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Different doses of Pilates-based exercise therapy for chronic low back pain: a randomised controlled trial with economic evaluation

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ABSTRACT

Objectives To evaluate the effectiveness and cost-utility of the addition of different doses of Pilates to an advice for non-specific chronic low back pain (NSCLBP) from a societal perspective.

Design Randomised controlled trial with economic evaluation.

Setting Physiotherapy clinic in São Paulo, Brazil.

Participants 296 patients with NSCLBP.

Interventions All patients received advice and were randomly allocated to four groups (n=74 per group): booklet group (BG), Pilates once a week (Pilates group 1, PG1), Pilates twice a week (Pilates group 2, PG2) and Pilates three times a week (Pilates group 3, PG3).

Main outcome measures Primary outcomes were pain and disability at 6-week follow-up.

Results Compared with the BG, all Pilates groups showed significant improvements in pain (PG1, mean difference (MD)=−1.2, 95% CI −2.2 to −0.3; PG2, MD=−2.3, 95% CI −3.2 to −1.4; PG3, MD=−2.1, 95% CI −3.0 to −1.1) and disability (PG1, MD=−1.9, 95% CI −3.6 to −0.1; PG2, MD=−4.7, 95% CI −6.4 to −3.0; PG3, MD=−3.3, 95% CI −5.0 to −1.6). Among the different doses, PG2 showed significant improvements in comparison with PG1 for pain (MD=−1.1, 95% CI −2.0 to −0.1) and disability (MD=−2.8, 95% CI −4.5 to −1.1). The cost-utility analysis showed that PG3 had a 0.78 probability of being cost-effective at a willingness-to-pay of £20 000 per quality-adjusted life-year gained.

Conclusions Adding two sessions of Pilates exercises to advice provided better outcomes in pain and disability than advice alone for patients with NSCLBP; non-specific elements such as greater attention or expectation might be part of this effect. The cost-utility analysis showed that Pilates three times a week was the preferred option.

Trial registration number NCT02241538, Completed.

INTRODUCTION

Low back pain represents a major health problem all over the world with an evident social and economic impact.[1–4] Low back pain is the leading cause of years lived with disability and work absence.[1–3] In the UK, the total annual cost of low back pain was estimated at £12 billion. In the USA, the total indirect costs of low back pain were estimated at US$7.4 billion.[4] These estimates show the importance of considering more effective and cost-effective treatments to minimise the global impact of low back pain.

Clinical practice guidelines recommend exercise therapy for patients with chronic low back pain,[5–7] with the goal of improving disability and reducing absence from work due to physical and functional recovery.[8 9] Exercise may also reduce pain by influencing the endogenous inhibitory system and inducing hypoalgesia.[10–12] Furthermore, catastrophising and kinesiophobia appear to be related with pain and disability in patients with chronic low back pain, and exercise may promote benefits to improve these psychological factors.[13 14]

Pilates is a specific type of exercise therapy used as a treatment for low back pain.[15] Pilates involves six basic principles: breathing, centering, concentration, control, precision and flow.[15] The powerhouse is a central concept within Pilates and includes mainly the isometric contraction of deep muscles (ie, multifidus, transversus, pelvic floor and diaphragm).[15] A Cochrane review[16] shows that there is low-quality to moderate-quality evidence that Pilates is more effective than a minimal intervention for pain and disability in patients with chronic low back pain, with moderate effects at short term and small effects at intermediate term, but there is no difference compared with other types of exercise. However, there is still no evidence for the effectiveness of Pilates at long term or the optimum dose of treatment.

As healthcare resources are scarce, the cost-effectiveness of treatments for low back pain is considered as important as their effectiveness.[17 18] A systematic review on the cost-effectiveness of conservative treatments for chronic low back pain found combined treatment (psychological and physical treatments), educational intervention, manual therapy, acupuncture and yoga exercises to be cost-effective compared with usual care.[19] However, the results for exercise therapy were equivocal and inconclusive for chronic low back pain,[19] and the cost-effectiveness of Pilates has not been evaluated yet. Therefore, the primary aim of this study was to evaluate the effectiveness of the addition of different doses of Pilates to an advice in the treatment of patients with non-specific chronic low back pain (NSCLBP). The secondary aim was

to evaluate the cost-effectiveness and cost-utility of different doses of Pilates from a societal perspective.

METHODS

Study design

We conducted a randomised controlled trial with economic evaluation. All patients signed an informed consent. This study was prospectively registered at ClinicalTrials.gov (NCT02241538, Completed). Details of the study design have been published elsewhere.[20]

Setting and location

The study was conducted at a physiotherapy clinic and a Pilates clinic in São Paulo, Brazil from 2014 to 2017. Patients were recruited from the community using newspaper advertisements, community posters and through the university website.

Study population

We included 296 patients aged 18 to 80 years who had NSCLBP lasting for more than 3 months. Exclusion criteria were: Pilates treatment for low back pain in the previous 3 months, serious spinal pathologies (eg, tumours, fractures and inflammatory diseases), nerve root compromise, previous or scheduled spinal surgery, any contraindication to physical exercise[21] and pregnancy.

Randomisation

Randomisation was performed after baseline assessment; treatment allocation was concealed through sealed opaque envelopes sequentially numbered by a researcher, blinded for patient characteristics. The random numbers were generated in Microsoft Excel for Windows (Microsoft, Redmond, Washington, USA). After assessment, patients were randomised to one of four groups: booklet group (BG), Pilates group 1 (PG1), Pilates group 2 (PG2) and Pilates group 3 (PG3).

Blinding

Due to the nature of the interventions, it was not possible to blind patients and intervention providers to group allocation. A blinded research assistant entered all data in the computer. Statistical analyses were performed blinded for treatment allocation.

Interventions

All groups received advice based on the educational booklet. The information in the educational booklet was explained by a physiotherapist. Cointerventions were discouraged in all groups. However, patients were allowed to use their usual medication, and this information was monitored at the 6-week, 6-month and 12-month follow-ups.

Booklet group

The booklet contained recommendations related to posture and movements of activities of daily living, information on low back pain and anatomy of the spine and pelvis.[22] The BG did not receive any additional treatment. Patients were informed that they would receive Pilates after the 12-month follow-up.

Pilates groups

A detailed description of the intervention programme and Pilates exercises used in this study was previously described.[20 23] In brief, all patients in the Pilates groups received an individual exercise programme including ground exercises (with or without accessories, such as ball, magic circle and toning ball) and apparatus exercises (Barrel, Cadillac, Chair and Reformer—Metalife, Santa Catarina, Brazil) for 6 weeks. Sessions lasted for 1 hour. In PG1, patients received treatment once a week (six treatment sessions), in PG2, twice a week (12 treatment sessions) and in PG3, three times a week (18 treatment sessions). The intervention was performed with one patient per physiotherapist (supervised individual treatment) and was provided by the same physiotherapist for each patient in all sessions.

