

A multidisciplinary rehabilitation programme improves disability, kinesiophobia and walking ability in subjects with chronic low back pain: results of a randomised controlled pilot study

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Introduction

Subjects with chronic low back pain (CLBP) have different neuromuscular control of the deep stabilising muscles of the spine from that of healthy people, and these changes can be attributed to the effects of pain on motor control [1, 2]. They also show articular stiffness, muscle weakness of the spine, and postural alterations [3].

The changes in neuromuscular control may also influence non-spinal motor tasks: patients with CLBP have a slower walking speed, and a shorter and asymmetrical step length than the pain-free counterparts [4]. The slower natural walking speed of CLBP patients becomes a functional adaptation as it may enable them to cope with internal and external perturbations [1]. It is also conceivable that it is associated with inability to adapt trunk–pelvis coordination to changes in speed, and may be considered a

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mechanism protecting against pain as patients try to avoid extensive hip and spine ranges of motion by minimising the forces acting on a weak trunk [5, 6].

According to bio-psychosocial models, CLBP is not only mechanically related to spinal and lower limb pathophysiology, but may also be influenced by attitudes, beliefs and behaviours [7–9]. Psychological factors such as fear-avoidance beliefs, maladaptive coping strategies, and mood alterations are important determinants of chronic symptoms, disability and their perception [10], and it is now widely recognised that kinesiophobia plays a central role in CLBP. It is assumed that fear-avoidance beliefs prevent patients from regaining of normal function, promote the development of guarded movements, and contribute to disability.

Recent systematic reviews have shown that multidisciplinary treatments are more effective in reducing the intensity of CLBP in the short term than no treatment, waiting lists, or active treatments such as physiotherapy or exercise [11, 12], and one recent randomised controlled trial demonstrated that a 13-month multidisciplinary programme was effective in reducing disability, kinesiophobia and pain, and enhancing the quality of life (QoL) of highly disabled CLBP patients [13]. However, there are still doubts concerning the clinical impact of shorter multidisciplinary programmes on back-related disability, psychological factors (e.g. kinesiophobia and catastrophizing), the QoL, and gait disturbances.

The hypothesis underlying this study was that a 2-month multidisciplinary rehabilitation programme of spinal stabilising exercises integrated with cognitive-behavioural therapy mainly aimed at managing the fear of movement would induce improvements in disability, kinesiophobia, catastrophizing, pain, QoL, and gait disturbances. The aim of this randomised and controlled pilot study was therefore to evaluate the efficacy of such a programme in comparison with usual exercises.

Methods

Experimental design

This randomised, parallel-group, controlled, superiority pilot study was conducted in conformity with ethical and humane principles of research at the Salvatore Maugeri Foundation's Scientific Institute in Lissone (Italy), and approved by our hospital's Institutional Review Board (No. 1; date of approval: 01/24/2012).

Immediately after the patients had given their consent, the principal investigator (PI) randomised them to one of the treatment programmes using a list of blinded treatment codes previously generated by a biostatistician [14] and an

automatic assignment system in order to conceal the allocation. Recruitment was stopped when the desired sample size of 20 patients was reached. The PI obtaining and assessing the outcome data, and the biostatisticians making the analyses were blinded to the treatments. The physiatrists, the psychologist, the physiotherapists, and the patients could not be blinded.

Participants

The study involved outpatients aged >18 years with non-specific CLBP (i.e. a documented history of pain lasting >3 months) and a good understanding of Italian who were referred to our hospital between January and June 2013.

Patients with central or peripheral neurological signs, cognitive impairment (i.e. deficits in higher reasoning, forgetfulness, learning disabilities, concentration difficulties, decreased intelligence and other reductions in mental functions), severe cardio-vascular and respiratory comorbidity, prior spine surgery, ambulation deficits due to neurological or orthopaedic impairments were excluded, as were those who were pregnant or who had previously participated in cognitive-behavioural interventions.

All of the patients satisfying the entry criteria were asked to give their written informed consent, to declare their willingness to comply with whichever treatment option they were randomly assigned to, and to attend all of the follow-up visits.

In order to limit expectation bias and reduce problems of crossover, the patients were blinded to the study hypothesis by telling them the trial was intended to compare two common rehabilitation approaches whose efficacy had not yet been established.

Interventional programmes

The intervention involved two physiatrists, a psychologist, an occupational therapist, and two physiotherapists. The experimental group followed a multidisciplinary programme consisting of motor training integrated with cognitive-behavioural therapy; the control group only did physical exercises.

