Articles

Effect of firmness of mattress on chronic non-specific low-back pain: randomised, double-blind, controlled, multicentre trial

Francisco M Kovacs, Víctor Abraira, Andrés Peña, José Gerardo Martín-Rodríguez, Manuel Sánchez-Vera, Enrique Ferrer, Domingo Ruano, Pedro Guillén, Mario Gestoso, Alfonso Muriel, Javier Zamora, María Teresa Gil del Real, Nicole Mufraggi

Summary

Background A firm mattress is commonly believed to be beneficial for low-back pain, although evidence supporting this recommendation is lacking. We assessed the effect of different firmnesses of mattresses on the clinical course of patients with chronic non-specific low-back pain.

Methods In a randomised, double-blind, controlled, multicentre trial, we assessed 313 adults who had chronic non-specific low-back pain, but no referred pain, who complained of backache while lying in bed and on rising. Mattress firmness is rated on a scale developed by the European Committee for Standardisation. The H_s scale starts at 1·0 (firmest) and stops at 10·0 (softest). We randomly assigned participants firm mattresses (H_s=2·3) or medium-firm mattresses (H_s=5·6). We did clinical assessments at baseline and at 90 days. Primary endpoints were improvements in pain while lying in bed, pain on rising, and disability.

Findings At 90 days, patients with medium-firm mattresses had better outcomes for pain in bed (odds ratio 2·36 [95% CI 1·13–4·93]), pain on rising (1·93 [0·97–3·86]), and disability (2·10 [1·24–3·56]) than did patients with firm mattresses. Throughout the study period, patients with medium-firm mattresses also had less daytime low-back pain (p=0·059), pain while lying in bed (p=0·064), and pain on rising (p=0·008) than did patients with firm mattresses.

Interpretation A mattress of medium firmness improves pain and disability among patients with chronic non-specific low-back pain.

Lancet 2003; **362:** 1599–604
See Commentary page 1594

Scientific Department, Kovacs Foundation, Palma de Mallorca, Spain (F M Kovacs PhD, M Gestoso MD, M T Gil del Real MPH, N Mufraggi MD)**; Unit of Clinical Biostatistics** (V Abraira PhD, A Muriel MSc, J Zamora PhD)**, and Service of Physical Rehabilitation** (A Peña MD)**, Hospital Ramón y Cajal, Madrid; Service of Neurosurgery, Hospital de la Zarzuela, Madrid** (J G Martín-Rodríguez MD)**; Service of Trauma, Clínica de la Luz, Madrid** (M Sánchez-Vera MD)**; Service of Neurosurgery, Hospital Clínic, University of Barcelona, Barcelona** (E Ferrer PhD)**; Department of Anatomy, University of Barcelona, Barcelona** (D Ruano PhD)**; and Service of Trauma, Clínica CEMTRO, Madrid** (P Guillén PhD)

Correspondence to: Dr Francisco M Kovacs, Scientific Department, Kovacs Foundation, Paseo Mallorca 36, E-07012 Palma de Mallorca, Spain
(e-mail: kovacs@kovacs.org)

Introduction

Non-specific low-back pain is defined as pain between the costal margins and the inferior gluteal folds that is generally accompanied by painful limitation of motion, is affected by physical activities and posture, and might be associated with referred pain.[1] The diagnosis implies that the syndrome is not related to underlying disorders, such as fractures, spondylitis, direct trauma, or systemic processes. Although the pain is frequently believed to be the result of degenerative disc syndrome, protrusion or hernia of intervertebral discs, facet-joint degeneration, or other disorders associated with position or movement of the spine, such as scoliosis, vertebral instability, or spondylolisthesis, in 85% of patients no organic cause can be established.[1]

Several biomechanical factors raise the risk of low-back pain.[2,3] In healthy people, characteristics of mattresses may trigger pain, especially in the morning.[4] People who have chronic low-back pain seem to be more sensitive to the firmness of mattresses than healthy people.[5] In patients undergoing percutaneous transluminal coronary angioplasty, the combination of an alternating air mattress and an exercise programme reduces the frequency and severity of low-back pain during the 48 h after the procedure,[6] and in a population-based study, feeling low-back pain in bed or on rising was the factor most strongly associated with low-back pain.[7]