In the first session, all patients received instructions on the Pilates principles and training for the activation of the powerhouse, which consists mainly of isometric contraction of the deep abdominal muscles (ie, pelvic floor, gluteus maximus, multifidus and transversus abdominis), while exhaling in all exercises.[15 24] Exercises consisted of 5 min of warm-up (breathing and mobility exercises), 50 min of Pilates exercises (stretching and strengthening exercises for muscles of the trunk and lower and upper limbs) and 5 min of cool down (relaxation exercises and massage with ball). Exercises were performed with concentric and eccentric contraction of trunk, spine, upper and lower limb muscles in all planes of movement.[15 24] Each exercise was done with a single series, with a 2 min interval between exercises, and the number of repetitions varied from 8 to 12, corresponding to approximately 60% to 70% of one maximum repetition as assessed with the Borg scale.[25 26] The exercises were performed at three levels of difficulty: basic, intermediate and advanced. The basic exercises were adapted to the conditions of each patient by reducing or increasing resistance (eg, the roll-up exercise using the tower bar on the Cadillac can be performed with the spring in the high position to make the movement easier or in the low position to make the movement more difficult).

The level of difficulty of the exercises was defined individually, and the evolution of the exercises depended on comfort and individual postural compensations, with modifications to the other exercise (according to the level of difficulty) or with increases of one or two repetitions in relation to the desired number (representing 2% to 10% load increase).[25 26] The strategy to prevent bias was an individual supervised approach by a trained physiotherapist and the control of the level of exercise difficulty presented by the patient. Thus, exercises were adapted if the patient's symptoms worsened. Patients were able to make up any missed sessions as long as the total intervention period, including make-up sessions, did not exceed 8 weeks. Adverse events were monitored by pain intensity during the execution of the exercises and before and after sessions.

Five physiotherapists (with a mean of 7.5 years of experience in Pilates) were responsible for the intervention. All physiotherapists were certified in Pilates. As the physiotherapists were certified at different Pilates schools, they received specific training on the Pilates-based exercise programme for this study.

Eligibility assessment

A physiotherapist who was not involved in the treatment of patients conducted the eligibility assessment and collected data on patient characteristics, information on medication and previous treatment for low back pain. First, the eligibility assessment was conducted over the phone. After this, patients were invited to a physical assessment to identify the presence of nerve root compromise or not.

Outcome measures

All of the scales and questionnaires[27–36] used to evaluate the primary and secondary outcomes have been translated and

adapted to Brazilian Portuguese and have adequate measurement properties.[27–36] Patients completed the assessment at baseline, 6 weeks, 6 months and 12 months after randomisation. The primary outcomes were pain intensity and disability at 6 weeks after randomisation. The secondary outcomes were pain intensity and disability at 6 and 12 months after randomisation, global perceived effect, patient-specific disability, catastrophising, kinesiophobia and health-related quality of life at 6 weeks, 6 months and 12 months after randomisation. The assessments at 6 weeks, 6 months and 12 months after randomisation were done over the phone by assessors blinded to patient allocation.

Primary outcomes

Pain intensity was measured by the 11-point Pain Numerical Rating Scale (0–10 points), with 0 being 'no pain' and 10 being 'the worst possible pain'. Patients were asked to rate their average pain during the last 7 days.[29] Disability was measured by the Roland-Morris Disability Questionnaire that consists of 24 'yes' or 'no' questions related to normal daily activities, with affirmative answers worth 1 point. The score is the sum of the points, and higher scores indicate greater limitation.[29 30 32]

Secondary outcomes

Global perceived effect was measured by the Global Perceived Effect Scale (−5 to +5) that varies from 'vastly worse' to 'completely recovered'. Higher scores indicate a better recovery.[29] Patient-specific disability was measured by the Patient-Specific Functional Scale, in which participants identify three important activities that they are having difficulties with or that they are unable to perform due to chronic low back pain at the time of the assessment. The participants marked on an 11-point scale (0–10 points) how capable they feel to perform these activities, with 0 meaning 'unable to perform the activity' and 10 meaning 'able to perform the activity at preinjury level'. The average of the scores of the three activities was calculated. Higher scores indicate a higher functional ability.[29]

Catastrophising was measured by the Pain Catastrophising Scale with 13 items regarding thoughts and feelings when patients experience pain. This instrument has three subscales: helplessness, rumination and magnification. The scores vary from 0 ('not at all') to 4 ('always') points, and the maximum score is 52 points. Higher scores indicate higher pain catastrophising.[33 35] Kinesiophobia was measured by the Tampa Scale for Kinesiophobia. This scale consists of 17 questions related to pain and intensity of symptoms. The scores vary from 0 to 4 points, with 1 point for the answer 'strongly disagree,' 2 points for 'somewhat disagree,' 3 points for 'somewhat agree' and 4 points for 'strongly agree'. The total score ranges from 17 to 68 points, and the higher the score is, the more severe the kinesiophobia.[31 34] Health-related quality of life was measured by the Short-Form 6 Dimensions Questionnaire (SF-6D).[27 28 36] The patients' SF-6D health states were converted to utility values using the Brazilian tariff,[27 28 36] and quality-adjusted life-years (QALYs) were calculated using linear interpolation between measurement points.

Treatment credibility and satisfaction were also measured after the first treatment session using the Credibility Scale.[37 38] The modified version comprises four questions that assessed the participants' degree of confidence that symptoms will improve and confidence in the proposed treatment. The scores vary from 0 ('not at all confident' or 'not at all logical') to 6 ('very confident' or 'very logical').[37 38] Treatment satisfaction was evaluated at the 6-week follow-up, in which patients reported their satisfaction or dissatisfaction with the treatment.

Resource use and valuation

The economic evaluation was conducted from a societal perspective with a 12-month follow-up. The index year was 2016. All costs were converted from Brazilian Real into Pound Sterling using purchasing power parities.[39] Discounting of costs was not necessary due to the 12-month follow-up.[40]

Intervention costs were estimated by determining the patient's total number of Pilates sessions during the intervention period (valuing them using physiotherapy council table fees)[41] and booklet costs (estimated at £0.30 per booklet). Pilates apparatus and accessory costs were based on invoices and were linearly depreciated over a period of 4 years. The number of Pilates sessions attended by each patient was registered by the physiotherapists.

All other cost measures were assessed every 6 weeks using telephone interviews. The interviews were based on structured questionnaires assessing direct and indirect costs. To reduce recall bias, all patients received a diary to report all resources used to improve symptoms per day for the complete trial follow-up. Direct costs comprised visits to physiotherapists, alternative therapists (chiropractic, massage and acupuncture), general practitioners, medical specialists, as well as the use of emergency and hospital care, diagnostic tests and medication.[42] Patients were asked to report their out-of-pocket costs, as well as their use of the public healthcare system. The use of the public healthcare system was valued using Brazilian standard costs.[42] Indirect costs comprised hours of absence from paid and unpaid work[43] and transportation (patient's car and public transport).[44] Absence hours from paid and unpaid work were valued using gender-specific price weights.[43] Transportation by car was valued using Brazilian gasoline prices (£0.10 per kilometre), and public transport was valued using the reference price of São Paulo city (£1.66 per trip).