Experimental group

The motor training involved spinal stabilising exercises in addition to usual-care rehabilitation (passive mobilisation, stretching, and postural control). These exercises were personalized for each patient and based on a physical examination conducted by the physiotherapist at the beginning of the motor training, and mainly focused on the observation of lumbar movement dysfunction within the

neutral zone and the associated finding of excessive intervertebral motion; once the best strategy for dynamic trunk stabilization was determined, basic exercises were gradually introduced to improve spinal deep muscle awareness, and the patients learned specific stabilizing techniques for the same muscles, progressively increasing the speed and complexity of the movement pattern with the final aim of becoming autonomous during the functional demands of daily living [2]. The patients were also involved in individual cognitive-behavioural training aimed at modifying their fear of movement beliefs, catastrophizing and negative feelings, and ensuring gradual reactions to illness behaviours, under the supervision of a clinical psychologist [15]. The main situations avoided by the patients were identified on the basis of the fear-avoidance beliefs emerging from their usual activities and the results of a presentation of images showing back-stressing activities. After explaining the fear-avoidance model, the team educated the patients to view pain as a situation that can be self-managed rather than a serious disease needing careful or vigilant protection. Correct re-learning and cognitive reconditioning was based on developing an awareness of the problem and seeking a means of reacting to frightening thoughts. The subjects were assisted in transferring their attention from kinesiophobia to increasing their level of activity by means of graded exposure to the situations they previously identified as dangerous.

Control group

The usual-care rehabilitation included passive spinal mobilisation, stretching, muscle strengthening, and postural control.

The subjects in the experimental group attended individual 60-min cognitive-behavioural sessions once a week for 8 weeks, and the subjects of both groups attended individual 60-min motor training sessions twice a week for 8 weeks. The two physiotherapists separately responsible for each randomised group were equally experienced and, in order to ensure that there was no variability in treatment administration during the course of the study, a fidelity check was made during each session and at the end of the interventional programme based on a treatment manual.

No other treatments (e.g. physical modalities or nerve blocks) were offered once the patients had been accepted for the programme, and no major pharmacological agents were allowed, although mild analgesics and NSAIDs were permitted. Spouses, relatives or significant others were asked to support patient compliance during the study, and to inform the staff promptly if any difficulty was encountered, in order to strengthen treatment adhesion and minimise drop-outs.

Outcome measures

Disability (primary outcome), kinesiophobia, catastrophizing, pain, QoL, gait parameters, and the global perceived effect were all investigated.

Disability was assessed using the Oswestry Disability Index (ODI), a self-administered, 10-item questionnaire: the first section rates the intensity of pain and the others describe its disabling effect on daily activities. The score for each item ranges from 0 to 5, and the sum of the ten scores is expressed as a percentage of the maximum score, and thus ranges from 0 (no disability) to 100 (maximum disability). We used the Italian version which has proved to be reliable, valid and responsive [16, 17].

Kinesiophobia was assessed using the validated Italian Tampa Scale of Kinesiophobia (TSK) [18], a 13-item self-report questionnaire in which each question is scored using a Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree); the total score is calculated by adding the scores of the individual items, and ranges from 13 (a low level of kinesiophobia) to 52 (a high level).

Catastrophizing was assessed using the validated Italian Pain Catastrophizing Scale (PCS), a 13-item self-report questionnaire [19]; the patients are asked to rate the degree to which they have any of the thoughts described in the questionnaire using a five-point scale, ranging from 0 (never) to 4 (always). The total score is calculated by adding the scores of the individual items, and ranges from 0 to 52.

Pain was assessed using an 11-point numerical rating scale (NRS) ranging from 0 (no pain) to 10 (the worst imaginable pain) [20].

The QoL was assessed using the validated Italian Short Form Health Survey (SF-36) [21, 22], a 36-item generic self-administered instrument that consists of eight subscales relating to various aspects of the QoL: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health. The eight subscales are scored from 0 to 100, with higher scores indicating better health status.

The six-minute walking test (6MWT), which measures the distance a patient can walk in a period of 6 min, was used to evaluate functional endurance.

