Management of catastrophising and kinesiophobia improves rehabilitation after fusion for lumbar spondylolisthesis and stenosis. A randomised controlled trial

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Introduction

Lumbar spondylolisthesis refers to the anterior displacement of a vertebra over the one below; it is called "degenerative" when associated with degeneration of the posterior facet joints and/or intervertebral disc and "isthmic" when associated with bilateral spondylolysis [1]. Degenerative and isthmic spondylolisthesis may progress to lumbar spinal stenosis (LSS), which is defined as a narrowing of the lumbar spinal canal commonly caused by

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degenerative spinal conditions [2]. Low back pain (LBP), radicular pain, lower limb motor impairment and claudication, caused by the entrapment and compression of intraspinal vascular and nervous structures, are reported in symptomatic subjects [1].

Patients with chronic and disabling symptoms secondary to spondylolisthesis and LSS who fail to respond to conservative management may be referred for surgery to reduce pain, improve spinal function, and increase the quality of life: after a careful analysis of indications and outcomes, lumbar fusion is recommended in the presence (i.e. spondylolisthesis) or expectation of spinal instability (e.g. following a wide laminectomy for LSS) [3, 4].

Over the last decades, spinal fusion procedures have significantly increased in Western countries as a result of various factors, including a better biomechanical understanding of the spine, improved diagnostic techniques, the evolution of spinal implants, and the growing size of the ageing population [5].

As a result of the experience of chronic pain, patients who undergo spinal fusion may still present a disuse syndrome characterised by the abnormal use of the spine, changes to the structure of the trunk muscles, physical inactivity and limitations to usual life activities [5–7]. With regard to the fear-avoidance model, psychological factors such as catastrophising, fear-avoidance beliefs, and mood alterations may coexist and become important determinants of chronic symptoms, disability and illness behaviours that induce subjects to sacrifice everyday tasks or the use of adaptive coping strategies [8].

Given the multidimensional nature of pain [9], rehabilitation programmes based on cognitive-behavioural therapies (CBT) have been recommended for subjects with chronic LBP, and are often used in addition to other therapies such as exercise [10, 11]. However, the use of CBT and exercise after lumbar fusion is poorly documented and widely debated, and it has been suggested that further evidence is required to improve post-surgical outcomes from a bio-psychosocial perspective [12–16].

Our hypothesis was that a rehabilitation programme of active exercises including the management of catastrophising and kinesiophobia improves disability, pain and the quality of life in subjects after lumbar fusion for degenerative spondylolisthesis and/or LSS. The aim of this randomised controlled study was to compare this programme with a programme of exercises usually delivered during post-surgical rehabilitation.

Materials and methods

Experimental design

Randomised, parallel-group, controlled-superiority trial.

Inclusion criteria

A primary diagnosis of degenerative or isthmic spondylolisthesis and/or LSS determined by expert spine surgeons; LBP and/or sciatica for more than 12 months and unresponsive to conservative treatment; patients selected for lumbar fusion with or without decompression; fluency in Italian; and age of >18 years.

Exclusion criteria

Previous spinal fusion, mental impairment, or systemic or neuromuscular diseases. Any subject who had previously undergone CBT was also excluded.

Setting

The study was conducted at the Salvatore Maugeri Foundation's Scientific Institute in Lissone (Italy), a specialised rehabilitation centre at which a multidisciplinary team of physiatrists, physiotherapists and psychologists experienced in spinal diseases and CBT treat more than 100 subjects with a lumbar fusion every year.

Patient enrolment

In-patients referred to our hospital were consecutively included in the study between January 2008 and December 2010. All the patients were evaluated by two physiatrists, and those satisfying the entry criteria were asked to declare their willingness to comply with whichever treatment option they were randomly assigned to, and to attend all the follow-up visits.

In order to partially limit expectation bias, 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. This explanation was also expected to reduce problems of crossover.

Those who agreed to take part in the study were asked to give their written informed consent.

Interventional programmes

These involved two physiatrists, a psychologist, and four physiotherapists. The experimental group underwent a programme consisting of CBT and exercises; the control group were only given exercises. Both programmes lasted 1 month.