Sample size

The sample size was set to detect a clinically relevant difference of 1.0 point change in the Pain Numerical Rating Scale (estimate for SD 1.84)[45] and 4.0 points change in the Roland-Morris Disability Questionnaire (estimate for SD 4.9).[45] Assuming a dropout rate of 15%, statistical power of 80% and significance level of 5%, 74 patients were needed per group.

Statistical analysis

Effectiveness

Data monitoring was performed by one researcher who was not involved with data collection and had no conflict of interest. All data were entered into the database twice. Baseline characteristics were compared between all Pilates groups and the BG.[46] The mean effects of the interventions and the group differences for all outcomes were calculated using linear mixed models that incorporate terms for the treatment groups, time (follow-ups) and interaction terms 'treatment groups' versus 'time.' The term 'time' was coded as a categorical variable (ie, four variables were created for the categories baseline, 6-week, 6-month and 12-month follow-ups). The coefficients of treatment versus time interactions were equivalent to the estimates of the group differences. No interim analysis was performed. The analyses followed the intention-to-treat principle. If a participant dropped out of treatment, no additional outcome was collected, and the missing data were not replaced. We used SPSS V.24 (IBM, Armonk, New York, USA) for all statistical analyses, and the level of significance was set at 5%.

Cost-effectiveness

The economic evaluation was also performed according to the intention-to-treat principle. The cost-effectiveness analysis was performed using pain intensity and disability as outcomes, and the cost-utility analysis using QALYs. Missing data were handled using Multiple Imputation by Chained Equations. The imputation model included age, gender, body mass index, duration of symptoms, marital status, academic level, income, previous treatments, use of medication, depression, smoking and all available baseline and follow-up cost and effect measure values. Ten complete datasets were created (loss-of-efficiency <5%). Pooled estimates were calculated according to Rubin's rules.[47] Mean between-group cost differences were calculated for total and disaggregated costs. Seemingly unrelated regression analyses were performed in which effect and cost differences were corrected for their baseline values if available, while also taking into account the possible correlation between effects and costs.[48] Incremental cost-effectiveness and cost-utility ratios were calculated by dividing the corrected difference in total costs by the difference in effects. Uncertainty surrounding the cost differences and incremental cost-effectiveness and cost-utility ratios were estimated using Bias Corrected and Accelerated bootstrapping techniques (5000 replications). The latter were graphically presented in cost-effectiveness planes.[49] Cost-effectiveness acceptability curves were estimated to indicate the interventions' probability of being cost-effective compared with each other at different values of willingness-to-pay.[50] Sensitivity analyses were performed in order to assess the robustness of the results. The first sensitivity analysis was performed for a healthcare perspective, and the second sensitivity analysis was performed per protocol (in which patients with compliance of treatment less than 75% were excluded). The economic evaluation was performed using STATA (V.14, StataCorp, College Station, Texas, USA).

RESULTS

Study participants

In total, 846 patients were screened for eligibility between September 2014 and October 2015 (figure 1). In the triage phase by phone, 481 patients were excluded because they did not answer, declined to participate due to practical reasons or did not meet the inclusion criteria. A total of 365 patients were invited for physical assessment; however, 69 of them were excluded due to nerve root compromise (n=30) or because they did not attend the physical assessment (n=39). After randomisation, one patient was excluded due to being diagnosed with cancer during the study. Thus, 295 participated in the trial.

The participants' demographic characteristics are described in table 1. The groups were similar at baseline. Most patients were married, overweight and women with tertiary education. Most patients had received previous treatment for low back pain and felt depressed during the last month. All groups presented moderate levels of pain intensity and disability at baseline.

Treatment adherence and adverse events

After 6 weeks of treatment, the mean number of sessions was 5.1 (SD 1.9) for PG1 (85% of sessions), 10.2 (SD 3.6) for PG2 (85% of sessions) and 14.7 (SD 5.8) for PG3 (82% of sessions). None of the patients reported any adverse events.

Treatment credibility and satisfaction

All Pilates groups presented good credibility and were satisfied in relation to the treatment; however, the BG considered the intervention less credible compared with the Pilates groups ($p<0.05$). Furthermore, the number of patients satisfied with treatment was significantly lower in the BG, being 46% in the BG, 78% in PG1, 85% in PG2 and 80% in PG3.

Effectiveness analysis

Pilates compared with advice

The results for primary and secondary outcomes are described in table 2. The results for the comparison between different doses of Pilates and advice showed that all Pilates groups presented statistically significant improvements in pain intensity (mean difference (MD): −1.2, 95% CI −2.2 to −0.3 for PG1; MD: −2.3, 95% CI −3.2 to −1.4 for PG2; MD: −2.1, 95% CI −3.0 to −1.1 for PG3) and disability (MD: −1.9, 95% CI −3.6 to −0.1 for PG1; MD: −4.7, 95% CI −6.4 to −3.0 for PG2; MD: −3.3, 95% CI −5.0 to −1.6 for PG3) at the 6-week follow-up. These results exceeded the threshold for clinical relevance in PG2 and PG3 for pain intensity (2.0 points change)[51] and only in PG2 for disability (4.0 points change).[51] Furthermore, there were no significant differences for PG1 and PG3 compared with the BG for pain intensity and disability at the 6-month and 12-month follow-ups. However, PG2 was more effective than the BG for pain intensity (MD: −1.0, 95% CI −2.0 to −0.1) and disability (MD: −2.4, 95% CI −4.1 to −0.6) at the 6-month follow-up.

Different Pilates doses

In the comparison between different doses of Pilates at the 6-week follow-up, we observed statistically significant differences in pain intensity (MD: −1.1, 95% CI −2.0 to −0.1) and disability (MD: −2.8, 95% CI −4.5 to −1.1) in favour of PG2 compared with PG1, but these differences were not clinically relevant. There were no differences between PG1 and PG3 at the time of the 6-week follow-up for any primary outcome. Furthermore, there were significant improvements for disability at the 6-month (MD: −2.4, 95% CI −4.1 to −0.7) and 12-month follow-ups (MD: −1.9, 95% CI −3.7 to −0.2) in favour of PG2 compared with PG1. PG3 was more effective than PG1 for disability at the 6-month follow-up (MD: −1.7, 95% CI −3.5 to −0.0). However, these results did not exceed the threshold for clinical relevance (table 2). The results for secondary outcomes are described in table 2.

Cost-effectiveness analysis

The mean QALYs and mean total and disaggregate costs per patient are described in table 3. Intervention costs per patient were estimated at £0.30 for booklet, £171 for PG1, £331 for PG2 and £469 for PG3. Total societal costs were not statistically significant in the Pilates groups compared with the BG.

Table 4 shows the results of the economic evaluation. Please note that point estimates may slightly deviate from those of the effectiveness analysis as different statistical approaches were used for the effectiveness analysis and the economic evaluation. For pain intensity, incremental cost-effectiveness ratios indicate that a 1-point increase in pain intensity was on average associated with a societal cost saving of £2247 for PG1 (ie, less costly and less effective), whereas a 1-point decrease in pain intensity was on average associated with a societal cost of £635 for PG2 and £421 for PG3 (ie, more costly and more effective) compared with the BG.