Spatio-temporal gait parameters (velocity, cadence, step length, step time, and single support time of both sides) were measured using the GAITRite[®] Walkway System (CIR System Inc., Clifton, NJ), a computerised 4.88-m walking mat capable of identifying footfall contacts. The GAITRite[®] was placed in the middle of a straight 10-m walking track in order to exclude the acceleration and deceleration phases from the kinematic analysis. The subjects were asked to do the trial three times, and their gait

Table 1 Baseline clinical and demographic characteristics of study participants

	Experimental group (n = 10)	Control group (n = 10)	p value
Age (years)	58.9 ± 16.4	56.6 ± 14.4	0.751
Gender (male/female)	3/7	6/4	
Body mass index (kg/m ²)	27.4 ± 4.9	25.2 ± 3.1	0.284
Pain duration (months)	14.7 ± 6.5	14.2 ± 5.1	0.856
Irradiation (yes/no)	6/4	4/6	
Occupation			
Student	1	0	
Employed	2	4	
Self-employed	1	0	
Pensioner	5	5	
Housewife	1	1	
Education			
Primary school	1	0	
Middle school	3	4	
High school	4	4	
University	2	2	
Comorbidities (principal)			
Cardiac diseases	0	1	
Respiratory diseases	2	1	
Gastroenteric diseases	2	0	
Kidney diseases	1	3	
Endocrine diseases	0	0	
Anxiety/depression	3	2	
Other	0	0	
Type of drug used			
Antidepressant/anti-anxiolytic	1	0	
Analgesic	3	3	
Muscle relaxant	0	0	
NSAIDs/corticosteroid	0	0	
Unable to participate/ perform usual activities, such as domestic duties, jobs (yes/no)	3/7	4/6	
Smokers (yes/no)	1/9	2/8	
Married (yes/no)	8/2	9/1	

NSAIDs non-steroidal anti-inflammatory drugs

parameters were computed as the mean value of the three repetitions.

Global perceived effect (GPE) was assessed by means of a self-administered measure of treatment satisfaction consisting of a five-level Likert scale with two improvement levels (much better = 1, better = 2), one no change level (approximately the same = 3) and two worsening levels (a little worse = 4, worse = 5) [23].

Table 2 Outcome measures at baseline

	Experimental group (n = 10)	Control group (n = 10)	p value
Primary outcome			
ODI (0–100)	26 (5)	24 (2)	0.430
Secondary outcomes			
TSK (13–52)	29 (7)	27 (5)	0.552
NRS (0–10)	5 (3)	4 (1)	0.669
PCS (0–52)	25 (6)	23 (4)	0.437
SF-36			
Physical activity (0–100)	41 (7)	43 (5)	0.551
Physical role (0–100)	38 (18)	35 (13)	0.722
Bodily pain (0–100)	45 (14)	48 (13)	0.629
General health (0–100)	34 (15)	39 (12)	0.476
Vitality (0–100)	54 (12)	54 (13)	0.931
Social functioning (0–100)	60 (10)	59 (10)	0.785
Emotional role (0–100)	47 (17)	43 (16)	0.660
Mental health (0–100)	59 (10)	57 (12)	0.747
6MWT			
Speed (m/s)	1.17 (0.22)	1.26 (0.18)	0.291
Spatio-temporal gait parameters			
Speed (m/s)	1.02 (0.06)	1.03 (0.10)	0.754
Cadence (steps/min)	106.0 (4.5)	105.8 (4.1)	0.842
Left step length (m)	0.56 (0.01)	0.56 (0.02)	0.728
Right step length (m)	0.53 (0.02)	0.53 (0.02)	0.628
Left step time (s)	0.65 (0.03)	0.66 (0.02)	0.624
Right step time (s)	0.62 (0.02)	0.62 (0.02)	0.416
Left single support time (s)	0.39 (0.01)	0.39 (0.01)	0.452
Right single support time (s)	0.36 (0.01)	0.36 (0.01)	0.657

ODI Oswestry Disability Index, TSK Tampa Scale of Kinesiophobia, NRS Numerical Rating Scale, PCS Pain Catastrophising Scale, SF-36 Short Form Health Survey, 6MWT six-minute walking test

Information on the ability to participate/perform usual activities (such as domestic duties, jobs) and medication use (raw data) were also recorded.

The questionnaires and walking tests were completed before treatment, 8 weeks later (post-treatment), and 3 months after the treatment ended (follow-up). After treatment, patients were asked to rate its GPE.

