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The Efficacy of a Short Education Program and a Short Physiotherapy Program for Treating Low Back Pain in Primary Care

A Cluster Randomized Trial

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Study Design. Cluster randomized clinical trial.

Objective. To assess the efficacy of a short education program and short physiotherapy program for treating low back pain (LBP) in primary care.

Summary of Background Data. There is sparse evidence on the effectiveness of education and physiotherapy programs that are short enough to be feasible in primary care.

Methods. Sixty-nine primary care physicians were randomly assigned to 3 groups and recruited 348 patients consulting for LBP; 265 (79.8%) were chronic. All patients received usual care, were given a booklet and received a consistent 15 minutes group talk on health education, which focused on healthy nutrition habits in the control group, and on active management for LBP in the "education" and "education + physiotherapy" groups. Additionally, in the "education + physiotherapy" group, patients were given a second booklet and a 15-minute group talk on postural hygiene, and 4 one-hour physiotherapy sessions of exercise and stretching which they were encouraged to keep practicing at home. The main outcome measure was improvement of LBP-related disability at 6 months. Patients' assessment and data analyses were blinded.

Results. During the 6-month follow-up period, improvement in the "control" group was negligible. Additional improvement in the "education" and "education + physiotherapy" groups was found for disability (2.0 and 2.2 Roland Morris Questionnaire points, respectively), LBP (1.8 and 2.10 Visual Analogue Scale points), referred pain (1.3 and 1.6 Visual Analogue Scale points), catastrophizing (1.6 and 1.8 Coping Strategies Questionnaire points), physical quality of life (2.9 and 2.9 SF-12 points), and mental quality of life (3.7 and 5.1 SF-12 points).

Conclusion. The addition of a short education program on active management to usual care in primary care leads to small but consistent improvements in disability, pain, and quality of life. The addition of a short physiotherapy program composed of education on postural hygiene and exercise intended to be continued at home, increases those improvements, although the magnitude of that increase is clinically irrelevant.

Key words: low back pain, primary care, education, physiotherapy, randomized clinical trial. **Spine 2010;35: 483–496**

Nonspecific or common low back pain (LBP) is defined as pain between the costal margins and the inferior gluteal folds, usually accompanied by painful limitation of movement and eventually associated with referred leg pain.[1,2] Diagnosing common LBP implies that the pain is not related to conditions such as fractures, spondylitis, direct trauma, or neoplastic, infectious, vascular, metabolic, or endocrine-related processes.[1,2]

There is sparse and contradictory evidence on the effectiveness of short physiotherapy and short education programs for LBP, either when compared to usual care, to a control intervention (placebo), or to each other.[3–23] Most studies on education and exercise have used methods that do not allow for control of the influence of unspecific effects, such as placebo or Hawthorn,[24,25] which may account for the inconsistency of results. Inconsistency may also derive from differences in the duration, contents, and practicalities of the programs which were assessed (e.g., educational methods—booklets, conferences, mass media advertising, *etc.*; exercise organization—intensity, frequency, *etc.*).

Educational programs for LBP patients essentially focus on postural hygiene, active management, or a combination of both approaches. Postural hygiene teaches how to perform daily activities, in such a way that spine load and back muscle tension are reduced.[3,11,13,18–20,24,25] "Active management" promotes staying as physically active as possible and, in the event of a LBP episode, avoiding bed rest and

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The study protocol was approved by the institutional review boards of the Kovacs Foundation, the Technical Directorate for Primary Care of Castilla and León, and the Primary Care Management of the Spanish National Health Service's western and eastern areas of Valladolid, and all patients gave written informed consent to participate in the study.

Trial Registration: Clinical Trials Gov. Registry: NCT00439764

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stopping only those activities that actually trigger or worsen pain.[2,3,6,7,20,24–26] The "Back Book" is a booklet designed to promote active management. There is some evidence suggesting that its handing out has a positive effect,[3,16] and it is recommended for treating low back pain by the corresponding evidence-based European clinical guidelines.[24,25]

The list of techniques labeled as "physiotherapy" varies from one setting to another, and includes procedures such as patients' education, exercise, stretching, manual therapy (*e.g.*, spinal manipulation or massage), the use of heat or cold, and electrotherapy (*e.g.*, TENS or laser). However, stretching and exercise are their most common components and those for which there is the strongest evidence of a positive effect.[17–31] However, that evidence is not fully consistent and does not permit defining practicalities such as the content, intensity, or duration.[24–31]

The Spanish National Health Service is a public organization in which all health care services are provided free to every citizen. Physicians working for the Spanish National Health Service have no restriction on the use of services (except for esthetic surgery or some dental procedures) and there is no incentive for referrals to specialists or indication for particular diagnostic tests or treatment methods. In the primary care routine clinical practice of the Spanish National Health Service, only short education or physiotherapy programs are feasible.

The objective of this study was to assess the efficacy of 2 programs added to usual practice in routine primary care of the Spanish National Health Service: a short education program on active management, and the same program plus physiotherapy including stretching, exercise and a second education program on postural hygiene.

■ Materials and Methods

Study Population

All the 78 physicians working in the eight primary care centers belonging to the Spanish National Health Service in the Western and Eastern areas of Valladolid, Spain, were invited to join the study. Those centers cover a population of approximately 156,409.

Physicians were asked to recruit patients who requested health care for low back pain, with or without referred pain, who did not show any "red flags" for systemic disease or referral to surgery, and who accepted signing the informed consent form to participate in this study. "Red flags" for potential underlying systemic disease were defined as[24,25,32–36]: pain that appears for the first time before 20 or after 55 years of age, not influenced by postures, movements or strain, only thoracic pain, widespread neurologic signs, persistent impossibility to flex the spine 5°, structural deformation of sudden onset, poor general condition, weight loss, fever, recent trauma, history of cancer, AIDS, long use of steroids, use of intravenous drugs, or depressed immune system. Red flags for potential referral to surgery were defined as[24,25,32]: relevant or progressive paresia, loss of sphincter control or saddle block anesthesia (possible *cauda equina*), intolerable radicular pain in spite of 6 or more weeks of conservative treatment with images of disc herniation at a consistent level on MRI, or neurogenic claudication with images of spinal stenosis on MRI or CT scan.

Exclusion criteria were: inability to fill out the questionnaires or read a booklet (*e.g.*, functional illiteracy, dementia, or blindness), being habitually bedridden, having been referred to physiotherapy in the last 12 months, a diagnosis of inflammatory rheumatologic disease (such as spondylitis, rheumatoid arthritis, Reiter syndrome, or psoriatic rheumatism), a diagnosis of fibromyalgia or signs for suspicion of fibromyalgia—defined as generalized muscle pain with unjustified tiredness or nonrestful sleep.

Inclusion and exclusion criteria were assessed by the recruiting physician, except for the willingness of the patient to participate in the study, which was assessed by research assistants acting as treatment coordinators. This was done to prevent any potential difference in the explanations provided to patients from physicians included in different groups.

Patients knew that the study's objective was to compare the effectiveness of different kinds of educational treatment and additional measures to routine treatment for LBP in primary care, but they did not know in detail what the different treatment regimes were. This was done to prevent the influence of patients' preferences for regimes other than the one they had been assigned to.

Sample Size

Since previous studies have established that the minimal clinically important change in disability is 2.5 points in the Roland Morris Questionnaire (RMQ),[37] sample size was established at 110 patients per group (total, 330) anticipating for a difference of at least 3 points in the RMQ,[38] with a standard deviation (SD) of 4, an alpha error of 0.05, a beta error of 0.2, a cluster size of 10 patients per physician, an intraclass correlation coefficient of 0.2, and a 5% loss to follow-up.