For disability, incremental cost-effectiveness ratios indicate that a 1-point decrease in disability was on average associated with a societal cost saving of £116 for PG1 (ie, less costly and more effective), whereas a 1-point decrease in disability was on average associated with a societal cost of £93 for PG2 and £96

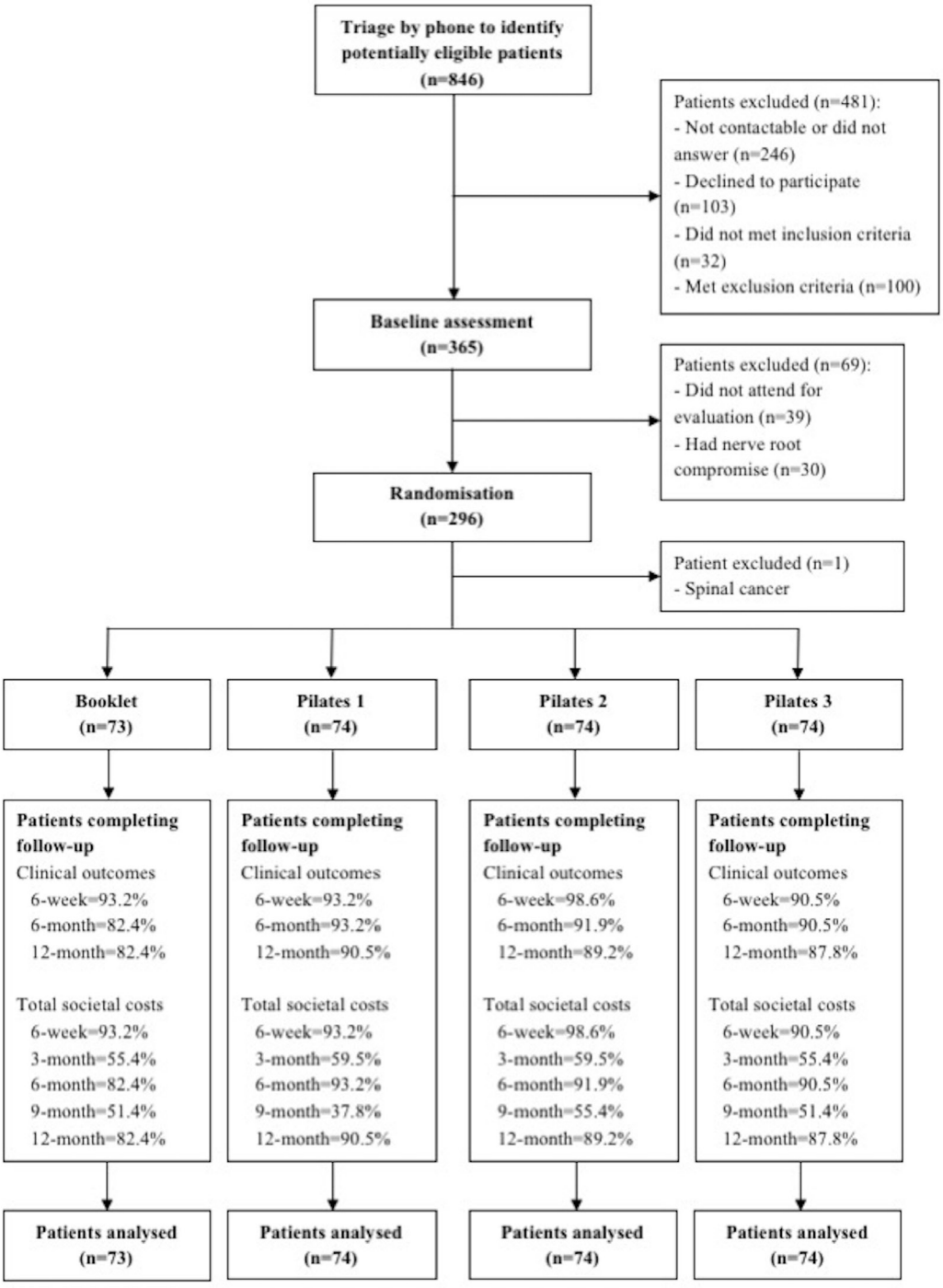

Figure 1 Flow diagram of the study.

for PG3 (ie, more costly and more effective) compared with the BG.

For QALYs, incremental cost-utility ratios indicate that one QALY gained was on average associated with a societal cost saving of £7008 for PG1 (ie, less costly and more effective), whereas one QALY gained was on average associated with a societal cost of £7053 for PG2 and £5503 for PG3 (ie, more costly and more effective) compared with the BG.

The cost-effectiveness acceptability curves for the comparisons between the four interventions showed that the probabilities of cost-effectiveness for pain intensity, disability and QALYs were about 0.67 in PG1, 0.01 in PG2, <0.01 in PG3 and 0.32 in the BG at a willingness-to-pay of zero per unit of effect gained (figure 2).

For pain intensity, PG2 showed the highest probability of being cost-effective at willingness-to-pay values of >£600 per point improvement, but this probability did not exceed 0.40 compared with the other interventions (figure 2A). For disability, PG3 showed the highest probability of being cost-effective at a willingness-to-pay of >£400 per point improvement, but this probability did not exceed 0.43 compared with the other interventions (figure 2B). For QALYs, PG3 seemed to be the preferred option, with a probability of being cost-effective compared with the other interventions of 0.78 at a willingness-to-pay of £20 000