Table 3 Changes over time within and between the control and experimental group

	Group	Pre-training	Post-training	Follow-up	<i>F</i> (<i>p</i> value) group effect	<i>F</i> (<i>p</i> value) time effect	<i>F</i> (<i>p</i> value) interaction effect
Primary outcome							
ODI (0–100)	Experimental	26 (5)	10 (5)	8 (6)	5.822 (0.027)	254.874 (<0.001)	28.939 (<0.001)
	Control	24 (2)	18 (3)	15 (3)			
Secondary outcomes							
TSK (13–52)	Experimental	29 (7)	19 (6)	15 (4)	7.736 (0.012)	30.727 (<0.001)	23.426 (<0.001)
	Control	27 (5)	25 (4)	27 (4)			
NRS (0–10)	Experimental	5 (3)	2 (1)	2 (1)	0 (1.00)	13.455 (<0.001)	0.463 (0.637)
	Control	4 (1)	2 (2)	3 (2)			
PCS (0–52)	Experimental	25 (6)	11 (6)	9 (5)	9.566 (0.006)	53.9 (<0.001)	14.934 (<0.001)
	Control	23 (4)	20 (4)	18 (4)			
SF-36							
Physical activity (0–100)	Experimental	41 (7)	80 (11)	84 (6)	10.841 (0.001)	139.849 (<0.001)	11.069 (0.001)
	Control	43 (5)	66 (10)	67 (10)			
Physical role (0–100)	Experimental	38 (18)	78 (22)	80 (16)	5.250 (0.034)	33.511 (0.002)	2.772 (0.089)
	Control	35 (13)	58 (29)	59 (11)			
Bodily pain (0–100)	Experimental	45 (14)	62 (15)	65 (12)	1.346 (0.261)	13.036 (<0.001)	3.151 (0.067)
	Control	48 (13)	53 (15)	55 (7)			
General Health (0–100)	Experimental	34 (15)	66 (10)	71 (5)	6.753 (0.018)	33.790 (<0.001)	4.902 (0.020)
	Control	39 (12)	53 (14)	55 (8)			
Vitality (0–100)	Experimental	54 (12)	76 (10)	82 (8)	8.880 (0.008)	16.659 (<0.001)	5.602 (0.013)
	Control	54 (13)	60 (14)	62 (11)			
Social function (0–100)	Experimental	60 (10)	78 (15)	81 (7)	15.278 (0.001)	9.437 (0.002)	6.775 (0.006)
	Control	59 (10)	60 (17)	61 (7)			
Emotional role (0–100)	Experimental	47 (17)	70 (19)	77 (16)	9.308 (0.007)	11.889 (0.001)	1.579 (0.233)
	Control	43 (16)	57 (16)	57 (16)			
Mental health (0–100)	Experimental	59 (10)	86 (13)	88 (10)	16.165 (0.001)	15.576 (<0.001)	4.107 (0.034)
	Control	57 (12)	66 (13)	67 (12)			
6MWT							
Speed (m/s)	Experimental	1.17 (0.22)	1.54 (0.18)	1.53 (0.18)	0.524 (0.478)	44.242 (<0.001)	11.119 (<0.001)
	Control	1.26 (0.18)	1.38 (0.20)	1.42 (0.21)			

ODI Oswestry Disability Index, *TSK* Tampa Scale of Kinesiophobia, *NRS* Numerical Rating Scale, *PCS* Pain Catastrophising Scale, *SF-36* Short Form Health Survey, *6MWT* six-minute walking test

The patients were also given a form to enter any serious and distressing symptoms experienced during the study that required further treatment.

Statistics

Baseline comparability was assessed using Student's *t* test for independent samples. Linear mixed model analyses for repeated measures ($p < 0.05$) were made of each of the outcome measures, with group and time entered as fixed effects, and the outcome measures as dependent variables

[24, 25]. The crossover effect of time and group was entered as an interaction term.

The between-group difference in satisfaction with the treatment (GPE scores) was assessed using the Mann–Whitney *U* test.

The data were analysed using SPSS 21.0 software.