Randomization

This being a study involving different education strategies, a high risk of contamination between patients sharing the same primary care physician was anticipated at the design phase. Therefore, it was decided to randomize at the physician (cluster) level.

Randomization to the 3 groups was performed blindly according to a random numbers table.[39] Before the recruitment of primary care physicians, a coordination office located in a different city (Palma de Mallorca) prepared consecutively numbered opaque and sealed envelopes containing an allocation number extracted from the random numbers table.[39] Primary care physicians (clusters) were included in the study, according to the order in which their responses to the invitation to take part in the study were received. Immediately after enrollment, 1 of the 2 treatment coordinators opened the envelope corresponding to that order number and assigned the physician to 1 of the 3 intervention groups based on the allocation number it contained.

Primary care physicians were not informed about which group they had been allocated to. In all groups, they were asked to treat their patients according to their usual practice, the only difference across groups being the additional treatments provided to patients in each group. This was decided at the design phase, in order to ensure that the assessment of patient evolution was blinded.

Patients recruited by participating physicians were referred to 1 of the 2 research assistants who acted as treatment coordinators. Only one of them knew the group to which the refer-

ring physician had been assigned. The other one explained all the characteristics of the study to the patients, and asked them to sign the informed consent. Those patients signing it were included in the study, and the treatment coordinator who knew the group to which the referring physician had been assigned was in charge of ensuring that every patient received the treatment corresponding to that group. That procedure was designed to ensure that patients refusing to participate were identified before being actually allocated to any of the treatment regimes.

At the end of the study, the study coordinator at the coordination office (F.M.K.) verified that the sequence of randomization matched the one determined in the random numbers table, and compared the list of patients recruited by each physician with the list of patients that had received each kind of treatment, in order to verify that randomization had been properly executed.

Interventions

All patients received the usual treatment for low back pain in the Spanish National Health Service as provided by their primary care physician. Patients have free access to their primary care physician either at primary care centers or, if they feel that their condition makes it impossible for them to go there, the physician visits them at home. Treatment in primary care includes advice, drug treatment, potential request for diagnostic procedures, or potential referral to physical therapy, rehabilitation, orthopedic surgery, neurosurgery, rheumatology, or pain units.[40] However, referral to usual physical therapy was postponed until the end of the patient's participation in the trial.

In addition to those treatments, patients treated by physicians assigned to the "control" group were given a booklet on healthy nutrition habits and were given a 15-minute group talk with a consistent message.

Patients treated by physicians assigned to the "education" group were given a "Back Book" and received one 15-minute group talk with a consistent message.

Patients treated by physicians allocated to the "education + physiotherapy" group received the same educational program as those in the "education" group. In addition, on a different day they were given a booklet on postural hygiene and a second 15-minute group talk with consistent information, focusing especially on load manipulation. Patients in this group also underwent 4 one-hour group sessions on consecutive days, with no more than 10 participants in each session. Sessions were directed by a senior physical therapist, with over 10 years experience in treating patients with low back pain (R.dP.). Those sessions were performed at the primary care center where the patients had been recruited. During those sessions patients were taught relaxation techniques, stretching and active exercises for the abdominal, lumbar and thoracic back extensors, psoas, ischiotibial, and pelvic muscles. Stretching and active exercises performed during the sessions were standardized, although the intensity (number of repetitions and frequency) was adapted to patients' ability. Patients were strongly encouraged to keep practicing at home after the end of the sessions. The detailed description of the relaxation techniques, stretching movements, and exercises that were used are available in Spanish from the authors.

All the education sessions were given to groups of 15 patients or less. Those on postural hygiene were given by the physical therapist (R.dP.). All of the other group talks in the 3 groups were given by the same physician (C.A.), who knew if the attendees had been assigned to the "control" or an "experimental" group but not to that of the 2 experimental groups ("education" or "education + physiotherapy") they had been assigned. Slide projections used in each of the group talks are available in Spanish from the authors.

Before the study, the lecturer had no experience in providing health education on low back pain. She only received a 2-hour training from a physician specialized in treating low back pain with more than 10 years experience in providing health education to patients (M.G.). During that training, the trainer confirmed that the lecturer had no preformed opinion on the comparative effectiveness of active or postural education strategies for back-related problems, and told her that it was foreseen that both kinds of educational intervention would have a similar effect.

Therefore, all treatments additional to usual care in primary care were provided by a physician and a physical therapist who had no contact with the primary care physicians.

Outcome Assessments

Patients were evaluated immediately when recruited (baseline assessment) and 90 and 180 days later. Intensity of low back pain and referred pain, disability, catastrophizing, and health-related quality of life were measured through previously validated instruments at each of these time points. Improvement of disability at 180 days was the primary outcome of this study. Intensity of low back and referred pain was separately measured with a 10-cm visual analog scale (VAS, where 0 = no pain, 10 = worst possible pain).[41] Disability was measured with the Spanish version of the RMQ (where 0 = no disability, 24 = worst possible disability),[38] catastrophizing with the Spanish version of the Coping Strategies Questionnaire (CSQ, where 0 = no catastrophizing, 36 = worst possible catastrophizing),[42,43] and quality of life with the SF-12.[44] Both the physical component summary (PCS) and the mental component summary (MCS) of SF-12 are normalized for the Spanish general population (mean, 50; SD, 10); PCS and MCS reference scores range from 2.86 (worst possible) to 71.67 (best possible physical quality of life), and from 11.61 (worst possible) to 71.24 (best possible mental quality of life), respectively.[44]

At baseline assessment, the following data were also collected: age, gender, family situation (single, married, divorced, widowed, other), academic level (less than elementary school, high school, university), working situation (employed, disabled, retired, without work, housewife, other), regular physical activity (at leisure or work, classified as "yes" or "no"), smoking (yes, no, ex-smoker), concomitant illnesses (gathered as free text and classified as "yes" or "no" in the analysis phase), medication for low back pain (gathered as free text and classified as "yes" or "no" in the analysis phase), and duration of the current episode of low back pain (gathered as free text and classified as "chronic" if 90 days or longer).

At the 90 and 180 day assessments, the following data were also collected: patient's satisfaction with care (very satisfied, satisfied, neither satisfied nor unsatisfied, unsatisfied, very unsatisfied), patient's subjective assessment about the evolution of low back pain (disappeared, improved, not changed, worsened), referred pain (disappeared, improved, not changed, worsened, not applicable—patients with no referred pain), disability (disappeared, improved, not changed, worsened, not applicable—patients feeling they had no disability), and potential adverse events attributed to the education or physiotherapy programs by the patient (free text).

In order to reduce the number of losses to follow-up, a treatment coordinator blinded to the kind of intervention patients had received, was in charge of reminding patients of their appointments, in writing, by phone, by SMS, and when necessary, personally.

In order to reduce the number of missing values, at each assessment the same treatment coordinator explained to the patients how important it was that they answer properly the questionnaires. All questionnaires were self-administered and completed by the patients on their own, unaccompanied by health care staff or third parties. Once they had answered them, the treatment coordinator verified that no questionnaire had been left unanswered.

The completed questionnaires were collected by the recruiting primary care physicians, who stapled them to the patients' data forms. The physician and the physical therapist involved in providing education and physiotherapy were not present when patients gave their self-reported questionnaires to their primary care physician, and had no access to them.