Cognitive-behavioural therapy (experimental group) Under the supervision of the psychologist, the purpose was to modify catastrophising and the fear of movement by ensuring gradual reactions to illness behaviours. After

explaining the fear-avoidance model [8], the patients were educated to view their pain as something that can be self-managed rather than a serious disease that needs vigilant protection. Correct relearning 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 a fear of movement to increasing their level of activity by means of graded exposure to the situations they had previously identified as dangerous. The reacquisition of adaptive coping strategies was promoted by means of communication, motivation and sharing the goals to be reached during common activities.

All the subjects attended individual 60-min CBT sessions twice a week for 4 weeks.

Exercise training (experimental and control group) This programme involved active spinal mobilisation aimed at gradually improving the range of motion, exercises to improve spinal deep muscle awareness by means of specific techniques for strengthening the same muscles, and segmentary stretching involving the lower limb and back muscles. Postural control was developed by means of functional exercises aimed at improving motor control of the spine and pelvis [17]. The patients were also given walking exercises and trained in how to change position. Ergonomic advice was provided in the form of a booklet given to the patients upon admission to facilitate the modification of their usual activities.

All the subjects followed the exercise programme individually. Two physiotherapists were separately responsible for each randomised group and arranged 90-min sessions five times a week for 4 weeks. The physiotherapists were experienced at the same level. Based on their clinical experience, scientific knowledge and self-convictions, the physiotherapists believed they were doing the best treatment for their patients.

In order to ensure 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 treatment programme based on a treatment manual for the administration of CBT and exercise training.

No other treatments (e.g. physical modalities, 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, significant others or parents 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.

Randomisation

Immediately after the patients had given their consent, the physiatrists mailed the principal investigator (PI), who randomised the subjects to one of the two treatment programmes using a list of blinded treatment codes previously generated by a biostatistician [18] and an automatic assignment system to assure the concealment of the allocation. The list of allocation included 132 codes and was created using random permuted blocks with random block length. The method used assured that each patient is equally likely to receive the two treatments, the number of patients allocated to the two groups can never differ by more than three and the possibility of selection bias is negligible [18].

Blinding

The PI obtaining and assessing the outcome data and the biostatisticians making the analyses were all blinded to the treatments. The physiatrists, psychologist and physiotherapists could not be blinded.

Outcome measures

Disability (primary outcome), catastrophising, kinesiophobia, pain, and the quality of life (secondary outcomes) were investigated.

Disability was assessed using the Italian version of the self-reported Oswestry Disability Index (ODI), which allows a comprehensive evaluation of back problems. The total score varies from 0 (no disability) to 100 (maximum disability) [19].

Catastrophising was evaluated by means of the 13-item Italian version of the self-reported Pain Catastrophising Scale (PCS), with each item being scored using a five-point scale (0 = never; 4 = always) [20]. The total score is calculated by adding the scores of the items (range 0–52), with higher scores representing greater catastrophising.

Fear-avoidance behaviours were assessed using the 13-item Italian version of the self-reported Tampa Scale for Kinesiophobia (TSK) [21]. Each item is scored using a four-point scale (1 = strongly disagree; 4 = strongly agree). The total score is calculated by adding the scores of the items (range 13–52), with higher scores representing greater kinesophobia.

Pain was assessed using an 11-point Numerical Rating Scale (NRS) ranging from 0 (no pain) to 10 (the worst imaginable pain) [22].

Quality of life (QoL) was assessed using the Italian version of the self-reported Short-Form Health Survey (SF-36) [23], and its eight domain scores of physical functioning (PF), physical role (PR), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), emotional role (ER), and mental health (MH) were calculated on the basis of the user's manual of the Italian version (0 = worst perceived, 100 = best perceived QoL) [24].

The questionnaires were completed before treatment (T1), 4 weeks later (post-treatment, T2), and 12 months after discharge from hospital (1 year follow-up, T3).

At T1/T2, the questionnaires were administered by secretarial staff who checked them and returned any uncompleted part to the patients for completion. At T3, the patients were met personally or contacted by phone by the same secretarial staff to ensure the questionnaires were properly completed.

At T2, the patients were also asked to rate the global perceived effect (GPE) of treatment using a 5-point scale (1 = helped a lot; 5 = made things worse).

The ODI, TSK and PCS questionnaires were routinely used in our clinical practise since 2007 in a not yet validated form, but following the same procedure reported in the subsequent validation studies conducted in 2008 [19, 21] and 2010 [20].

Adverse effects

Using a specific form, the patients were asked to report any serious and distressing symptoms they experienced during the study that required further treatment.