In daily practice, physicians are frequently requested to counsel on the characteristics of beds and mattresses to lessen back pain. In a survey of orthopaedic surgeons, 95% believed that mattresses played a part in the management of low-back pain, with 76% recommending a firm mattress.[8] However, evidence supporting this advice is lacking. The effect of mattress characteristics on low-back pain has been analysed in a limited number of studies,[6,9–12] but the results are weakened by shortcomings in the methods. Few treatments are effective for chronic low-back pain, a disorder that causes most social costs in developed countries.[13,14]

We assessed the effect of the firmness of mattresses on the clinical course of chronic low-back pain and disability. We postulated that the effect of the mattress would be more noticeable while lying in bed or on rising.

Methods

Study population

We recruited adults who had participated in a previous population-based study on the prevalence and risk factors for common low-back pain in adolescents and their parents.[7] Adults were eligible if they reported low-back pain while lying in bed or on rising. A research assistant visited people at home to assess inclusion and exclusion criteria before inviting them to participate.

Inclusion criteria were: age 18 years or older, presence of chronic low-back pain for 3 months or more without referred pain, presence of pain while lying in bed or on

For personal use. Only reproduce with permission from The Lancet publishing Group.

rising, and voluntary agreement to particpate. Exclusion criteria were: habitual prostration, signs of possible systemic disease,[15] a diagnosis of inflammatory disease or cancer, a diagnosis or clinical suspicion of fibromyalgia (defined as pain spread throughout large muscle masses with unjustified fatigue or non-restful sleep), pregnancy, habitually sleeping in a different bed 2 or more nights per week, taking anti-inflammatory medication with a 24 h effect at any time of the day, and taking hypnotic, analgesic, anti-inflammatory, or relaxant medication for any reason from 1700 h to the time at which pain on rising was assessed.

For participants who fulfilled the inclusion criteria and who shared beds (eg, couples), only one person using the bed was allowed to participate. Daytime medications for low-back pain were not withdrawn. New mattresses were installed for free but patients were not further remunerated. We told participants that the study objective was to assess the effect of the mattress on low-back pain, but not that two different kinds of mattresses were going to be compared. Participants were informed that they could withdraw from the study at any time and that if the new mattress made their pain worse we would supply a new replacement of their choice free of charge. All patients gave written informed consent to participate. The study protocol was approved by the ethics committees of the participating institutions.

Intervention

Randomisation was done in a central office, according to a table of random permutations[16] before interventions were assigned. One of the researchers (MG) randomly selected the starting point for reading the table of permutations. The staff of the central office, which was independent from the research staff involved in recruiting the patients, wrote correlative numbers on the front of opaque envelopes. A numeric code from the table of permutations was copied in the inside of the envelope (the number on the front corresponded to the order of that numeric code in the table). Envelopes were then sealed and interventions were assigned to numbers in the table. Once a patient had been included in the study, the research assistant informed the person responsible for randomising patients, who wrote the participant's name on the envelope showing on its front the number corresponding to the order in which the patient had been included in the study. The person in charge opened the envelope and assigned the participant to one group or the other, depending on the number shown inside the envelope.

After baseline assessments, the mattresses of all participants were substituted for new spring mattresses of the same size. The firmness of mattresses (H_s) was rated according to the European Committee for Standardization scale.[17] The scale starts at 1·0 (firmest) and stops at 10·0 (softest). The firm mattresses we used were H_s 2·3 the medium-firm mattresses H_s 5·6. We selected these mattresses because they cost similar amounts (average price: €450 [US$522] for firm and €445 [US$516] for medium firm, respectively), and their firmness represented the extreme and medium values of those available in the market.