Scores for VAS, RMQ, and CSQ were calculated at a coordination centralized office, separately by 2 administrative assistants who double-checked the ratings to identify any potential scoring error. Since the calculation of SF-12 PCS and MCS values is complex, it was done in the analysis phase.

Data were entered in a database at a coordination centralized office by 2 administrative assistants who double-checked that data entered coincided with ratings from the patients in the VAS, RMQ, CSQ, and SF-12 questionnaires.

Analysis

Data were analyzed at the individual and cluster levels.[45] At the individual level, frequencies were used for categorical variables. For continuous ones, medians and interquartile range or mean and SD were used depending on whether data were normally distributed. At the cluster level, medians and interquartile range of the statistics used at the individual level were calculated.

The primary outcome of this study was the improvement of disability at the cluster level, at 180 days. Improvement was defined as scores of the Roland-Morris questionnaire at baseline minus scores at the corresponding follow-up, so that positive values reflect improvement and the higher the value, the higher the improvement. The intraclass correlation coefficient was estimated for improvement of disability.[46] Because of the cluster design, to estimate the effect of the dependent variable on the improvement of disability, generalized estimating equations models were used to adjust for possible confounding factors.[47]

In all the models, intervention ("control," "education," or "education + physiotherapy") was the independent variable. Education intervention was coded as a "dummy variable," and "control" was used as the reference in all the models, so that the effect size reflects the difference between "control" and experimental groups ("education" or "education + physiotherapy"). At the design phase, it was decided that maximum models would include as potential confounding variables those with imbalances between groups at the preintervention assessment, as well as demographic variables (age, sex, family and working situations, and academic level) and the potentially clinically meaningful (chronicity, medication, concomitant illnesses, usual physical activity, smoking, and baseline values for low back pain, referred pain, disability, catastrophizing, and quality of life). A backward strategy was used; those variables that when eliminated produced a change of $\geq$10% of the effect size were considered confounding variables.

Analyses were performed by a team of statisticians (A.R., J.Z., A.M., V.A.) who were independent from the rest of the staff involved in the trial, and who worked in a different city (Madrid). They knew that three intervention groups had been set up, but were unaware of the treatment protocol that was implemented in each group.

SPSS (version 16.0) and Stata (version 10.0; Stata Corp., College Station, TX) statistical programs were used for analysis.

■ Results

Among the 78 physicians who were invited to join the study, 69 (88.5%) accepted and were randomly assigned to the "control" (23 physicians), "education" (23), and "education + physiotherapy" (23) groups.

Between March 1, 2007 and September 30, 2007, those 69 physicians screened 527 patients for inclusion in the study. Among those patients, 179 (34.0%) refused to commit to attending the follow-up visits planned at 3 and 6 months, and therefore declined to participate in the study.

The remaining 348 patients accepted to participate, and none were excluded. Among those patients, 109 had been recruited by physicians assigned to the "control" group, 139 by those from the "education group," and 100 by physicians from the "education + physiotherapy" group. They were followed up until March 31, 2008, and none were lost. A flow chart of the study population in accordance with CONSORT guidelines for trials randomized by clusters is shown in Figure 1.[45]

Baseline characteristics of patients in the 3 study groups are shown in Tables 1 and 2, including analyses at the individual and cluster levels. As seen in Table 1, the median age of recruited patients ranged between 51.0 and 52.5 years, between 28.4% and 36.7% of the patients were males, between 54.0% and 64.2% had completed high school or university degrees, and between 71.6% and 89.0% were chronic patients with low back pain. Median of pain intensity ranged between 7 and 8 VAS for low back pain, and between 6 and 7 VAS points for referred pain. Physical quality of life was reduced (values range between 35.8 and 36.8 SF-12 points), but disability and catastrophizing were mild (between 8 and 9 RMQ points and between 6 and 7 CSQ points, respectively), and mental quality of life was virtually normal (between 47.9 and 48.9 SF-12 points). As seen in Table 2, groups were very similar, although academic level was slightly worse in the education group, and in the control group there were more chronic patients and concomitant illnesses were less common. Therefore, these variables were included in the models.

There were no losses to follow-up, and data at the 90 day and 180 day assessments are shown in Tables 3–5. The evolution of the VAS, RMQ, CSQ, and PCS and MCS SF-12, as well as patients' subjective assessment and satisfaction with care were generally better in the

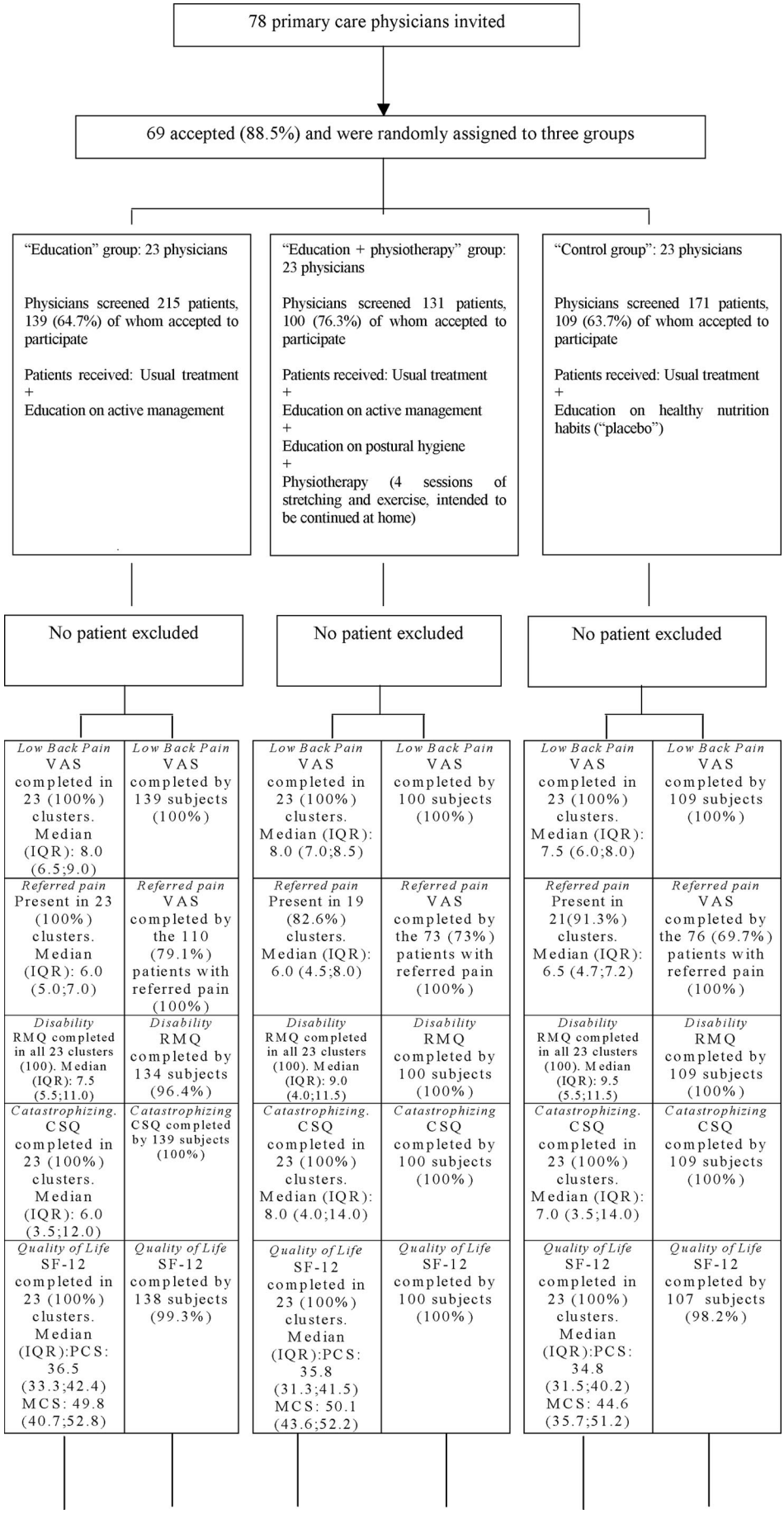

Figure 1. Flow chart of the study.