Statistics

The primary endpoint was the pre- and post-treatment difference (T2−T1) in total ODI scores. The sample size was computed using the Italian ODI, for which it is estimated that the minimum clinical important change is 10 with an effect size of about 0.53 [25]. In order to assure 90 % statistical power, 110 patients were required, but 130 were actually recruited to allow for a drop-out rate of about 15 %.

Baseline comparability was assessed using Student's t test for continuous variables, and the χ^2 test for categorical and ordinal variables.

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 [26, 27]. The crossover effect of time and group was entered as an interaction term.

Because of its non-parametric distribution, GPE was analysed using the Mann–Whitney test.

The data were analysed using SPSS 20.0 software.

IRB approval

The study was approved by our hospital's Institutional Review Board (number: 12; date of approval: 10/12/2007), and was conducted in conformity with ethical and humane principles of research.

Results

Patient flow

Of the 224 screened patients, 130 (58 %) were eligible and agreed to enter the study: 65 were randomised to the experimental group and 65 to the control group. Six patients dropped out from the experimental group and seven from the control group during the course of the study. Figure 1 shows the study flowchart.

No crossover problems arose, as no patient asked to swap groups.

Effects of the interventional programme

Baseline comparison Table 1 shows the characteristics of the participants.

Primary outcome The effect of treatment was significantly greater in the experimental group than in the control group (T2−T1 mean change 26.8 vs. 15.4). The linear mixed model for repeated measures revealed significant main effects for group ($F(1,122.8) = 95.78$, $p < 0.001$) and time ($F(2,120.1) = 432.02$, $p < 0.001$) in favour of the experimental group. There was also a significant group × time interaction effect ($F(2,120.1) = 20.37$, $p < 0.001$) (Table 2).

Secondary outcomes All the scores significantly improved between T1 and T3 in the experimental group, whereas there was less change in the control group. The statistical analyses of all the outcome measures revealed a significant effect of time, group and interaction in favour of the experimental group (Table 2).

GPE This was significantly better ($p < 0.001$) in the experimental group (median 1, interquartile range 1) than in the control group (median 2, interquartile range 2).

Adverse effects

Minor effects of transitory pain worsening ($n = 9$ in the experimental group, and $n = 8$ in the control group) and mood alterations ($n = 3$ and $n = 5$) were easily managed by means of symptomatic drugs and psychological interventions.

Discussion

The results of this trial showed that the rehabilitation programme including the management of catastrophising and kinesiophobia was superior to the exercise programme in reducing disability, fear-avoidance beliefs, catastrophic thoughts and pain, and enhancing the quality of life of