Results

Twenty-eight patients were screened, and 20 agreed to participate and were randomised. Eight subjects were

Table 4 Changes over time in spatio-temporal gait parameters within and between the control and experimental group

	Group	Pre-training	Post-training	Follow-up	<i>F</i> (<i>p</i> value) group effect	<i>F</i> (<i>p</i> value) time effect	<i>F</i> (<i>p</i> value) interaction effect
Spatio-temporal gait parameters							
Speed (m/s)	Experimental	1.02 (0.06)	1.36 (0.24)	1.42 (0.21)	4.213 (0.055)	34.673 (<0.001)	2.573 (0.104)
	Control	1.03 (0.01)	1.21 (0.05)	1.25 (0.05)			
	Healthy ^a	1.50 (0.20)					
Cadence (steps/min)	Experimental	106.0 (4.5)	120.9 (9.3)	126.4 (8.3)	7.627 (0.013)	42.413 (<0.001)	5.323 (0.015)
	Control	105.8 (4.1)	111.4 (4.4)	116.2 (7.0)			
	Healthy ^a	120.8 (8.3)					
Left step length (m)	Experimental	0.56 (0.01)	0.69 (0.10)	0.70 (0.09)	0.211 (0.651)	40.837 (<0.001)	1.401 (0.272)
	Control	0.56 (0.01)	0.66 (0.04)	0.70 (0.05)			
	Healthy ^a	0.74 (0.07)					
Right step length (m)	Experimental	0.53 (0.02)	0.69 (0.11)	0.70 (0.09)	1.032 (0.323)	48.624 (<0.001)	2.082 (0.154)
	Control	0.53 (0.02)	0.64 (0.04)	0.67 (0.05)			
	Healthy ^a	0.74 (0.07)					
Left step time (s)	Experimental	0.65 (0.03)	0.55 (0.04)	0.52 (0.03)	5.618 (0.029)	87.305 (<0.001)	3.416 (0.055)
	Control	0.66 (0.02)	0.50 (0.02)	0.50 (0.05)			
	Healthy ^a	0.50 (0.04)					
Right step time (s)	Experimental	0.62 (0.02)	0.54 (0.05)	0.52 (0.03)	12.194 (0.003)	81.403 (<0.001)	6.834 (0.006)
	Control	0.62 (0.02)	0.48 (0.03)	0.48 (0.05)			
	Healthy ^a	0.50 (0.04)					
Left single support time (s)	Experimental	0.39 (0.01)	0.41 (0.06)	0.41 (0.05)	1.761 (0.201)	0.810 (0.460)	0.818 (0.457)
	Control	0.39 (0.01)	0.39 (0.02)	0.38 (0.03)			
	Healthy ^a	0.43 (0.02)					
Right single support time (s)	Experimental	0.36 (0.01)	0.41 (0.06)	0.41 (0.05)	3.127 (0.094)	5.783 (0.011)	1.832 (0.189)
	Control	0.36 (0.01)	0.37 (0.02)	0.37 (0.03)			
	Healthy ^a	0.43 (0.02)					

^a Values of healthy subjects are derived from [29]

excluded since they did not give their consent (2); had logistical problems (3); had other problems, such as mental disorders (1), systemic diseases (1), or had previously undergone CBT (1).

All of the participants completed the treatment interventions and all of the assessment tests. No crossover problems arose.

Table 1 shows the clinical and demographic details of the study subjects: there were no differences between the groups in terms of age, body mass index, or the duration of pain before study enrolment. All of the outcome measures were similar in the two groups at baseline (Table 2).

After training, disability improved by about 61 % in the experimental group and by about 25 % in the control group, indicating a significant effect of time ($p < 0.001$), group ($p = 0.027$), and time-by-group interaction ($p < 0.001$) in favour of the experimental group (Table 3).

The experimental group showed a significant reduction in kinesiophobia, which was maintained during follow-up, whereas there were no significant changes over time in the control group (Table 3). Catastrophizing was greatly

reduced (by about 56 %) in the experimental group, but only slightly so in the control group (by about 13 %) (Table 3).

Time had a significant effect on pain ($p < 0.001$) (Table 3).

There was a significant effect of time, group and time by group interaction on most of the SF-36 domains (Table 3), but no significant between-group difference in the pain domain.

Average speed during the 6MWT increased in both groups after training, but there was a significant time-by-group interaction ($p < 0.001$) in favour of the experimental group (Table 3). The improvements were maintained during follow-up.

After training, gait cadence increased by about 14 % in the experimental group and 5 % in the control group, thus indicating a significant effect of time ($p < 0.001$), group ($p = 0.013$) and time-by-group interaction ($p = 0.015$). Cadence further increased in both groups during follow-up. The control group showed a more significant reduction in step time after training (about 24 and 22 % for the left and

right step respectively vs about 15 and 13 %). All of the other gait parameters showed a significant effect of time except for the left single support time, thus indicating a general improvement in gait kinematics in both groups (Table 4).