Table 1 Patient characteristics*

Variable	Booklet (n=74)	Pilates 1 (n=74)	Pilates 2 (n=74)	Pilates 3 (n=74)
Age (years)	48.6 (15.8)	47.0 (11.5)	47.1 (14.9)	48.9 (16.6)
Gender				
Male	18 (24.3)	16 (21.6)	22 (29.7)	16 (21.6)
Female	56 (75.7)	58 (78.4)	52 (70.3)	58 (78.4)
Weight (kg)	71.3 (15.1)	74.3 (15.5)	72.3 (14.9)	71.0 (13.5)
Height (m)	1.6 (0.1)	1.6 (0.1)	1.7 (0.1)	1.6 (0.1)
Body mass index (kg/m²)	26.9 (5.3)	27.4 (5.3)	25.7 (3.8)	27.0 (4.9)
Family income (£/month)	1936 (1364)	2156 (1936)	2332 (1936)	2112 (3500)
Duration of symptoms (months)†	48.0 (3 to 372)	57.0 (3 to 240)	36.0 (3 to 480)	42.0 (3 to 420)
Marital status				
Single	23 (31.1)	16 (21.5)	18 (24.3)	22 (29.7)
Married	35 (47.3)	44 (59.5)	47 (63.5)	34 (45.9)
Divorced	12 (16.2)	11 (14.9)	7 (9.5)	10 (13.5)
Widower	4 (5.4)	3 (4.1)	2 (2.7)	8 (10.8)
Academic level				
Primary education	17 (23.0)	10 (13.5)	13 (17.5)	17 (23.0)
Secondary education	24 (32.4)	26 (35.1)	24 (32.5)	21 (28.4)
Tertiary education	33 (44.6)	38 (51.4)	37 (50.0)	36 (48.6)
Previous treatment				
No	31 (41.9)	28 (35.1)	25 (33.8)	24 (32.4)
Yes	43 (58.1)	48 (64.9)	49 (66.2)	50 (67.6)
Use of medication				
No	22 (29.7)	36 (48.6)	41 (55.4)	37 (50.0)
Yes	52 (70.3)	38 (51.4)	33 (44.6)	37 (50.0)
Smoking				
No	70 (94.6)	64 (86.5)	67 (90.5)	70 (94.6)
Yes	4 (5.4)	10 (13.5)	7 (9.5)	4 (5.4)
Feeling depressed during the last month				
No	30 (40.5)	27 (36.5)	33 (44.6)	30 (40.5)
Yes	44 (59.5)	47 (63.5)	41 (55.4)	44 (59.5)
Pain intensity at baseline (0 to 10)	6.3 (1.8)	6.1 (2.0)	6.4 (2.9)	6.0 (1.9)
Disability at baseline (0 to 24)	12.3 (5.5)	11.0 (5.1)	12.8 (4.8)	10.6 (4.7)
Patient-specific disability (0 to 10)	3.6 (1.6)	3.7 (1.7)	3.8 (1.6)	3.9 (1.8)
Global impression of recovery (−5 to +5)	−0.8 (2.8)	−1.0 (3.1)	−1.5 (2.9)	−1.2 (2.9)
Catastrophising (0 to 52)	26.8 (12.3)	24.7 (10.4)	25.9 (11.6)	23.6 (10.3)
Kinesiophobia (17 to 68)	40.7 (9.1)	39.7 (7.5)	40.8 (7.5)	38.3 (7.2)
Health-related quality of life (0 to 1)‡	0.76 (0.07)	0.75 (0.06)	0.75 (0.06)	0.77 (0.07)

*Categorical variables are expressed as number (%); continuous variables are expressed as mean (SD).
†Duration of symptoms is expressed as median (minimum to maximum).
‡This variable is usually described with two decimals.

per QALY gained and a 0.85 probability of cost-effectiveness at a willingness-to-pay of £30 000 per QALY gained (figure 2C).

The overall conclusion of the economic evaluation would not change when using the results of the sensitivity analyses (online supplementary appendix 1 and 2).

DISCUSSION

This randomised controlled trial showed small to moderate short-term improvements in pain intensity and disability in patients who received treatment based on Pilates in addition to an advice (booklet) compared with the advice alone. Additionally, patients who received treatment twice a week had small short-term improvements for pain intensity and disability compared with patients who received treatment once a week. However, patients who received treatment three times a week did not have additional improvements compared with patients who received treatment once and twice a week for pain intensity and disability at short term. The cost-utility analysis showed that Pilates exercises three times a week is the preferred option with a probability of being cost-effective of 0.78 at a willingness-to-pay of £20 000 per QALY gained and 0.85 at £30 000 per QALY gained (threshold set by the UK's National Institute for Health and Clinical Excellence (NICE)).[52 53] However, Pilates exercises do not seem to be cost-effective compared with an advice for pain intensity and disability.

Generalisability, strengths and weaknesses of the study

The strengths of this trial are the large sample, the randomisation of patients and the concealed allocation, the intention to treat analysis, the long-term assessment and the excellent adherence in all Pilates groups (ie, more than 82%). Furthermore, this was the first study to investigate the cost-effectiveness of Pilates compared with advice and to compare different doses of Pilates in the treatment of patients with NSCLBP. Another strength

Table 2 Between-group differences for primary and secondary outcomes at the 6-week, 6-month and 12-month follow-ups*