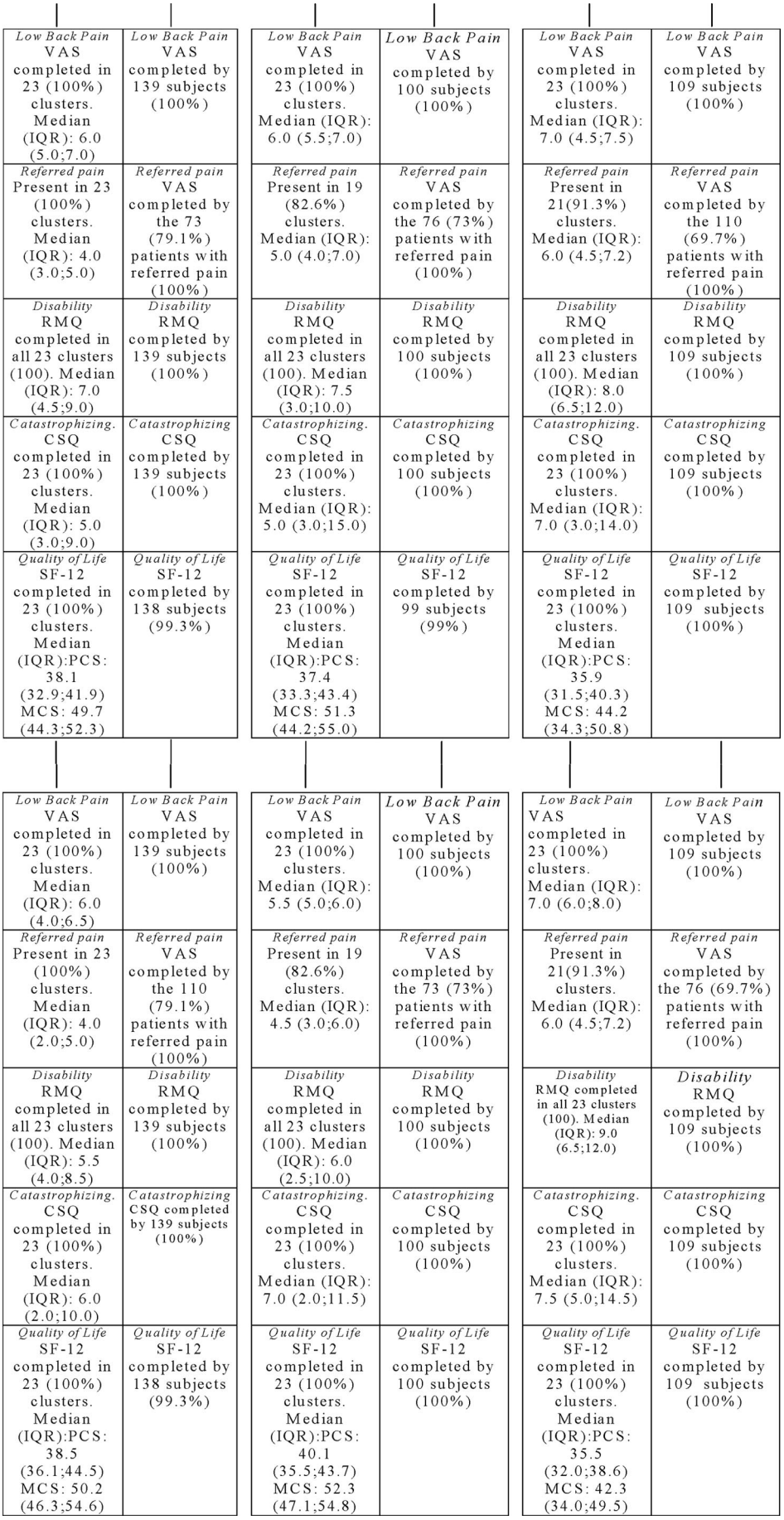

Figure 1. (Continued).

Table 1. Baseline Characteristics of the Study Population—Analysis at the Individual Level

Variable	Control Group n = 109		Education n = 139		Education + Physiotherapy n = 100	
Age (yr) median (IQR)	108	52.5 (45.0; 61.7)	139	51.0 (42.0; 58.0)	100	51.0 (42.0; 59.7)
Gender (males) n (%)	109	31 (28.4)	139	51 (36.7)	100	32 (32.0)
Family situation n (%)	103		136		98	
Single		18 (17.5)		16 (11.8)		18 (18.4)
Married		74 (71.8)		104 (76.5)		74 (75.5)
Divorced		3 (2.9)		6 (4.4)		2 (2.0)
Widowed		8 (7.8)		10 (7.4)		4 (4.1)
Academic level n (%)	106		137		99	
Less than elementary school		7 (6.6)		9 (6.6)		4 (4.0)
Elementary school		31 (29.2)		54 (39.4)		35 (35.4)
High school		45 (42.5)		39 (28.5)		43 (43.4)
University		23 (21.7)		35 (25.5)		17 (17.2)
Working situation n (%)	109		137		99	
Employed		55 (50.5)		79 (57.7)		58 (58.6)
Disabled		2 (1.8)		1 (0.7)		0 (0.0)
Retired		16 (14.7)		19 (13.9)		13 (13.1)
Without work		7 (6.4)		5 (3.6)		10 (10.1)
Housewife		29 (26.6)		33 (24.1)		18 (18.2)
Regular physical activity (yes) n (%)	96	61 (63.5)	129	87 (67.4)	94	62 (66.0)
Smoking n (%)	101		136		97	
Yes		25 (24.8)		36 (26.5)		20 (20.6)
No		56 (55.4)		72 (52.9)		59 (60.8)
Ex-smoker		20 (19.8)		28 (20.6)		18 (18.6)
Concomitant illness (yes) n (%)	90	31 (34.4)	112	55 (49.1)	77	36 (46.8)
Medication (yes) n (%)	101	54 (53.5)	127	68 (53.5)	95	61 (64.2)
Chronic low back pain (>3 mo) (yes) n (%)	109	97 (89.0)	128	100 (78.1)	95	68 (71.6)

IQR indicates interquartile range.

experimental groups ("education" and "education + physiotherapy") than in the "control" group, and results in the 2 experimental groups were similar. No adverse events were reported in any of the groups.