Mattresses were distinguishable only by fictitious names that were unrelated to firmness and were similar to commercially available models. The mattresses were installed in the participants' homes under identical conditions by the same workers, who were unaware of which type of mattresses they were installing. Existing mattress support bases were substituted with a firm base if the original base supported less than 50% of the mattress surface (ie, wooden or plastic slats). Only the person who did the randomisation knew which mattress had been installed, but that person had no access to data obtained throughout the trial.

We assessed patients at baseline and at 90 days. Each patient was assessed at home with validated self-assessment instruments and by a research assistant. At baseline, patients self-assessed intensity of pain while lying in bed, the intensity of pain on rising, and the degree of disability. Pain was assessed with a visual analogue scale (VAS), which ranges from zero (least) to ten (most intense pain).[18] We asked patients to rate their low-back pain as soon as they woke up (pain while lying in bed) and within 30 min of rising (pain on rising). Disability was assessed by a previously validated Spanish version of the Roland Morris questionnaire,[19] consisting of 24 items related to activities of daily living. Scores range from zero (no disability) to 24 (maximum disability). We asked patients to fill out the the VAS and Roland Morris questionnaire with no-one else present.

At baseline assessment, the research assistants recorded the variables that might affect the clinical course of low-back pain and those related to exposure to the mattress: age, sex, weight, height, socioeconomic status, occupation, exposure to repeated flexion-extension movements with load or whole-body vibration at work, smoking habit, sports activity, duration of low-back pain, low-back pain in bed, and low-back pain on rising, use of medication for low-back pain (listing separately analgesics, anti-inflammatory agents, muscle relaxants, and other agents), most common sleeping position, sharing of the bed, partner's low-back pain in bed, number of minutes in bed daily (weekdays and weekends); age, length, width, and thickness of the original mattress, type of support base; thickness of the board placed over the support base if any; and subjective feeling on firmness of the original mattress. Finally, the research assistant fully explained to patients how to fill out the scales for intensity of pain and disability.

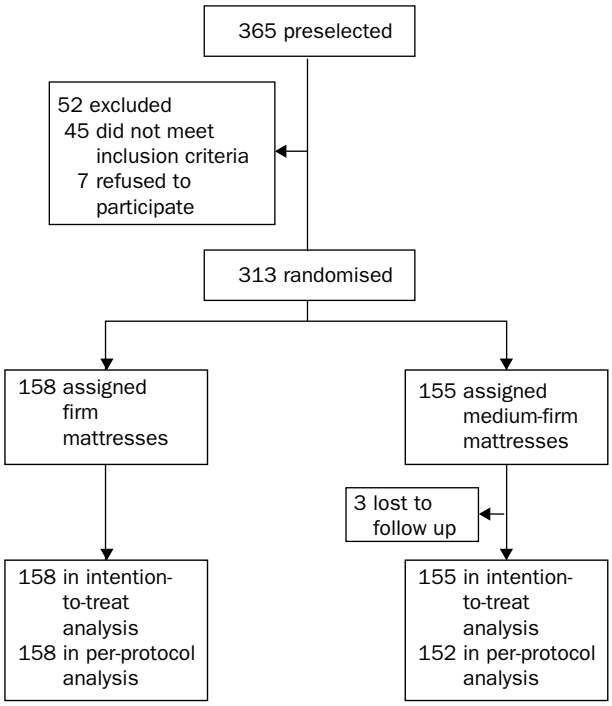
At 90 days, every participant assessed their intensity of low-back pain while lying in bed and on rising, and disability. The research assistants asssessed the following variables: characteristics of occupation, exposure to repeated flexion-extension movements with load and to whole-body vibrations at work, smoking, body position when sleeping, sharing of the bed, subjective feeling on firmness of the new mattress, whether their partner had pain in bed, use of medication for low-back pain, daily low-back pain, low-back pain while lying in bed and on rising throughout the study (follow-up period), whether he or she experienced more pain in bed when more time spent in it.