Outcome	Unadjusted mean (SD)				Adjusted mean difference (95% CI)					
	Booklet	Pilates 1	Pilates 2	Pilates 3	Booklet versus Pilates 1	Booklet versus Pilates 2	Booklet versus Pilates 3	Pilates 1 versus Pilates 2	Pilates 1 versus Pilates 3	Pilates 2 versus Pilates 3
Pain intensity (0–10)										
6-week follow-up	5.6 (2.6)	4.0 (2.7)	3.3 (2.3)	3.2 (2.4)	−1.2† (−2.2 to −0.3)	−2.3‡ (−3.2 to −1.4)	−2.1‡ (−3.0 to −1.1)	−1.1§ (−2.0 to −0.1)	−0.9 (−1.8 to 0.1)	0.2 (−0.7 to 1.1)
6-month follow-up	5.4 (2.7)	5.0 (2.9)	4.4 (2.9)	4.3 (2.6)	−0.3 (−1.3 to 0.6)	−1.0§ (−2.0 to −0.1)	−0.7 (−1.7 to 0.2)	−0.7 (−1.7 to 0.2)	−0.4 (−1.4 to 0.5)	0.3 (−0.6 to 1.2)
12-month follow-up	4.9 (2.8)	4.8 (2.8)	4.1 (3.1)	4.1 (2.8)	0.1 (−0.9 to 1.0)	−0.8 (−1.8 to 0.2)	−0.4 (−1.4 to 0.6)	−0.9 (−1.8 to 0.1)	−0.5 (−1.4 to 0.5)	0.4 (−0.5 to 1.3)
Disability (0–24)										
6-week follow-up	11.3 (6.1)	7.8 (5.2)	6.8 (5.2)	6.1 (5.5)	−1.9§ (−3.6 to −0.1)	−4.7‡ (−6.4 to −3.0)	−3.3‡ (−5.0 to −1.6)	−2.8‡ (−4.5 to −1.1)	−1.4 (−3.2 to 0.3)	1.4 (−0.3 to 3.1)
6-month follow-up	10.2 (6.1)	8.8 (5.5)	7.9 (6.5)	6.4 (5.6)	0.0 (−1.7 to 1.8)	−2.4† (−4.1 to −0.6)	−1.7 (−3.5 to 0.1)	−2.4† (−4.1 to −0.7)	−1.7§ (−3.5 to −0.0)	0.6 (−1.1 to 2.4)
12-month follow-up	8.9 (6.8)	7.3 (5.7)	7.2 (6.4)	5.9 (5.2)	0.2 (−1.6 to 2.0)	−1.7 (−3.5 to 0.0)	−0.7 (−2.5 to 1.1)	−1.9§ (−3.7 to −0.2)	−0.9 (−2.6 to 0.8)	1.0 (−0.7 to 2.8)
PSD (0–10)										
6-week follow-up	5.0 (2.6)	6.3 (2.0)	6.9 (2.1)	6.8 (2.1)	1.2† (0.4 to 2.0)	1.8‡ (1.0 to 2.5)	1.4‡ (0.6 to 2.3)	0.5 (−0.3 to 1.3)	0.2 (−0.6 to 1.0)	−0.3 (−1.1 to 0.5)
6-month follow-up	6.0 (2.2)	5.5 (2.4)	6.5 (2.4)	6.7 (2.0)	−0.5 (−1.3 to 0.3)	0.4 (−0.4 to 1.2)	0.3 (−0.5 to 1.2)	0.9§ (0.1 to 1.7)	0.9§ (0.1 to 1.7)	0.0 (−0.8 to 0.8)
12-month follow-up	6.2 (2.2)	6.1 (2.1)	6.9 (2.7)	6.6 (2.2)	−0.2 (−1.0 to 0.6)	0.5 (−0.4 to 1.3)	0.0 (−0.8 to 0.8)	0.6 (−0.2 to 1.4)	0.1 (−0.6 to 1.0)	−0.5 (−1.3 to 0.3)
GPE (−5 to +5)										
6-week follow-up	0.7 (2.7)	2.5 (1.9)	3.1 (1.9)	3.1 (2.2)	1.9‡ (0.8 to 2.9)	3.1‡ (2.0 to 4.1)	2.7‡ (1.7 to 3.8)	1.2§ (0.1 to 2.2)	0.8 (−0.2 to 1.9)	−0.3 (−1.4 to 0.7)
6-month follow-up	1.2 (2.7)	1.5 (2.6)	2.1 (2.6)	2.6 (2.1)	0.5 (−0.5 to 1.6)	1.5† (0.4 to 2.6)	1.7† (0.6 to 2.8)	1.0 (−0.1 to 2.0)	1.2§ (0.1 to 2.2)	0.2 (−0.9 to 1.2)
12-month follow-up	1.9 (2.4)	1.6 (2.5)	2.1 (2.8)	2.6 (2.3)	−0.1 (−1.2 to 1.0)	0.9 (−0.2 to 1.9)	1.0 (−0.1 to 2.1)	1.0 (−0.1 to 2.0)	1.1§ (0.0 to 2.2)	0.1 (−0.9 to 1.2)
Catastrophising (0–52)										
6-week follow-up	26.9 (12.0)	21.4 (11.7)	19.6 (11.2)	20.9 (11.9)	−3.0 (−6.5 to 0.5)	−5.9‡ (−9.4 to −2.4)	−2.4 (−5.9 to 1.1)	−2.9 (−6.3 to 0.5)	0.6 (−2.9 to 4.1)	3.5§ (0.0 to 7.0)
6-month follow-up	24.8 (12.9)	21.4 (11.5)	19.6 (12.0)	18.8 (11.0)	−1.4 (−5.0 to 2.1)	−4.5† (−8.1 to −0.9)	−2.9 (−6.5 to 0.7)	−3.0 (−6.5 to 0.5)	−1.4 (−4.9 to 2.1)	1.5 (−1.9 to 5.1)
12-month follow-up	22.7 (12.8)	22.0 (11.1)	17.0 (12.7)	17.6 (11.2)	1.4 (−2.1 to 5.0)	−4.4† (−8.1 to −0.8)	−1.8 (−5.5 to 1.8)	−5.9‡ (−9.4 to −2.3)	−3.3 (−6.8 to 0.2)	2.6 (−1.0 to 6.1)
Kinesiophobia (17–68)										
6-week follow-up	41.6 (8.4)	37.1 (7.4)	37.4 (8.7)	35.4 (8.0)	−3.4† (−6.1 to −0.8)	−4.2† (−6.8 to −1.5)	−3.8† (−6.5 to −1.2)	−0.7 (−3.3 to 1.9)	−0.4 (−3.1 to 2.3)	0.3 (−2.3 to 3.0)
6-month follow-up	40.4 (9.3)	38.3 (8.4)	37.9 (8.6)	37.2 (8.3)	−1.1 (−3.9 to 1.5)	−2.6 (−5.3 to 0.1)	−0.7 (−3.5 to 1.9)	−1.4 (−4.1 to 1.2)	0.4 (−2.3 to 3.1)	1.8 (−0.8 to 4.5)
12-month follow-up	38.0 (9.9)	37.6 (8.1)	36.4 (8.1)	37.5 (9.0)	0.6 (−2.2 to 3.2)	−1.6 (−4.3 to 1.2)	2.1 (−0.7 to 4.8)	−2.1 (−4.8 to 0.5)	1.5 (−1.2 to 4.2)	3.6† (0.9 to 6.3)
HRQL (0–1)										
6-week follow-up	0.78 (0.08)	0.81 (0.08)	0.81 (0.07)	0.83 (0.09)	0.03† (0.01 to 0.06)	0.03† (0.01 to 0.06)	0.04‡ (0.01 to 0.06)	0.00 (−0.03 to 0.03)	0.01 (−0.02 to 0.04)	0.01 (−0.02 to 0.04)
6-month follow-up	0.80 (0.08)	0.80 (0.08)	0.82 (0.09)	0.84 (0.09)	0.01 (−0.02 to 0.03)	0.02 (−0.00 to 0.05)	0.03§ (0.00 to 0.06)	0.02 (−0.01 to 0.04)	0.02 (−0.00 to 0.05)	0.01 (−0.02 to 0.03)
12-month follow-up	0.80 (0.07)	0.81 (0.08)	0.83 (0.10)	0.84 (0.10)	0.01 (−0.01 to 0.04)	0.04† (0.01 to 0.06)	0.03§ (0.02 to 0.07)	0.02 (−0.01 to 0.05)	0.02 (−0.01 to 0.05)	0.00 (−0.03 to 0.03)

*Negative treatment effects favour Pilates groups in comparison with BG, favour PG3 in comparison with PG1 and PG2 and favour PG2 in comparison with PG1 for pain intensity, disability, catastrophising and kinesiophobia. Positive treatment effects favour Pilates groups in comparison with BG, favour PG3 in comparison with PG1 and PG2 and favour PG2 in comparison with PG1 for patient-specific disability, global perceived effect and health-related quality of life.
†Significant difference between groups (p≤0.01).
‡Significant difference between groups (p≤0.001).
§Significant difference between groups (p<0.05).
GPE, global perceived effect; HRQL, health-related quality of life; PG1, Pilates group 1; PG2, Pilates group 2; PG3, Pilates group 3; PSD, patient-specific disability.