All demographic and clinically meaningful variables defined at the design phase were incorporated in the models, including those which were unbalanced at baseline assessment. Results of the generalized estimating

Table 2. Baseline Characteristics of the Study Population—Analysis at the Cluster Level

Variable	Control Group n = 23		Education n = 23		Education + Physiotherapy n = 23	
No. patients median (IQR)	23	3.0 (2.0; 6.0)	23	6.0 (1.5; 9.0)	23	3.0 (1.0; 6.0)
Age (yr) median (IQR)	23	56.5 (50.0; 62.0)	23	50.0 (43.8; 56.0)	23	48.0 (41.0; 52.2)
Gender (males) n (%)	23	9.1 (0.0; 50.0)	23	33.3 (25.0; 50.0)	23	33.3 (0.0; 50.0)
Family situation n (%)	23		23		22	
Single		12.5 (0.0; 25.0)		9.1 (0.0; 27.3)		4.5 (0.0; 29.8)
Married		66.7 (50.0; 93.3)		75.0 (63.6; 87.5)		80.9 (66.7; 100.0)
Divorced		0.0 (0.0; 0.0)		0.0 (0.0; 9.1)		0.0 (0.0; 0.0)
Widowed		0.0 (0.0; 11.8)		0.0 (0.0; 12.5)		0.0 (0.0; 0.0)
Academic level n (%)	23		23		23	
Less than elementary school		0.0 (0.0; 11.8)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Elementary school		25.0 (0.0; 50.0)		33.3 (0.0; 50.0)		28.6 (0.0; 50.0)
High school		33.3 (0.0; 62.5)		33.3 (12.5; 75.0)		42.8 (0.0; 80.0)
University		17.6 (0.0; 50.0)		0.0 (0.0; 37.5)		0.0 (0.0; 28.6)
Working situation n (%)	23		23		23	
Employed		50.0 (20.0; 66.7)		66.7 (50.0; 100.0)		66.7 (42.8; 100.0)
Disabled		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Retired		0.0 (0.0; 25.0)		0.0 (0.0; 25.0)		0.0 (0.0; 14.3)
Without work		0.0 (0.0; 5.9)		0.0 (0.0; 0.0)		0.0 (0.0; 14.3)
Housewife		20.0 (0.0; 45.4)		20.0 (0.0; 25.0)		14.3 (0.0; 16.7)
Regular physical activity (yes) n (%)	23	66.7 (46.7; 100.0)	23	71.4 (33.3; 81.8)	23	66.7 (40.0; 100.0)
Smoking n (%)	23		22		23	
Yes		23.5 (0.0; 50.0)		26.1 (13.8;53.1)		0.0 (0.0; 33.3)
No		50.0 (37.5; 100.0)		50.0 (36.4; 66.7)		66.7 (50.0; 100.0)
Ex-smoker		0.0 (0.0; 40.0)		16.2 (0.0; 28.1)		16.7 (0.0; 33.3)
Concomitant illness (yes) n (%)	23	33.3 (0.0; 66.7)	23	50.0 (0.0; 60.0)	21	40.0 (0.0; 63.3)
Medication (yes) n (%)	23	62.5 (40.0; 100.0)	23	50.0 (0.0; 66.7)	23	66.7 (40.0; 100.0)
Chronic low back pain (>3 mo) (yes) n (%)	23	100.0 (81.8; 100.0)	23	81.8 (71.4; 100.0)	23	83.3 (63.6; 100.0)

IQR indicates interquartile range.

Table 3. Data at Follow-up: Analysis at the Individual Level

Variable; n (%)	Control Group n = 109	Education n = 139	Education + Physiotherapy n = 100
Assessment at 3 mo			
Patients' subjective assessment			
Satisfaction with care	109	139	100
Very satisfied	2 (1.8)	15 (10.8)	9 (9.0)
Satisfied	37 (33.9)	43 (30.9)	24 (24.0)
Neither satisfied nor unsatisfied	50 (45.9)	45 (32.4)	46 (46.0)
Unsatisfied	15 (13.8)	22 (15.8)	17 (17.0)
Very unsatisfied	5 (4.6)	14 (10.1)	4 (4.0)
Evolution of low back pain	109	139	100
Disappeared	8 (7.3)	13 (9.4)	7 (7.0)
Improved	31 (28.4)	102 (73.4)	70 (70.0)
Unchanged	57 (52.3)	22 (15.8)	21 (21.0)
Worsened	11 (10.1)	1 (0.7)	1 (1.0)
Missing	2 (1.8)	1 (0.7)	1 (1.0)
Evolution of referred pain	109	139	100
Disappeared	5 (4.6)	20 (14.4)	14 (14.0)
Improved	21 (19.3)	66 (47.5)	44 (44.0)
Unchanged	39 (35.8)	21 (15.1)	19 (19.0)
Worsened	5 (4.6)	2 (1.4)	0 (0.0)
Not applicable	39 (35.8)	30 (21.6)	23 (23.0)
Subjective evolution of disability	109	139	100
Recovered	4 (3.7)	16 (11.5)	11 (11.0)
Improved	35 (32.1)	65 (46.8)	38 (38.0)
Unchanged	55 (50.5)	47 (33.8)	45 (45.0)
Worsened	10 (9.2)	5 (3.6)	4 (4.0)
Not applicable	5 (4.6)	6 (4.3)	2 (2.0)
Assessment at 6 mo			
Patients' subjective assessment			
Satisfaction with care	109	137	100
Very satisfied	3(2.8)	15 (10.9)	9 (9.0)
Satisfied	35 (32.1)	43 (31.4)	23 (23.0)
Neither satisfied nor unsatisfied	50 (45.9)	44 (32.1)	46 (46.0)
Unsatisfied	16 (14.7)	22 (16.1)	18 (18.0)
Very unsatisfied	5 (4.6)	13 (9.5)	4 (4.0)
Evolution of low back pain	109	139	100
Disappeared	10 (9.2)	16 (11.5)	13 (13.0)
Improved	5 (4.6)	77 (55.4)	68 (68.0)
Unchanged	57 (52.3)	32 (23.0)	16 (16.0)
Worsened	35 (32.1)	13 (9.4)	2 (2.0)
Missing	2 (1.8)	1 (0.7)	1 (1.0)
Evolution of referred pain evolution	109	139	100
Disappeared	7 (6.4)	27 (19.4)	25 (25.0)
Improved	4 (3.7)	45 (32.4)	39 (39.0)
Unchanged	42 (38.5)	32 (23.0)	14 (14.0)
Worsened	18 (16.5)	7 (5.0)	1 (1.0)
Not applicable	38 (34.9)	28 (20.1)	21 (21.0)
Subjective evolution of disability	109	139	100
Recovered	5 (4.6)	17 (12.2)	11 (11.0)
Improved	23 (21.1)	54 (38.8)	37 (37.7)
Unchanged	63 (57.8)	54 (38.8)	47 (47.0)
Worsened	14 (12.8)	8 (5.8)	4 (4.0)
Not applicable	4 (3.7)	6 (4.3)	1 (1.0)

equations after adjusting for confounding factors are shown in Table 6. As seen in that table, 180 days after the intervention, the addition of education on active management to usual treatment led to an improvement in disability of 2.0 (95% CI: 1.3, 2.7) RMQ points, which increased to 2.2 (1.4, 3.0) RMQ points when physiotherapy and education on postural hygiene were added. Corresponding values were 1.8 (1.4, 2.2) and 2.1 (1.7, 2.5) points for low back pain, 1.3 (0.8, 1.8) and 1.6 (1.1, 2.2) for referred pain, 1.6 (0.7, 2.5) and 1.8 (0.8, 2.8) for catastrophizing, 2.9 (1.3, 4.6) and 2.9 (1.2, 4.7) for physical quality of life, and 3.7 (1.7, 5.7) and 5.1 (2.9, 7.2) for mental quality of life (Table 6).

In general, results were similar although slightly worse at 90 days than at 180 days (Table 6). However, at 90 days, the evolution of low back pain, referred pain and catastrophizing was slightly better in the "education" group than in the "education + physiotherapy" group, and the improvements seen in one of the intervention groups for referred pain, disability, and catastrophizing, and in both groups for physical quality of life, were not statistically significant.