Primary outcomes were the intensity of pain while lying in bed and on rising, and the degree of disability. Secondary outcomes included low-back pain, low-back pain in bed or on rising throughout the study period, and more intense pain in bed when lying down for an extended time. We recorded complaints of pain while lying in bed from the participants' partners as a side-effect.

Statistical analysis

We established the size of the study population at 125 patients per group, according to Lemeshow's tables,[20] assuming a difference in the proportion of patients improving in each group of at least 20% and that the prevalence of improvement in one of the groups would be 50%. A type I error of 0·05 and a type II error of 0·10 were accepted. We increased the study population to

For personal use. Only reproduce with permission from The Lancet publishing Group.



Trial profile

313 participants to compensate for an anticipated 20% loss of patients during follow-up.

Analyses were done by a team of statisticians who were unaware of mattress assignment. The scores on the last measurement (day 90) were subtracted from those obtained at baseline; positive values indicated improvement—improvement increasing with increasing value—and negative values corresponded to worsening. Analyses were done on SPSS (version 10.0) and PRESTA (version 2.21)[21] for collinearity diagnosis. We present data on continuous variables as medians and ranges, and crude analyses were done with the Mann-Whitney *U* test because distribution of data departed from normality. We analysed categorical variables with the χ^2 test. We did analyses by intention to treat and per protocol. To assume the most conservative approach, we decided that for the intention-to-treat analysis the poorest observed results would be assigned to losses in the group showing the best evolution, and vice versa.[22]

We used multiple logistic regression models to assess the association between the independent variable group and improvement of pain in bed, pain on rising, and disability, after adjustment for possible confounding factors.[23] Improvement was defined as a positive change, whatever the magnitude, between baseline and follow-up assessment. Variables with imbalance between the groups at baseline were included in the models, as well as those that could exert confounding on the effect of the mattress on low-back pain. Therefore, the three maximum models included age, sex, height, and weight (combined as the fat coefficient),[24] height-to-length bed ratio, characteristics of job, exposure to repeated flexion-extension movements with load, exposure to whole-body vibration at work, sports (we classified sports as not relevant if they were done once or less per week, and relevant if they were done twice or more per week or at competition level), smoking (yes or no), history of low-back pain (years), sharing of bed (yes or no), age of original mattress (years), subjective perception of the firmness of the new mattress, posture while sleeping at baseline and at 90 days (correct=supine with knees bent, lying on the side in the fetal position, or three quarters—ie, any position with knees bent between fetal and prone; incorrect=other positions), VAS in bed at baseline, VAS on rising at baseline, Roland Morris