Table 3 Mean QALYs and costs per patient in the Pilates groups and booklet group and adjusted mean cost differences between study groups during the 12-month follow-up period (based on the imputed dataset)

	Mean (SEM)				Δ Costs (95% CI)		
Cost category	Booklet	Pilates 1	Pilates 2	Pilates 3	Booklet versus Pilates 1	Booklet versus Pilates 2	Booklet versus Pilates 3
QALYs	0.79 (0.01)	0.80 (0.01)	0.82 (0.01)	0.83 (0.01)	0.01 (–0.01 to 0.03)	0.02* (0.00 to 0.05)	0.04* (0.02 to 0.07)
Intervention costs	0.3 (0.0)	171 (6)	331 (13)	469 (20)	171* (155 to 183)	331* (301 to 353)	469* (423 to 504)
Medication costs							
Patient	65 (9)	31 (5)	38 (8)	25 (4)	–33* (–57 to –13)	–26* (–52 to –1)	–39* (–63 to –20)
Public health system	3 (1)	2 (1)	2 (0.4)	4 (1)	–1 (–3 to 2)	–1* (–4 to –0.2)	0.6 (–2 to 3)
Primary care costs							
Patient	198 (67)	59 (12)	108 (34)	47 (11)	–138* (–370 to –45)	–89 (–290 to 25)	–150* (–371 to –57)
Public health system	12 (2)	12 (2)	7 (2)	8 (1)	0.2 (–7 to 7)	–4 (–12 to 1)	–4 (–12 to 1)
Secondary care costs							
Patient	19 (11)	0 (0)	19 (16)	13 (8)	–19* (–70 to –6)	–0.5 (–29 to 56)	–5 (–39 to 17)
Public health system	27 (8)	27 (6)	37 (11)	26 (8)	0.2 (–23 to 18)	9 (–14 to 39)	–1 (–23 to 24)
Other costs							
Patient	73 (28)	63 (25)	48 (25)	50 (16)	–9 (–90 to 63)	–24 (–102 to 51)	–23 (–107 to 28)
Transportation costs	10 (1)	20 (2)	28 (6)	26 (4)	9 (4 to 16)	17 (9 to 40)	15 (8 to 27)
Absenteeism costs	238 (63)	183 (57)	201 (57)	207 (75)	–54 (–226 to 114)	–36 (–209 to 125)	–30 (–209 to 174)
Total societal costs	649 (129)	574 (82)	824 (89)	880 (90)	–75 (–438 to 188)	174 (–201 to 441)	230 (–152 to 494)

*Significant difference between groups (p<0.05).
QALY, quality-adjusted life-year.
Note: Costs are expressed in 2016 Pounds Sterling.

point of this study was the assessment of all costs using prospective diaries because it may reduce the recall bias.

A potential limitation of this study was the inability to blind the therapists and participants to treatment allocation due to the nature of the intervention. Another limitation is the fact that patients were recruited from advertisements, which may affect the generalisability of results. A possible limitation of the economic evaluation was the percentage of dropouts at

Table 4 Differences in pooled mean costs and effects (95% CIs), incremental cost-effectiveness ratios and the distribution of incremental cost-effect pairs around the quadrants of the cost-effectiveness planes for the main analysis from a societal perspective

	Δ Costs (95% CI)	Δ Effects (95% CI)	ICER	Distribution CE-plane (%)			
Outcome	£	Points	£/point	NE*	SE†	SW‡	NW§
Pilates 1 compared with booklet							
Pain intensity (0 to 10)	–75 (–434 to 179)	0.2 (–0.8 to 1.2)	–2247	10.6	23.1	44.7	21.6
Disability (0 to 24)	–75 (–434 to 179)	–0.8 (–2.5 to 0.9)	116	26.1	56.5	11.3	6.1
QALY (0 to 1)	–75 (–434 to 179)	0.01 (–0.01 to 0.03)	–7008	25.0	56.8	11.0	7.2
Pilates 2 compared with booklet							
Pain intensity (0 to 10)	174 (–187 to 440)	–0.5 (–1.6 to 0.7)	–635	68.4	10.5	2.6	18.5
Disability (0 to 24)	174 (–187 to 440)	–1.9 (–3.7 to –0.1)	–93	85.1	13.0	0.1	1.8
QALY (0 to 1)	174 (–187 to 440)	0.02 (0.00 to 0.05)	7053	85.1	13.0	0.1	1.8
Pilates 3 compared with booklet							
Pain intensity (0 to 10)	231 (–187 to 440)	–0.3 (–0.9 to 0.3)	–421	63.2	0.0	7.5	29.3
Disability (0 to 24)	231 (–187 to 440)	–2.1 (–3.7 to –0.5)	–96	91.9	0.0	7.5	0.6
QALY (0 to 1)	231 (–187 to 440)	0.04 (0.02 to 0.07)	5503	92.5	0.0	7.5	0.0

*Refers to the northeast quadrant of the CE-plane, indicating that the Pilates groups are more effective and more costly than booklet.
†Refers to the southeast quadrant of the CE-plane, indicating that the Pilates groups are more effective and less costly than booklet.
‡Refers to the northwest quadrant of the CE-plane, indicating that the Pilates groups are less effective and more costly than booklet.
§Refers to the southwest quadrant of the CE-plane, indicating that the Pilates groups are less effective and less costly than booklet.
CE-plane, cost-effectiveness plane; ICER, incremental cost-effectiveness ratio; NE, north-east; NW, north-west; QALY, quality-adjusted life-year; SE, south-east; SW, south-west.
Costs are expressed in 2016 Pounds Sterling.

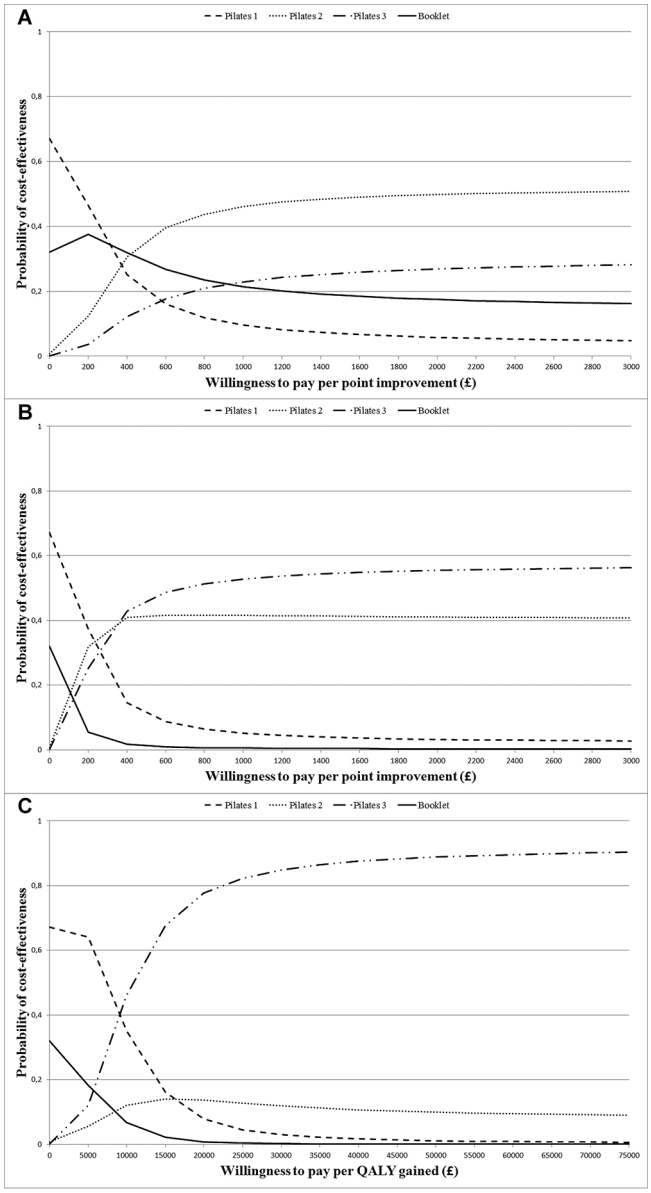

Figure 2 Cost-effectiveness acceptability curves for: (A) pain intensity, (B) disability and (C) QALYs from a societal perspective. QALY, quality-adjusted life-years.

the 3-month and 9-month assessments. However, the dropout rate in the main evaluations (6-week, 6-month and 12 month follow-ups after randomisation) was less than 20%, and we used multiple imputations to deal with this limitation. Furthermore, the transferability of the economic evaluation results across countries may be hampered by differences in healthcare and social security systems.