At post-treatment the median GPE values (interquartile range) were 1 (0) in the experimental group, and 2.5 (1) in the control group. The significant between-group difference ($p = 0.005$) suggested a greater perception of the efficacy of the training in the experimental group.

All of the subjects in the experimental group had returned to their usual activities (including work activities) by the end of treatment and at follow-up, whereas three controls were unable to do so after training, and two were unable to do so after the follow-up. Moreover, all of the patients in the experimental entirely eliminated their medication use at the end of training, maintaining this habit also at follow-up; the patients belonging to the control group slightly reduced their medication use at the end of treatment (analgesic: 2), but increased it at follow-up (analgesic: 5; muscle relaxant: 2).

Minor episodes of transitory pain worsening (three in the experimental group, and two in the control group) and mood alterations (one in the experimental group and two in the control group) were easily managed by means of symptomatic drugs and psychological interventions.

Discussion

The results of this pilot study suggest that the 2-month multidisciplinary rehabilitation programme was superior to the exercise programme alone in reducing disability, kinesiophobia, and catastrophizing, and enhancing QoL of subjects with CLBP. Gait cadence improved significantly more in the experimental group, with all of the other gait parameters improving in both groups. The effects lasted for at least 3 months after the interventions.

Disability had improved in both groups by the end of treatment, but more in the experimental group. Based on a motor learning model, the use of spinal stabilising exercises resulted in better control of deep spinal muscles, increasing the coordinated muscle recruitment between large trunk muscles and small intrinsic muscles, reducing the excessive intersegmental motion and hindering the presence of compensatory movement strategies due to lumbar dysfunction. Hence, subjects had the possibility of being retrained into functional tasks specific to the patient's individual needs and progressively regaining independence in activities turned vulnerable due to abnormal movement patterns, such as sitting, standing, bending, twisting, lifting, washing, dressing, sleeping, walking and travelling [2, 16].

Moreover, the subjects had positive attitudes towards the exercises throughout the course of the intervention, and their physical performance gradually increased: the key factor was learning how to modify kinesiophobia and control catastrophizing, which may have modified the perception of being disabled. In the experimental group, there was a further improvement in disability at follow-up that was probably due to the levels of catastrophizing and kinesiophobia, which improved in the experimental group but remained unchanged in the control group and thus continued to be a major barrier [26].

The QoL improved in both groups, as shown by the improvements in most of the SF-36 domains at the end of treatment and follow-up; the better results in the experimental group suggest the potential benefits of cognitive interventions in relation to the mental domains. A previous study showed that a 4-week cognitive-behavioural therapy carried out on a full-time basis (33–34 h per week) improved health and favoured a return to work and usual activities [27]. Our results showed that even a less intensive training (3 h per week for 8 weeks) was able to achieve similar results.

Pain had decreased in both groups by the end of treatment and at follow-up, and reflected the positive effects of interventions based on active approaches. During the follow-up period, these effects slightly declined in the control group, suggesting it is difficult to modify pain perception effectively in chronic populations without adequate cognitive-behavioural management [28, 29].

In line with the findings of previous studies of walking performance in patients with CLBP [1], the participants walked more slowly at baseline due to a combination of reduced step length and increased step time. After training, both groups significantly increased their walking speed, with the experimental group showing a greater, although not significant improvement. This difference might be related to the more significant improvements in kinesiophobia in the experimental group as it has been suggested that the anticipation of pain and kinesiophobia are the strongest predictors of speed deficits in patients with CLBP [1]. More significant improvements in cadence (up to normal ranges) were achieved by the experimental group, which suggests that reduced kinesiophobia and a stronger spine had a positive influence. The improvements in step length and step time were significant in both groups, with values very near the reference estimates [30]. The single support time was already close to normal at baseline and did not change over time in either group.

The GPE scores showed higher rates of treatment satisfaction in the experimental group, thus suggesting its superiority over a purely physical approach as addressing fears and engaging attention in solving them was probably perceived as a better answer to ongoing problems.

However, caution is required when interpreting these findings as the physiotherapists and psychologist could not be blinded to the study hypothesis, and they may have influenced the patients' expectations about the treatments.