	Firmness of mattress	
	Firm (n=158)	Medium firm (n=155)
Characteristic		
Sex		
Male	42 (26·6%)	42 (27·1%)
Female	116 (73·4%)	113 (72·9%)
Median (range) age (years)	44·0 (18·0–78·0)	45·1 (19·0–82·0)
Median (range) weight (kg)	69 (45–122)	65 (45–104)
Median (range) height (cm)	164 (146–190)	164 (145–190)
Educational level		
No studies or primary education	69 (43·6%)	71 (45·8%)
Secondary education or higher	89 (56·3%)	84 (54·2%)
Smoking habit		
Never or ex-smoker	113 (71·5%)	112 (72·3%)
Current smoker	45 (28·5%)	43 (27·7%)
In employment	88 (55·7%)	91 (58·7%)
Characteristics of occupation		
Sedentary or ambulatory without strain	106 (67·1%)	105 (67·7%)
Ambulatory with strain or non-ambulatory with strain	52 (32·9%)	53 (32·2%)
Exposures at work to		
Flex-extension movements with load	42 (26·6%)	40 (25·8%)
Whole-body vibrations	8 (5·1%)	6 (3·9%)
Sport activity (>twice per week or competition level)*	86 (54·4%)	77 (49·7%)
Median (range) time in bed (min)	480 (300–771)	480 (300–626)
Most common position during sleep		
Supine knees bent	9 (5·7%)	6 (3·9%)
Supine knees straight	35 (22·2%)	41 (26·5%)
Prone	16 (10·1%)	10 (6·5%)
Fetal	86 (54·4%)	87 (56·1%)
Three-quarters	7 (4·4%)	4 (2·6%)
Other	5 (3·2%)	7 (4·5%)
Shared bed	111 (70·3%)	111 (71·6%)
Characteristics of mattress		
Median (range) age (years)	7 (2–33)	8 (2–34)
Median (range) length (cm)	190 (180–210)	182 (180–200)
Median (range) width (cm)	135 (90–180)	135 (80–190)
Median (range) thickness (cm)	16 (8–25)	16 (7–22)
Median (range) thickness of board (cm)	2 (0·3–8)	2 (1–5)
Type of base		
English mesh	16 (10·3%)	13 (8·6%)
Square-link mesh	11 (7·1%)	7 (4·6%)
Box spring	54 (34·6%)	64 (42·1%)
Board with >50% support	38 (24·4%)	30 (19·7%)
Firm base	35 (22·4%)	30 (19·7%)
Other	2 (1·3%)	8 (5·3%)
Subjective perception of the firmness of mattress		
Very soft	1 (0·6%)	5 (3·2%)
Soft	17 (10·8%)	21 (13·5%)
Neither soft nor firm	67 (42·7%)	72 (46·5%)
Firm	59 (37·6%)	51 (32·9%)
Very firm	13 (8·3%)	6 (3·9%)
Back pain of partner in bed	48 (43·2%)	40 (36·0%)
Median (range) duration of low-back pain (years)	10 (1–42)	9 (0–53)
Median (range) duration of low-back pain while lying in bed (years)	7 (1–42)	6 (0–53)
Median (range) duration of low-back pain on rising (years)	7 (1–42)	5·5 (0–53)
Median (range) pain in bed on VAS	5 (0–10)	5 (0–9)
Median (range) pain on rising on VAS	7 (0–10)	7 (0–10)
Median (range) pain-related disability on RMQ	9 (0–20)	8 (0–21)
Taking medication for low-back pain	40 (25·3%)	32 (20·6%)

RMQ=Roland Morris questionnaire. *Football, swimming, volleyball, judo, basketball, athletics, sailing, tennis, gymnastics, aerobics, indoor football, paddle-tennis, squash, and handball.

Table 1: **Baseline characteristics**

For personal use. Only reproduce with permission from The Lancet publishing Group.

questionnaire score at baseline, mean daily time in bed ([min]; working days=mean time for 5–7 days; days off work=mean time for 2–7 days), type of base (firm=firm base or boards supporting ⩾50% of the mattress' surface, not firm=English mesh, square link mesh, box spring, or boards supporting <50% of the mattress' surface), and medication for low-back pain (yes or no). For each regression model, we took improvement as the dependent variable. The collinearity of the maximum models was assessed with the criteria proposed by Belsley.[25] We deemed variables to be confounding if the estimate of the coefficient of the variable group changed by more than 10% when that variable was removed from the maximum model. A backward strategy was used.

Results

365 patients were selected for the study. 52 were excluded for the following reasons: use of medication under the conditions of the exclusion criteria (27), fibromyalgia (eight), refusal to take part in the study (seven), presence of a systemic inflammatory disease (six), sleeping away from home more than 2 days per week (three), and habitual prostration (one). Therefore, 313 patients (84 men and 229 women) were included in the study and randomised. 158 participants were assigned firm mattresses and 155 mattresses of medium firmness (figure). Three patients from the firm mattress group were lost to follow-up because of a change in their place of residence.

In the intention-to-treat analysis, baseline data of patients in the two groups were similar (table 1). Most patients reported a long history of low-back pain. Pain intensity on VAS was graded as moderate to severe (median [range] score while lying in bed: 5 [0–10] firm, 5 [0–9] medium-firm mattresses; and on rising, both groups 7 [0–10]), and the degree of disability on Roland Morris questionnaire was notable (9 [0–20] firm, 8 [0–21] medium-firm mattresses, table 1).