Table 4. Data at Follow-up: Analysis at the Cluster Level

Variable Median (IQR)	Control Group n = 23		Education n = 23		Education + Physiotherapy n = 23	
Assessment at 3 mo						
Patients' subjective assessment						
Satisfaction with care	23		23		23	
Very satisfied		0.0 (0.0; 0.0)		0.0 (0.0; 18.2)		0.0 (0.0; 14.3)
Satisfied		33.3 (0.0; 50.0)		25.0 (0.0; 41.7)		16.7 (0.0; 33.3)
Neither satisfied nor unsatisfied		50.0 (0.0; 60.0)		27.3 (0.0; 50.0)		50.0 (33.3; 100.0)
Unsatisfied		0.0 (0.0; 12.5)		0.0 (0.0; 25.0)		0.0 (0.0; 33.3)
Very unsatisfied		0.0 (0.0; 0.0)		0.0 (0.0; 16.7)		0.0 (0.0; 0.0)
Evolution of low back pain	23		23		23	
Disappeared		0.0 (0.0; 0.0)		0.0 (0.0; 16.7)		0.0 (0.0; 0.0)
Improved		18.7 (0.0; 50.0)		75.0 (66.7; 100.0)		83.3 (50.0; 100.0)
Unchanged		50.0 (0.0; 66.7)		8.3 (0.0; 25.0)		14.3 (0.0; 28.6)
Worsened		0.0 (0.0; 18.2)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Missing		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Evolution of referred pain	23		23		23	
Disappeared		0.0 (0.0; 0.0)		0.0 (0.0; 33.3)		0.0 (0.0; 16.7)
Improved		16.7 (0.0; 25.0)		30.8 (16.7; 63.6)		50.0 (0.0; 66.7)
Unchanged		25.0 (0.0; 50.0)		0.0 (0.0; 25.0)		9.1 (0.0; 28.6)
Worsened		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Not applicable		33.3 (0.0; 50.0)		11.1 (0.0; 25.0)		16.7 (0.0; 33.3)
Subjective evolution of disability	23		23		23	
Recovered		0.0 (0.0; 0.0)		0.0 (0.0; 12.5)		0.0 (0.0; 16.7)
Improved		25.0 (0.0; 50.0)		50.0 (33.3; 55.5)		33.3 (0.0; 63.6)
Unchanged		50.0 (0.0; 75.0)		33.3 (12.5; 41.7)		50.0 (20.0; 100.0)
Worsened		0.0 (0.0; 16.7)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Not applicable		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Assessment at 6 mo						
Patients' subjective assessment	23		23		23	
Satisfaction with care		0.0 (0.0; 0.0)		0.0 (0.0; 18.2)		0.0 (0.0; 14.3)
Very satisfied		27.8 (0.0; 50.0)		25.0 (0.0; 41.7)		16.7 (0.0; 33.3)
Satisfied		50.0 (0.0; 63.6)		27.3 (0.0; 50.0)		50.0 (33.3; 100.0)
Neither satisfied nor unsatisfied		0.0 (0.0; 12.5)		12.5 (0.0; 27.3)		0.0 (0.0; 33.3)
Unsatisfied		0.0 (0.0; 0.0)		0.0 (0.0; 16.7)		0.0 (0.0; 0.0)
Very unsatisfied						
Evolution of low back pain	23		23		23	
Disappeared		0.0 (0.0; 0.0)		0.0 (0.0; 16.7)		0.0 (0.0; 25.0)
Improved		0.0 (0.0; 9.1)		62.5 (38.5; 100.0)		66.7 (42.8; 100.0)
Unchanged		50.0 (0.0; 61.1)		16.7 (0.0; 30.8)		0.0 (0.0; 25.0)
Worsened		33.3 (0.0; 50.0)		0.0 (0.0; 11.1)		0.0 (0.0; 0.0)
Missing		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Evolution of referred pain	23		23		23	
Disappeared		0.0 (0.0; 5.5)		16.7 (0.0; 33.3)		18.2 (0.0; 50.0)
Improved		0.0 (0.0; 0.0)		25.0 (7.7; 50.0)		33.3 (0.0; 60.0)
Unchanged		33.3 (0.0; 66.7)		8.3 (0.0; 37.5)		0.0 (0.0; 14.3)
Worsened		0.0 (0.0; 20.0)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)
Not applicable		27.8 (0.0; 50.0)		11.1 (0.0; 25.0)		16.7 (0.0; 33.3)
Subjective evolution of disability	23		23		23	
Recovered		0.0 (0.0; 0.0)		0.0 (0.0; 18.2)		0.0 (0.0; 0.0)
Improved		12.5 (0.0; 50.0)		33.3 (0.0; 58.3)		33.3 (0.0; 80.0)
Unchanged		50.0 (33.3; 80.0)		37.5 (25.0; 55.5)		45.4 (14.3; 100.0)
Worsened		0.0 (0.0; 18.2)		0.0 (0.0; 8.3)		0.0 (0.0; 0.0)
Not applicable		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)		0.0 (0.0; 0.0)

IQR indicates interquartile range.

■ Discussion

These results show that a simple and short education program on active management improved disability, pain severity, catastrophizing, and quality of life in patients with low back pain treated in the routine practice of primary care. In general, results were already noticeable 3 months later, and they further improved at 6 months. Although those effects are statistically significant, their magnitude is small. At 6 months, they surpass the cut-off point for clinical relevance for low back pain severity (1.5 VAS points), and they are only close to it for disability (2.5 RMQ points).[37] However, improvement is consistent for all the variables, and usual treatment led to virtually no improvement in the control group (Tables 3 and 4). Therefore, even if small, benefits from a program that only consists of the handing out of a booklet and a 15-minute group talk may be of potential clinical value, especially in primary care.

The addition of a second short education program on postural hygiene and four one-hour sessions of physiotherapy only led to a very slight improvement of results, which is clinically irrelevant (Table 6).

Table 5. Changes of the Main Outcome Variables From Baseline to the Final Follow-up Assessment

