienced some back spasms but were able to continue. In summary, slightly fewer adverse events were reported in the clinical Pilates group (7%) than in the general exercise group (10%), and these were less severe in terms of participants being able to resume their exercise program.

DISCUSSION

The results show that a physiotherapist-delivered individualized clinical Pilates program produced similar beneficial effects on self-reported disability, pain, function, and health-related quality of life as a general exercise program in a cohort of community volunteers with CLBP. Both groups showed significant improvements in the majority of outcome measures immediately after the 6-wk exercise intervention and at follow-up. The results do not support the research hypothesis, which postulated that a clinical Pilates program would produce better outcomes than a general exercise program.

Although there was a trend toward greater improvement in the clinical Pilates group for the primary outcome ($P = 0.07$), inadequate statistical power and a type 2 error is unlikely to explain the failure of this result to reach significance. The sample size calculation was based on a minimal clinically important difference (MCID) of 14 points on the Quebec scale as recommended by Kopec (20) and Davidson and Keating (4). Although smaller MCID values have been reported (e.g., 11 points by Hicks and Manal (17) and 8.5 points by van der Roer et al. (35)), the mean difference between groups and the 95% CI was still lower than any of the MCID values found in the literature.

There are several potential explanations for our failure to find a difference in outcome between the exercise groups. The first relates to characteristics of the cohort. In particular, participants reported a mild level of disability possibly reflecting recruitment of community volunteers and the exclusion of people seeking treatment in the past 6 months (37). Thus, there was less scope for improvement than if the disability scores had been higher at baseline.

Patient heterogeneity is also cited as a reason for failure to find differences between therapies for CLBP (7). Subgroups of CLBP patients with certain common characteristics may respond differently to treatment than other groups with different characteristics. Clinical Pilates may have been more effective for some individuals than for others leading to an attenuation of overall treatment effects and thus no difference between the two exercise interventions.

Another possible explanation for the results may relate to the interventions. Because both involved back exercises the two interventions may not have been different enough to cause a differential outcome. Furthermore, the 6-wk intervention period was relatively short, and given a trend toward clinical Pilates being more effective, it is possible that a longer period of intervention may have led to more divergence in outcome between groups. Hayden et al. (14) recommended a minimum of 20 h instruction/supervised intervention, whereas this study used only 12–14 h, which may have been inadequate to achieve optimal results.

The mechanisms underpinning the effectiveness of exercise in reducing pain and disability in CLBP have not been clearly established. Indeed, the similar outcomes of the two exercise programs in this study might suggest that both are able to affect specific physical impairments seen in CLBP, although these were not measured. Furthermore, both exercise interventions may be similarly influencing pain and dysfunction through their effects on psychosocial or cortical factors (9,12).

Both groups showed significant improvements on the primary outcome measure and on the majority of secondary outcome measures immediately after the intervention and at follow-up. These improvements could arise from the specific effects of exercise on physical and psychological parameters as well as from placebo effects or from spontaneous recovery and regression to the mean (21). A recent meta-analysis showed that, for active treatment of chronic pain conditions (not specifically CLBP), placebo effects contribute around 30%, whereas spontaneous improvement contributes around 10% (21). Placebo effects are common in individuals with CLBP, and improvements in pain of up to 32% have been demonstrated with a range of sham treatments including placebo drugs (33). Treatment expectation is also important. Most participants (92%) in this trial expected to experience a moderate to large benefit, or even complete recovery, and such positive expectations are associated with improved outcomes (3). The improvements seen after treatment may also reflect spontaneous recovery (21). Symptoms associated with chronic conditions such as CLBP typically fluctuate over time (24), with patients often seeking medical care or enrolling in research projects when symptoms are at their worst. The next change in symptoms is likely to be an improvement. The tendency for extreme symptoms at baseline to return toward a more typical state at reassessment is known as regression toward the mean (27). Because a third "no treatment" arm was not included in the study design, the influence of spontaneous improvement, or regression to the mean, cannot be assessed. However, this is less likely to account for the improvements seen in both groups given the chronicity of the sample and the fact that 82% of patients with nonrecent onset of pain still have pain 1 yr later (13).

Of the limited number of studies investigating the effects of clinical Pilates for LBP, only two have compared Pilates-based exercise to another form of exercise (8,29). In both studies, Pilates was compared with lumbar-stabilizing exercises. The results of a meta-analysis showed no difference between the two forms of exercise for pain or function, although the sample size was small, with only 15 in the Pilates group and 16 in the lumbar stabilizing group (31).

The other Pilates-based exercise studies reported in the literature have compared Pilates with control groups receiving passive, minimal, or no intervention (2,11,29,32,34) or with a back school approach (5). One recent meta-analysis concluded that Pilates exercise leads to superior pain relief compared with minimal intervention (25). However, another meta-analysis failed to find a benefit of Pilates exercise when clinical trials of lower methodological quality were excluded (31). Numerous other studies have also compared a range of other exercise programs varying in length, content, duration and intensity in patients with CLBP (36). The results of these are consistent with the current study whereby there is a failure to find differences between various exercise approaches in the management of CLBP.

Our study had several strengths including a blinded independent assessor, concealed block randomization, and intention-to-treat analysis. The two groups were comparable at baseline on participant characteristics known to influence response to treatment as well as on outcome measures. Both interventions were delivered by the same treating physiotherapists to minimize differences in therapist style and personality. Dropout rates during the intervention period were low (<5%), whereas exercise adherence was relatively good during the intervention and similar in both groups. The clinical Pilates and general exercise programs were designed to reflect current clinical practice in terms of their content and dosage.

A limitation of the study is that participants were not blinded. However, participants were not informed as to the research hypothesis, and knowledge of the type of exercise being studied did not seem to bias reported treatment outcome expectations. Thus, it is unlikely that any preconceived notion of the benefit of one type of exercise over another had a bearing on the results (3).

Another limitation is that the dropout rate for the 6-month follow-up period was relatively high (approximately 30%). This is likely because the exercises were unsupervised, and there was no contact from the researchers to help maintain motivation. Although dropout can bias results, those participants lost to follow-up had similar baseline and clinical characteristics to those completing the study except that they were, on average, 7 yr younger. The extent to which this influenced the longer-term results is not known.

The study participants were community volunteers, most of who responded to advertisements placed in the print media. Thus, they may differ from patients seeking treatment for their CLBP and perhaps even from volunteers recruited through medical practitioners (10). Furthermore, the results cannot be generalized to compensable patients who were excluded from the study and who have different profiles and longer recovery times than those not receiving compensation (16). The inclusion rate for the study was 48%, with most people being excluded because of low pain levels or inability to attend treatment appointments. Although this inclusion rate may seem low, it largely reflects the fact that the media advertising contained only limited information about study eligibility and treatment details.

CONCLUSIONS

This study showed that specific clinical Pilates exercise programs are as effective in reducing pain and disability and improving function in adults with CLBP as traditional general exercises when both programs are used by physiotherapists. Further research is needed to define whether there are subgroups of patients who respond better to individualized programs.

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