Comparison with other studies

A Cochrane review[16] evaluated 10 studies on the effects of Pilates in the treatment of patients with non-specific low back pain. The authors found that Pilates was more effective than minimal intervention for pain intensity and disability, with moderate effects at short term and small effects at intermediate term for chronic low back pain. These results are similar to those of the present study, especially for Pilates performed twice and three times a week. However, none of the studies evaluated its effectiveness at long-term follow-up and its cost-effectiveness.

There are no studies on different doses of Pilates. However, a Delphi study[54] was performed among 30 physiotherapists/Pilates therapists to reach a consensus about the application of Pilates in the treatment of patients with chronic low back pain. The physiotherapists recommended that Pilates should be performed twice a week during 3 and 6 months. The results of the present study showed that Pilates had small to moderate effects[16] for patients with NSCLBP. However, treatment twice a week for 6 weeks seems to be somewhat more effective than Pilates exercises once a week. A systematic review with metaregression[55 56] on the effects of exercise therapy in the treatment of patients with low back pain confirmed these findings, as the results showed that 12 sessions (high doses) of exercise therapy were more effective than 6 sessions (low doses) in the improvement of pain intensity and disability in patients with chronic low back pain. However,[55 56] 18 sessions of exercise therapy did not show more benefits than 6 and 12 sessions. Thus, 12 sessions seem to be sufficient to gain these improvements.

In this economic evaluation, the total costs of the interventions were rather low in all groups. Other economic evaluations of exercise therapy for chronic low back pain showed more costs for patients compared with the results found in our study.[57–61] It may be due to our recruitment through advertisements, which may have attracted patients who were not looking for treatment and did not have substantial work absenteeism.

Currently, there are three systematic reviews[19 62 63] that evaluated the cost-effectiveness of conservative treatments for low back pain, including exercise therapy. Although one systematic review[63] found exercise therapy to be cost-effective in comparison with usual care, two systematic reviews[19 62] concluded that the results for the cost-effectiveness of exercise therapy are still inconsistent in the treatment of patients with chronic low back pain. Our economic evaluation showed that Pilates-based exercise therapy three times a week may probably be considered cost-effective, although this depends on the willingness-to-pay of decision makers.

Meaning of the study

This study suggests that Pilates twice a week may be more effective for patients with NSCLBP. The results showed clinically relevant improvements for Pilates exercises twice a week and three times a week at short term using a 2.0 point difference as cut-off for pain intensity[51] and for Pilates exercises twice a week at short term using a 4.0 point difference as cut-off for disability compared with advice. A possible explanation for the larger effects in the patients allocated to Pilates may be the attention received from the therapists when attending the sessions. The non-specific elements (such as attention, empathy, positive regard, compassion, hope, enthusiasm, expectation, professional speaking, relationship between therapist and patient, quality of service and equipment) may influence the treatment effect size.[64] Thus, non-specific elements, specially therapist–patient relationship, may have biased the results of this study. Furthermore, exercise therapy is an intervention that may increase cardiovascular conditioning, flexibility, strength and endurance[8 9] and may induce hypoalgesia.[10–12] Thus, we believe that Pilates exercises twice a week were more effective because this dose promotes more physical and functional recovery than Pilates exercises once a week.[25]

The cost-utility analysis showed that Pilates three times a week is the preferred option. Whether PG3 can be considered cost-effective depends on what decision makers consider acceptable. However, the probabilities of PG3 being

cost-effective of 0.78, at a willingness-to-pay of £20 000 per QALY gained, and of 0.85 at £30 000 per QALY gained are high and are within the threshold recommended by NICE. The cost-effectiveness and cost-utility analyses compare differences in effects with differences in societal costs at long term. Although Pilates exercises twice a week seemed to be more effective than advice at short and intermediate term for pain intensity and disability in the effectiveness analysis, when we considered the economic evaluation (effects and costs at long term), Pilates exercises were not cost-effective compared with advice for these clinical outcomes. However, the cost-utility analysis showed that Pilates exercises three times a week were the preferred option. This intervention group showed the highest probability of being cost-effective compared with the other intervention groups.

Unanswered questions and future research

We suggest that future studies include patients who are seeking care with a treatment period of more than 6 weeks with group sessions and comparison with other types of interventions. Individualised exercise based on preference, dose and compliance could be a good way forward. Studies evaluating the effectiveness and cost-effectiveness of this individualised approach would also be useful. Additionally, we recommend that other studies with the same approach of this study should be conducted in different countries. Then, we will be able to know if the results of this study may be generalised to other population and settings, especially for economic evaluation.

CONCLUSION

The results of this study suggest that adding Pilates treatment to an advice provides small to moderate benefits over advice alone for pain intensity and disability in the treatment of NSCLBP. However, non-specific elements such as greater attention or expectation might be part of this effect. PG2 seems to be better than Pilates once a week, and PG3 shows similar effects to twice a week. Furthermore, Pilates exercises three times a week is the preferred option for QALYs if cost-effectiveness is considered. However, Pilates exercises do not seem to be cost-effective compared with an advice for pain intensity and disability.

What are the findings?

- Pilates exercises seem to be more effective than advice.
- 12 sessions (higher doses) of exercise seem to be more effective than 6 sessions (lower doses).
- Pilates exercises three times a week seem to be cost-effective compared with advice, Pilates twice a week and Pilates once a week.

How might it impact on clinical practice in the near future?

- This study may help professionals to integrate the exercise doses concept into clinical practice to improve symptoms of patients with non-specific low back pain.
- The results of the cost-utility analysis may help decision-makers to consider Pilates as a cost-effective intervention for patients with non-specific chronic low back pain.

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Contributors GCM was involved in setting the research question, trial design, protocol writing, data analysis and manuscript preparation. GCM, KFMF, YRdSF and NTBdO were the therapists of the study. ANCB was the assessor for baseline assessment. DDVA and MLdS were the blinded assessors for follow-up assessment. CMNC contributed in randomisation schedule preparation, protocol writing, and manuscript preparation. MWvT and JMvD contributed in data interpretation and statistical analysis strategy. All authors reviewed and approved the manuscript prior to submission.

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Competing interests GCM is an instructor of NeoPilates courses.

Patient consent Obtained.

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