Variable*	Control Group		Education		Education and Physiotherapy	
	Individual Level (n = 109)	Cluster Level (n = 23)	Individual Level (n = 139)	Cluster Level (n = 23)	Individual Level (n = 100)	Cluster Level (n = 23)
Intensity of low back pain (VAS)						
Baseline	8.0 (5.0–9.0)	7.5 (6.0–8.0)	8.0 (6.0–9.0)	8.0 (6.5–9.0)	7.0 (6.0–9.0)	8.0 (7.0–8.5)
3 mo	7.0 (5.0–8.0)	7.0 (4.5–7.5)	6.0 (4.0–8.0)	6.0 (5.0–7.0)	6.0 (4.0–7.0)	6.0 (5.5–7.0)
6 mo	8.0 (6.0–9.0)	7.0 (6.0–8.0)	6.0 (3.0–7.0)	6.0 (4.0–6.5)	5.0 (4.0–6.0)	5.5 (5.0–6.0)
Intensity of referred pain (VAS)†						
Baseline	7.0 (4.0–8.0)	6.5 (4.7–7.2)	6.0 (3.0–8.0)	6.0 (5.0–7.0)	7.0 (4.0–8.0)	6.0 (4.5–8.0)
3 mo	6.0 (4.0–8.0)	6.0 (4.5–7.2)	4.5 (2.0–7.0)	4.0 (3.0–5.0)	5.0 (4.0–7.0)	5.0 (4.0–7.0)
6 mo	6.5 (4.2–8.0)	6.0 (4.5–7.2)	4.0 (2.0–6.2)	4.0 (2.0–5.0)	5.0 (3.0–6.0)	4.5 (3.0–6.0)
Disability (RMQ)						
Baseline	9.0 (4.0–12.0)	9.5 (5.5–11.5)	8.0 (4.0–12.0)	7.5 (5.5–11.0)	8.5 (4.0–12.0)	9.0 (4.0–11.5)
3 mo	8.0 (4.0–11.0)	8.0 (6.5–12.0)	6.0 (3.0–10.0)	7.0 (4.5–9.0)	7.5 (3.0–11.0)	7.5 (3.0–10.0)
Improvement at 3 mo	0.3 (2.2)	0.1 (−0.5–1.2)	1.1 (2.1)	1.2 (0.7–1.6)	1.1 (1.7)	1.0 (0.0–1.5)
6 mo	9.0 (4.0–12.5)	9.0 (6.5–12.0)	6.0 (3.0–10.0)	5.5 (4.0–8.5)	6.0 (3.0–10.0)	6.0 (2.5–10.0)
Improvement at 6 mo	−0.3 (1.6)	−0.1 (−0.6–0.7)	1.6 (2.6)	1.3 (0.8–2.5)	2.0 (2.5)	1.7 (1.0–2.6)
Catastrophizing (CSQ)						
Baseline	7.0 (2.0–14.0)	7.0 (3.5–14.0)	6.0 (1.0–14.0)	6.0 (3.5–12.0)	6.0 (3.0–14.0)	8.0 (4.0–14.0)
3 mo	7.0 (1.0–15.0)	7.0 (3.0–14.0)	5.0 (0.0–12.0)	5.0 (3.0–9.0)	5.0 (1.0–14.7)	5.0 (3.0–15.0)
6 mo	9.0 (0.5–16.0)	7.5 (5.0–14.5)	5.0 (0.0–13.0)	6.0 (2.0–10.0)	5.0 (1.0–12.7)	7.0 (2.0–11.5)
Physical QL (SF-12)						
Baseline	36.1 (31.2–42.7)	34.8 (31.5–40.2)	36.8 (31.2–44.3)	36.5 (33.1–42.4)	35.8 (30.2–44.4)	35.8 (31.3–41.5)
3 mo	36.7 (31.1–43.2)	35.9 (31.5–40.3)	37.9 (32.6–44.8)	38.1 (32.9–41.9)	37.4 (32.0–44.9)	37.4 (33.3–43.4)
6 mo	35.5 (31.2–40.4)	35.5 (32.0–38.6)	39.2 (33.6–46.4)	38.5 (36.1–44.5)	39.0 (32.9–46.9)	40.1 (35.5–43.7)
Mental QL (SF-12)						
Baseline	48.0 (33.2–55.2)	44.6 (35.7–51.2)	48.9 (33.5–54.9)	49.8 (40.7–52.8)	47.9 (35.4–57.0)	50.1 (43.6–52.2)
3 mo	44.6 (33.5–54.2)	44.2 (34.3–50.8)	50.4 (33.6–55.8)	49.7 (44.3–52.3)	48.9 (37.5–57.3)	51.3 (44.2–55.0)
6 mo	41.9 (32.3–53.4)	42.3 (34.4–49.5)	50.7 (37.2–56.4)	50.2 (46.3–54.6)	50.7 (41.7–57.4)	52.3 (47.1–54.8)

*Data are expressed as median and interquartile range, except for the improvement of disability at individual level. Since data on the latter were normally distributed, they are expressed as mean (SD).
†Number of patients who had referred pain at baseline is 76 in the "control" group (in 21 clusters), 110 in the "education" group (in 23 clusters), and 73 in the "education and physiotherapy" group (in 19 clusters).
VAS: visual analogue scale (range from best to worst) 0–10.
RMQ: Roland Morris questionnaire (range from best to worst) 0–24.
CSQ: Coping Strategies questionnaire (range from best to worst) 0–36.
Physical quality of life (range from best to worst) 2.86–71.67.
Mental quality of life (range from best to worst) 11.61–72.24.

Previous studies have shown exercise to have a clinically small effect at long-term.[26] It is possible that the physiotherapy program implemented in this study was too short to produce any clinically relevant benefit, and that longer programs, in patients motivated enough to follow them, might produce better results. However, this trial did not aim to assess the effectiveness of a long exercise program in a highly motivated or select population, but the effectiveness of a program feasible in primary care for the routine treatment of the average patient. For that reason, the shortest possible "core" physiotherapy intervention was implemented, aimed at teaching the patients the appropriate stretching and exercises, and encouraging patients to continue them at home. Compliance with exercise at home was not measured in this trial, since it is irrelevant to the study's objective. No matter if patients did or did not follow that recommendation, the fact is that the education on postural hygiene, the short physiotherapy program and the recommendation to keep practicing at home implied much more time (and therefore, they are likely to be associated with higher costs) and led to clinically irrelevant differences when compared to the simpler, shorter education program on active management.

The physiotherapy treatment used in this study can be seen as a very narrow one, since it only consisted of exercise (both stretching and active exercise). However, the available evidence consistently supports the effectiveness of exercise,[24–26] while that is not the case for techniques such as electrotherapy, massage, or spinal manipulation.[24–31] In fact, results from this study are consistent with previous randomized trials in which some of these other techniques were also used. For instance, in acute patients, a brief education program led to results virtually identical to those from physiotherapy, including manual therapy.[48] Similarly, in the UK BEAM trial,[49] in which chronic patients were included and data were analyzed favoring spinal manipulation,[50] the addition of the latter to exercise led to no clinically relevant improvement.[49,50] For those reasons, education and exercise were the only treatments which were selected to be used in the "physiotherapy + education" group in the current trial. The simplicity of the experimental interventions in the current study may account for the lack of losses to follow-up, and is one of its strengths. Nevertheless, further studies could evaluate if results from active education further improve by adding other physiotherapy regimes, as long as they are feasible in primary care.

Table 6. Results of the Generalized Estimating Equations (GEE)—Improvement in Each Experimental Group, Additional to the One in the Control Group*

Additional Improvement to the One in the Control Group	Education Effect Size (95% CI)	Education + Physiotherapy Effect Size (95% CI)
Disability† (n = 245)		
At 90 days (RMQ)	0.599 (−0.089, 1.286)	0.753 (0.014, 1.492)
At 180 days (RMQ)	1.970 (1.252, 2.687)	2.187 (1.413, 2.961)
Low back pain (n = 247)		
At 90 days (VAS)	0.925 (0.571, 1.280)	0.900 (0.517, 1.282)
At 180 days (VAS)	1.767 (1.363, 2.171)	2.096 (1.660, 2.533)
Referred pain (n = 178)		
At 90 days (VAS)	0.608 (0.157, 1.058)	0.477 (−0.026, 0.981)
At 180 days (VAS)	1.327 (0.831, 1.823)	1.616 (1.055, 2.177)
Catastrophizing‡ (n = 245)		
At 90 days (CSQ)	0.999 (0.479, 1.518)	0.144 (−0.428, 0.716)
At 180 days (CSQ)	1.594 (0.659, 2.529)	1.838 (0.834, 2.842)
Physical quality of life§ (n = 243)		
At 90 days (SF-12)	0.480 (−0.736, 1.695)	0.649 (−0.668, 1.967)
At 180 days (SF-12)	2.904 (1.256, 4.553)	2.934 (1.163, 4.705)
Mental quality of life (n = 243)		
At 90 days (SF-12)	1.653 (0.097, 3.209)	2.330 (0.642, 4.018)
At 180 days (SF-12)	3.687 (1.711, 5.664)	5.067 (2.933, 7.201)