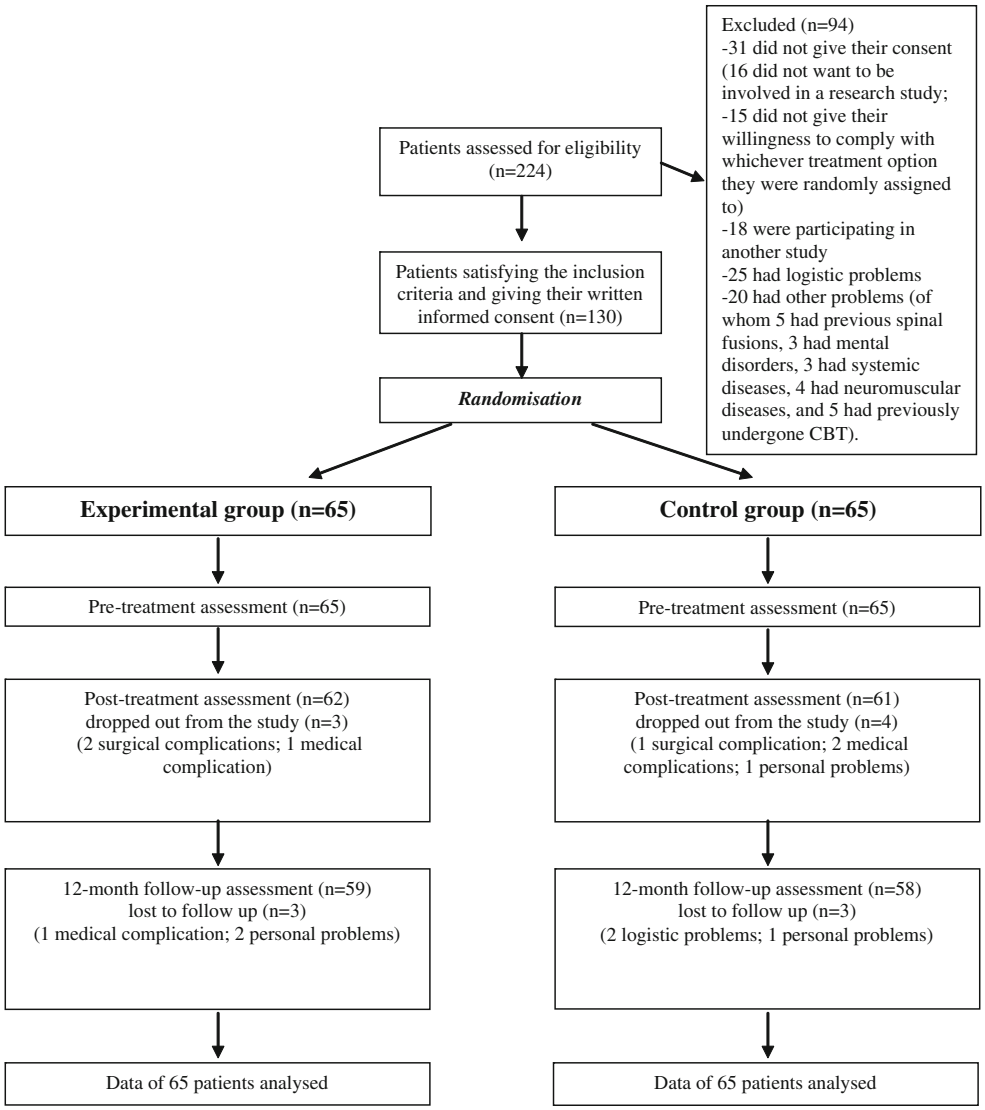

Fig. 1 Flowchart of the formation of study groups

patients after lumbar fusion for degenerative spondylolisthesis and/or LSS.

Disability had improved in both groups by the end of treatment, but the improvement was greater in the experimental group. Explaining to the patients how to control catastrophising and modify mistaken fears, and encouraging them to adopt appropriate behaviours induced helpful attitudes towards perceived disability: this enhanced their positive attitude towards the exercises and increased their physical performance, as previously advocated [9]. With regard to the fear-avoidance model [8], satisfactory levels were maintained until the end of the follow-up, probably because of the patients' consolidation of appropriate behaviours. The significant between-group difference in disability was due to the levels of catastrophising and kinesiophobia, which improved in the experimental group but remained unchanged throughout the study in the control group, thus representing a major barrier to improved physical performance and disability, as stated by Crombez et al. [28].

Pain perception had decreased in both groups by the end of treatment and follow-up, and reflected the synergistic effects of surgery and active exercises. As suggested [12, 29], pain has a strongly subjective component, and the way patients react when they are in pain can modify their self-perception, which explains the better results achieved by subjects who are helped to develop appropriate cognitive-behavioural strategies.

The important effect of treatment on all of the SF-36 subscales suggests the benefits of gaining control over catastrophising and kinesiophobia. The improvement was always significantly greater in the experimental group.

Table 1 Patient characteristics at baseline

	Experimental group ($n = 65$)	Control group ($n = 65$)	p value
Age (years)	58.75 ± 11.81	55.91 ± 14.16	n.s.
Gender (male/female)	21/44	30/35	n.s.
Smokers (yes/no)	34/31	37/28	n s
Married (yes/no)	54/11	55/10	n.s.
Employed (yes/no)	41/24	39/26	n.s.
Physical activity (yes/no)	21/44	22/43	n.s.
Education			
Primary school	12	11	
Middle school	28	34	n.s.
High school	21	18	
University	4	2	
Comorbidities			
None	23	20	
Musculoskeletal	14	18	n.s.
Non-musculoskeletal	28	27	
Pain duration (months)	33.15 ± 14.16	30.44 ± 14.43	n.s.
Pain			
NRS back	6.57 ± 1.67	6.72 ± 1.66	n.s.
NRS leg	5.28 ± 1.29	5.25 ± 1.38	
ODI	49.06 ± 5.84	48.51 ± 12.62	n.s.
TSK	29.63 ± 6.41	30.03 ± 7.18	n.s.
PCS	24.82 ± 9.28	26.95 ± 8.73	n.s.
SF-36			
PF	32.31 ± 21.12	28.85 ± 27.10	n.s.
PR	26.54 ± 34.48	28.46 ± 33.62	n.s.
BP	35.11 ± 21.11	34.58 ± 21.57	n.s.
GH	44.38 ± 16.48	46.69 ± 12.48	n.s.
VT	47.00 ± 22.37	50.08 ± 19.79	n.s.
SF	50.58 ± 13.70	50.77 ± 10.10	n.s.
ER	32.82 ± 33.06	25.64 ± 31.60	n.s.
MH	48.35 ± 13.85	48.25 ± 10.02	n.s.