It is worth noting that the experimental programme has to be considered at low cost, as about 230 € are provided from the Italian healthcare system for the entire programme per patient; as expected, the innovative programme is slightly more expensive than traditional approaches based only on physical exercises (about 160 €) but, based on the positive findings on pain, disability and QoL above described, this intervention might have a crucial role also in preventing additional costs owing to the excessive use of pain-killers, as well as limitations in usual life activities due to high levels of kinesiophobia.

Although the study sample was small, it was representative of the general population undergoing rehabilitation for CLBP in Italy [13]. However, the study does have some other limitations: the small sample reduced its internal validity; aspects other than kinesiophobia and catastrophizing were not targeted during the psychological sessions; questions can be raised concerning the differences in contact time between the groups; and the long-term follow-up was not evaluated. Furthermore, treatment expectations were not considered, and this confounding factor could only be partially limited by telling the patients during enrolment that the efficacy of both treatments had not yet been established, and that both approaches might contribute to improving their disability. Finally, neither interventional programmes included task-specific gait training. Given the slight gait impairment of this population, locomotion should be trained under difficult conditions such as unstable surfaces, the presence of obstacles, during acceleration and deceleration, and with increasing weights in order to better reflect daily life. In the future, it would be interesting to investigate whether the incorporation of such training might further improve the walking ability and QoL of subjects with CLBP.

Conclusions

Our findings suggest the effectiveness of a 2-month multidisciplinary rehabilitation programme in improving disability, kinesiophobia, catastrophizing, and the QoL of subjects with CLBP. The treatment effect was also tangible in terms of gait cadence, thus suggesting the positive impact of cognitive-behavioral therapy on non-spinal motor tasks such as walking. In order to confirm the generalizability of these results, an adequately sized randomised controlled trial, including a long-term follow-up, is recommended.

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Ethical standards Our Institutional Review Board approved the study, which was conducted in conformity with ethical and humane principles of research.

References

1. Al Obaidi SM, Al-Zoabi B, Al-Shuwaie N, Al-Zaabie N, Nelson RM (2003) The influence of pain and pain-related fear and disability beliefs on walking velocity in chronic low back pain. *Int J Rehab Res* 26(2):101–108
2. O'Sullivan PB (2000) Lumbar segmental 'instability': clinical presentation and specific stabilizing exercise management. *Man Ther* 5(1):2–12
3. Della Volpe R, Popa T, Ginanneschi F, Spidalieri R, Mazzocchio R, Rossi A (2006) Changes in coordination of postural control during dynamic stance in chronic low back pain patients. *Gait Posture* 24:349–355
4. Elbaz A, Mirovsky Y, Mor A, Enosh S, Debbi E, Segal G, Barzilay Y, Debi R (2009) A novel biomechanical device improves gait pattern in patient with chronic nonspecific low back pain. *Spine (Phila Pa)* 34(15):E507–E512
5. Lamoth CJC, Daffertshofer A, Meijer OG, Beek PJ (2006) How do persons with chronic low back pain speed up and slow down? Trunk–pelvis coordination and lumbar erector spinae activity during gait. *Gait Posture* 23:230–239
6. Mok NW, Brauer SG, Hodges PW (2004) Hip strategy for balance control in quiet standing is reduced in people with low back pain. *Spine (Phila Pa)* 29(6):E107–E112
7. Vlaeyen JWS, Kole-Snijders AMJ, Boeren RGB, van Eek H (1995) Fear of movement/(re)injury in chronic low back pain and its relation to behavioural performance. *Pain* 62:363–372
8. Vlaeyen JWS, Linton SJ (2000) Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 85:317–332
9. Waddell G (2004) *The Back pain revolution*, 2nd edn. Churchill Livingstone, London
10. Pincus T, Vlaeyen JW, Kendall NA, Von Korff MR, Kaloupek DA, Reis S (2002) Cognitive-behavioral therapy and psychosocial factors in low back pain. *Directions for the future. Spine (Phila Pa)* 27(5):E133–E138
11. van Middelkoop M, Rubinstein SM, Kuijpers T, Verhagen AP, Ostelo R, Koes BW, van Tulder MW (2011) A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. *Eur Spine J* 20:19–39
12. Henschke N, Ostelo RW, van Tulder MW, Vlaeyen JW, Morley S, Assendelft WJ, Main CJ (2010) Behavioural treatment for chronic low-back pain. *Cochrane Database of Systematic Reviews Issue 7. Art. No.: CD002014*
13. Monticone M, Ferrante S, Rocca B, Baiardi P, Dal Farra F, Foti C (2013) Effect of a long-lasting multidisciplinary programme on disability and fear-avoidance behaviours in subjects with chronic low back pain. Results of a randomised controlled trial. *Clin J Pain* 29(11):929–938
14. Matthews John NS (2006) *Methods of allocation. Introduction to randomized controlled clinical trials*, 2nd edn. Chapman and Hall/CRC, New York, pp 43–64
15. Monticone M, Ferrante S, Teli M, Rocca B, Foti C, Lovi A, Brayda Bruno M (2014) Management of catastrophizing and kinesiophobia improves rehabilitation after fusion for lumbar spondylolisthesis and stenosis. A randomised controlled trial. *Eur Spine J* 23(1):87–95