*In all models, age, sex, family and working situations, academic level, chronicity, medication, concomitant illnesses, usual physical activity, smoking, and baseline values for low back pain, referred pain, disability, catastrophizing, and quality of life were included as potential confounding variables.
†Adjusted by age.
‡Adjusted by chronicity, family situation, smoking, low back pain, catastrophizing and mental and physical quality of life at baseline assessment.
§Adjusted by chronicity, low back pain and physical quality of life at baseline assessment.
RMQ: Roland Morris Questionnaire. Range (from best to worst): 0–24.
VAS: Visual Analogue Scale. Range (from best to worst): 0–10.
CSQ: Coping Strategies Questionnaire. Range (from best to worst): 0–36.
SF-12: Range (from best to worst): Physical Quality of Life: 2.86–71.67.
Mental Quality of Life: 11.61–72.14.

This study aimed to assess the efficacy of 2 intervention programs ("education" and "education + physiotherapy") in routine clinical practice. However, at the design phase it was decided to implement a "placebo" intervention in the control group (*i.e.*, an education program on healthy nutrition habits). Two factors led to that decision. First, it was felt that comparing the effectiveness of interventions may be useless when none of them has previously shown to be superior to appropriate placebos, because results may reflect only the relative strength of their unspecific effects.[51] Additionally, because the longer time spent by LBP patients with therapists is usually associated with better results, it was felt appropriate to provide patients in the control group with an intervention requiring the same amount of time as the one in the "education" group (15 minutes for the group talk). This was considered to be the most feasible placebo intervention, since only the content of the education varied from the "control" to the "education" group.

The generalizability of these results should be discussed. The proportion of women in this study is high (between 63.7% and 77.6%), but gender had no influence on results (Table 4). Over 70% of the patients included in this study were chronic. This may be due to recruitment bias, as chronic patients may be more likely to commit to follow-up visits for up to 6 months. Nevertheless, chronicity had no influence on results for pain, disability and mental quality of life, and the effect of the interventions on catastrophizing and physical quality of life remained positive after adjusting for chronicity (Table 6). Although baseline pain intensity was severe and physical quality of life was restricted, disability and catastrophizing were mild and mental quality of life was normal (Tables 1 and 2). Disparity between pain severity and functional and psychological impairment has often been found in studies conducted with chronic Spanish back pain patients,[52–56] and may reflect the effect of cultural influences and/or adaptation to chronic states.[52–57] Measures to reduce losses to follow-up and missing values worked well (Figure 1), which increases the validity of results and their generalizability to comparable populations. This study was performed in Valladolid, a mid-sized town in northern Spain. Available data show that primary care physicians' management of patients with low back pain and patients' evolution is generally in accordance with current evidence based clinical Guidelines and quite homogenous across the Spanish National Health Service.[17,18,40] Therefore, the setting where the study took place does not appear to jeopardize the generalizability of results to other regions. However, cultural and psychosocial factors might affect the effect of short education programs, so further studies should assess the generalization of these results to other cultural settings.

This study was designed to assess the effectiveness in primary care of short education and physiotherapy programs for LBP patients. The underlying mechanisms which explain its results can only be hypothesized. It is unlikely that specific psychological mechanisms play a major role in the effect of active education for 2 reasons.

First, and contrary to Anglo-Saxons and Scandinavians,[58–74] the influence of fear avoidance beliefs and catastrophizing in Spanish subjects is either nonexistent or clinically meaningless.[16,52–54] Second, although in this study catastrophizing improved in both experimental groups as opposed to the control group, catastrophizing did not influence the improvement of disability (Table 6). This suggests that active education improved both catastrophizing and disability, as opposed to the improvement in disability being mediated by catastrophizing. This is consistent with results from a previous study with Spanish elderly subjects, in which the same short education program on active management improved both disability and fear avoidance beliefs, although the improvement of fear avoidance beliefs did not mediate the improvement of disability.[16]

One might hypothesize that the active education program was effective simply because it encouraged LBP patients to increase the level of physical activity in their daily lives, and that this caused the improvements in disability and pain. In turn, improvements in both disability and pain led to the improvement in quality of life, as has been shown in previous studies.[16,55,56] Because it is likely that patients progressively increase their level of physical activity as they realize that it does not worsen their pain, this would help to explain why improvements in the experimental groups were higher at 180 days than at 90 (Table 6). In fact, the same pattern was observed in a previous study involving Spanish elderly patients where the same education program was implemented.[16]

Although the higher degree of improvement in the "education + physiotherapy" group when compared to the one in the "education" group is very small, it is consistent for all the variables. Therefore, the potential mechanisms involved in it should also be discussed. According to the available evidence, the 15-minute education lecture on postural hygiene is not likely to account for any noticeable effect 6 months later (either positive or negative).[16] Studies on exercise generally show that only a minority of patients comply with it.[17–30] This suggests that the only exercise most patients in the "education + physiotherapy" group did, consisted of 4 hours of supervised training during the first 4 days of a 6-month follow-up period, which is unlikely to trigger any biologic long-term improvement. Unspecific effects may also account for that small additional improvement in that group, since the amount of time patients spent with therapists in the "education + physiotherapy" group was approximately 10 times longer than the time patients spent in the "control" and "education group" (2-group 15-minute talks—one on active management and a second one on postural hygiene—plus 4 hours for physiotherapy, *versus* a single 15-minute group talk). This would underline the need, in potential further trials, to implement interventions in the "control" and experimental groups that require a similar amount of time in contact with therapists.

All of the above would imply that the short education program used in this study is effective at improving disability, pain, and quality of life, essentially by convincing patients to increase their level of physical daily activity. Results from this study show that results from this short education program do not really improve by adding an exercise program that is feasible in primary care, probably because of its short duration and/or low patients' compliance with it. Therefore, although intense exercise programs practiced in the long-term are generally beneficial for those LBP patients adhering to it,[16–26] in primary care it can be more practical to implement the short education program on active management which was used in this study.

In conclusion, results from this study show that a short education program (composed of the handing out of the "Back Book" and a consistent 15-minute group talk) on active management, which is feasible in primary care, leads to small but consistent improvements in disability, pain and quality of life. The addition of a short education program on postural hygiene and a short physiotherapy program intended to be continued at home increases those effects, but the magnitude of that increase is clinically irrelevant.

■ Key Points

- Sixty-nine primary care physicians were randomized to 3 groups ("control," "education," and "education physiotherapy"), and recruited 348 LBP patients. Of them, 79.8% were chronic.
- Patients in the 3 groups received usual care, were given a booklet and received a consistent 15-minute group talk on health education. The booklet and the talk focused on healthy nutrition in the control group, and on active LBP management in the other 2 groups. Additionally, patients in the "education + physiotherapy" group received education on postural hygiene, and 4 one-hour physiotherapy sessions of exercise and stretching, which they were encouraged to continue at home.
- Patients' assessment and data analyses were blinded. During the 6-month follow-up period, improvement in the "control" group was irrelevant. In the "education" and "education + physiotherapy" groups, improvements for disability, severity of LBP, severity of referred pain, catastrophizing, and quality of life were observed. In the "education + physiotherapy" group, the improvement was larger than the one in the "education" group, although that difference was meaningless.

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