Mean values ± standard deviation

NRS Numerical Rating Scale, *ODI* Oswestry Disability Index, *TSK* Tampa Scale for Kinesiophobia, *PCS* Pain Catastrophising Scale, *SF-36* Short-Form Health Survey, *PF* physical functioning, *PR* physical role, *BP* bodily pain, *GH* general health, *VT* vitality, *SF* social functioning, *ER* emotional role, *MH* mental health

The higher rates of treatment satisfaction in the experimental group indicate the superiority of this approach, probably because addressing patients' fears and engaging their attention in solving them was perceived as a better means of responding to their ongoing problems. However, caution should be used when interpreting these findings as the physiotherapists could not be blinded to the study hypothesis and, as a consequence, they might have influenced patients' expectations about treatments.

Christensen et al. [12] have also highlighted the long-term pain and daily function benefits of adding a psychological intervention to exercises; their programme started 3 months after lumbar fusion but, as it has been shown that early exercise does not overload internal lumbar fixation [30], delaying the beginning of rehabilitation does not seem to be mandatory. Earlier intervention is supported by our findings and the results of Abbott et al. [16] showed that motor interventions and CBT were safe and induced long-lasting effects on disability, pain, and kinesiophobia when delivered soon after fusion surgery. Unlike previous studies [12, 16], we planned an entirely hospital-based programme characterised by more frequent and intensive sessions of supervised exercises to guarantee that they were correctly carried out and reinforced learning; our CBT training was also more intensive and required the presence of a psychologist to give prompt assistance in the case of cognitive difficulties and mind reconditioning. Furthermore, it was primarily aimed at controlling catastrophising, kinesiophobia and maladaptive behaviours rather than developing relaxation techniques and cognitive coping strategies.

This trial had a high level of internal validity, was capable of distinguishing effects in the two treatment groups, was adequately sized, involved concealed randomisation, blinded data collection, and the effective