16. Monticone M, Baiardi P, Ferrari S, Foti C, Mugnai R, Pillastrini P, Vanti C, Zanolini G (2009) Development of the Italian version of the Oswestry Disability Index, ODI-I. A cross-cultural adaptation, reliability and validity study. *Spine (Phila Pa)* 34(19): 2090–2095
17. Monticone M, Baiardi P, Vanti C, Ferrari S, Pillastrini P, Mugnai R, Foti C (2012) Responsiveness of the Oswestry Disability Index and the Roland Morris Disability Questionnaire in Italian subjects with sub-acute and chronic low back pain. *Eur Spine J* 21: 122–129
18. Monticone M, Giorgi I, Baiardi P, Barbieri M, Rocca B, Bonezzi C (2010) Development of the Italian version of the Tampa Scale of Kinesiophobia, TSK-I. Cross-cultural adaptation, factor analysis, reliability and validity. *Spine (Phila Pa 1976)* 35: 1241–1246
19. Monticone M, Baiardi P, Ferrari S, Foti C, Mugnai R, Pillastrini P, Rocca B, Vanti C (2012) Development of the Italian version of the Pain Catastrophizing Scale (PCS-I): cross-cultural adaptation, factor analysis, reliability, validity and sensitivity to change. *Qual Life Res* 21(6):1045–1050
20. Huskinson EC (1974) Measurement of pain. *Lancet* 2:1127–1131
21. Apolone G, Mosconi P (1998) The Italian SF-36 survey: translation, validation and norming. *J Clin Epidemiol* 51(11): 1025–1036
22. Apolone G, Mosconi P, Ware J (2000) Questionario sullo stato di salute SF-36. Manuale d'uso e guida all'interpretazione dei risultati. (SF-36 quality of life questionnaire. User's manual and guide to the interpretation of results). Guerini e Associati Editors, Milan (in Italian)
23. Kamper SJ, Ostelo RWJG, Knol DL, Maher CG, De Vet HCW, Hancock MJ (2010) Global perceived effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. *J Clin Epidemiol* 63(7):760–766
24. Fielding S, Fayers P, Ramsay CR (2012) Analysing randomised controlled trials with missing data: choice of approach affects conclusions. *Contemp Clin Trials* 33:461–469
25. Siddiqui O, Hung HM, O'Neill R (2009) MMRM vs. LOCF: a comprehensive comparison based on simulation study and 25 NDA datasets. *J Biopharm Stat* 19:227–246
26. Crombez G, Vlaeyen JWS, Heuts PHTG, Lysens R (1999) Fear of pain is more disabling than pain itself. Evidence on the role of pain-related fear in chronic back pain disability. *Pain* 80:329–340
27. Jensen IB, Bergstrom G, Ljungquist T, Bodin L (2005) A 3-year follow-up of a multidisciplinary rehabilitation programme for back and neck pain. *Pain* 115:273–283
28. Kaapa EH, Frantsi K, Sarna S, Malmivaara A (2006) Multidisciplinary group rehabilitation versus individual physiotherapy for chronic nonspecific low back pain: a randomized trial. *Spine* 31:371–376
29. Smeets RJ, Vlaeyen JW, Hidding A, Kester AD, van der Heijden GJ, Knottnerus JA (2008) Chronic low back pain: physical training, graded activity with problem solving training, or both? The one-year post-treatment results of a randomized controlled trial. *Pain* 134:263–276
30. Titianova EB, Mateev PS, Tarkka IM (2004) Footprint analysis of gait using a pressure sensor system. *J Electromyogr Kinesiol* 14(2):275–281