Table 2 Changes over time within and between treatment groups

	Experimental group ($n = 65$)			Control group ($n = 65$)			F (p value) group effect	F (p value) time effect	F (p value) interaction effect
	T1	T2	T3	T1	T2	T3			
NRS back	6.57 ± 1.67	3.18 ± 1.29	2.06 ± 0.93	6.72 ± 1.66	5.31 ± 1.71	4.98 ± 1.38	73.83 ($p < 0.001$)	207.66 ($p < 0.001$)	40.87 ($p < 0.001$)
NRS leg	5.28 ± 1.29	2.29 ± 1.01	1.19 ± 1.01	5.25 ± 1.38	3.23 ± 1.31	2.50 ± 0.54	35.98 ($p < 0.001$)	320.36 ($p < 0.001$)	12.32 ($p < 0.001$)
ODI	49.06 ± 5.84	22.29 ± 3.06	15.98 ± 5.15	48.51 ± 12.62	33.11 ± 3.16	26.53 ± 5.14	95.78 ($p < 0.001$)	432.02 ($p < 0.001$)	20.37 ($p < 0.001$)
TSK	29.63 ± 6.41	19.60 ± 7.53	15.19 ± 5.27	30.03 ± 7.18	27.41 ± 6.59	26.31 ± 6.24	44.66 ($p < 0.001$)	114.58 ($p < 0.001$)	42.95 ($p < 0.001$)
PCS	24.82 ± 9.28	14.79 ± 7.28	12.64 ± 5.57	26.95 ± 8.73	22.85 ± 6.20	23.09 ± 6.13	36.28 ($p < 0.001$)	73.81 ($p < 0.001$)	19.20 ($p < 0.001$)
SF-36									
PF	32.31 ± 21.12	70.09 ± 12.72	78.47 ± 13.40	28.85 ± 27.10	49.67 ± 12.00	56.81 ± 15.35	57.02 ($p < 0.001$)	112.54 ($p < 0.001$)	7.64 ($p = 0.001$)
PR	26.54 ± 34.48	70.16 ± 18.58	82.63 ± 14.87	28.46 ± 33.62	54.92 ± 18.15	64.65 ± 19.89	13.97 ($p < 0.001$)	96.61 ($p < 0.001$)	4.36 ($p = 0.015$)
BP	35.11 ± 21.11	50.18 ± 19.09	60.29 ± 13.98	34.58 ± 21.57	36.33 ± 18.86	39.26 ± 16.57	23.28 ($p < 0.001$)	32.74 ($p < 0.001$)	12.25 ($p < 0.001$)
GH	44.38 ± 16.48	58.63 ± 11.20	67.20 ± 12.97	46.69 ± 12.48	45.42 ± 11.40	45.17 ± 11.43	46.47 ($p < 0.001$)	21.10 ($p < 0.001$)	25.67 ($p < 0.001$)
VT	47.00 ± 22.37	68.95 ± 16.65	79.74 ± 15.24	50.08 ± 19.79	53.77 ± 15.29	54.31 ± 15.32	37.48 ($p < 0.001$)	36.67 ($p < 0.001$)	25.38 ($p < 0.001$)
SF	50.58 ± 13.70	66.33 ± 20.94	79.66 ± 12.26	50.77 ± 10.10	53.07 ± 22.90	57.11 ± 14.45	28.70 ($p < 0.001$)	78.35 ($p < 0.001$)	29.26 ($p < 0.001$)
ER	32.82 ± 33.06	73.66 ± 23.48	87.57 ± 20.43	25.64 ± 31.60	37.70 ± 24.70	49.42 ± 21.84	72.29 ($p < 0.001$)	75.82 ($p < 0.001$)	11.57 ($p < 0.001$)
MH	48.35 ± 13.85	76.97 ± 23.48	81.49 ± 12.27	48.25 ± 10.02	53.97 ± 13.40	58.21 ± 14.10	97.84 ($p < 0.001$)	84.95 ($p < 0.001$)	28.19 ($p < 0.001$)

Mean values ± standard deviation

T1 = before treatment, T2 = post-treatment, T3 = 1-year follow-up

NRS Numerical Rating Scale, *ODI* Oswestry Disability Index, *TSK* Tampa Scale for Kinesiophobia, *PCS* Pain Catastrophising Scale, *SF-36* Short-Form Health Survey, *PF* physical functioning, *PR* physical role, *BP* bodily pain, *GH* general health, *VT* vitality, *SF* social functioning, *ER* emotional role, *MH* mental health

masking of assessors and analysts. The support of relatives and staff helped in creating a protected situation, thus limiting the drop-out rate and minimising adverse effects.

The sample was representative of the general population undergoing surgery for lumbar degenerative diseases in Italy [31], but the data cannot be generalised to surgical revisions. Furthermore, the described intervention cannot be delivered in every setting as it requires a staff specialised in chronic pain management and a rehabilitation team specialised in CBT.

The study also has some limitations. First, we exclusively used self-reported measures and did not investigate their relationships with physical measures or behavioural tests. Second, during the first phase of the study the enrolled patients used, in part, not yet validated scales; however, the procedure employed to administer these scales was exactly the same reported in the validation studies, preserving the validity of our results. Third, components other than catastrophising and fear-avoidance beliefs were not specifically targeted during the psychological sessions, which were therefore not representative of full CBT. Fourth, questions can be raised concerning the differences in contact time between the treatment groups due to the psychological intervention; however, the potential biasing effects were limited by means of the close involvement of relatives and staff who greatly supported the patients' compliance throughout the course of the study. Finally, treatment expectations were not addressed: this confounding factor could be only 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. However, patients' expectations could have been influenced also by their prior representations and experiences regarding the usefulness of exercises and CBT therapy, their psychological factors, activity and rest.

Conclusion

Our findings suggest that a rehabilitation programme including the management of catastrophising and kinesiophobia is useful in improving the course of patients' disability, catastrophising, fear-avoidance beliefs, pain and the quality of life. We recommend its use in specialised secondary care settings, whose staff is adequately trained in the management of chronic pain and spinal disorders management.

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Conflict of interest None of the authors has any potential conflict of interest.

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