Mean time between randomisation and installation of new mattresses was 10 days (SD 6·5). All participants had bed bases supporting more than 50% of the mattress surface and, therefore, no bed-base changes were made. At day 90, participants in both groups had experienced improvements compared with baseline in the intensity of pain while lying in bed (mean intensity improvement 70% firm and 80% medium-firm mattresses), intensity of pain on rising (each 57%), and disability (30% and 50%). Although there were differences in favour of medium-firm mattresses in all variables at day 90, only those in the degree of improvement of disability and pain on rising throughout follow-up were significant (p=0·008, table 2). Differences in the degree of improvement of pain on rising (p=0·053), having had low-back pain throughout follow-up (p=0·059), and pain while lying in bed throughout follow-up (p=0·064) were close to significance (table 2). The firmness of the new mattress was generally perceived accurately by participants; 77·2% of patients in the firm mattress group perceived their mattress to be firm or very firm, compared with 43·5% in the medium-firm mattress group who though their mattress was firm (p<0·0001, table 2). When they entered the study, 63 of the 111 individuals who shared beds with participants in the firm mattress group and 71 of the 111 who shared beds with those from the medium-firm mattress group had pain in bed (p=0·27). At the end of the study, 19 from the firm mattress group and 14 from the medium-firm mattress group had pain (p=0·35).

In most patients, the change of mattress was associated with an improvement of pain while lying in bed (firm mattress 77·8% *vs* 82·6% medium-firm mattress, odds ratio 1·35 [95% CI 0·77–2·36], p=0·29) and on rising (80·4% *vs* 85·8%, odds ratio 1·48 [0·81–6·68], p=0·201). Pain-related disability improved in both groups, although in a significantly higher proportion of patients in the

	Firmness of mattress		p
	Firm mattress (n=158)	Medium firm (n=155)	
Characteristic			
Characteristics of occupation			0·399
Sedentary or ambulatory without strain	108 (68·4%)	97 (63·8%)	
Ambulatory with strain or non-ambulatory with strain	50 (31·6%)	55 (36·2%)	
Exposures at work			
Flex-extension movements with load	38 (24·1%)	43 (28·6%)	0·396
Whole-body vibrations	4 (2·5%)	4 (2·6%)	0·956
Most common position during sleep throughout follow-up			0·379
Supine knees bent	4 (2·5%)	2 (1·3%)	
Supine	41 (25·9%)	31 (20·5%)	
Prone	12 (7·6%)	18 (5·3%)	
Fetal	93 (58·9%)	104 (68·9%)	
Three-quarters	6 (3·8%)	6 (4·0%)	
Other	2 (1·3%)	0	
Shared bed	109 (69·0%)	106 (69·7%)	0·866
Subjective perception of the firmness of mattress			<0·0001
Very soft	0	1 (0·6%)	
Soft	0	5 (3·2%)	
Neither soft nor firm	36 (22·8%)	81 (52·6%)	
Firm	102 (64·5%)	64 (41·6%)	
Very firm	20 (12·7%)	3 (1·9%)	
Collapsed categories			<0·0001
Very soft/soft/neither soft nor firm	36 (22·8%)	87 (56·4%)	
Firm/very firm	122 (77·2%)	67 (43·5%)	
Back pain of the partner in bed			0·407
No	90 (82·6%)	91 (86·7%)	
Yes	19 (17·4%)	14 (13·3%)	
Back pain of the partner in bed*			0·192
No	26 (64·4%)	28 (77·8%)	
Yes	16 (35·6%)	8 (22·2%)	
Back pain of the partner in bed†			0·386
No	57 (95·0%)	61 (91·0%)	
Yes	3 (5·0%)	6 (9·0%)	
Taking medication for low-back pain			0·983
No	135 (85·4%)	130 (85·5%)	
Yes	23 (14·6%)	22 (14·5%)	
Had low-back pain throughout follow-up			0·059
No	36 (22·8%)	48 (32·4%)	
Yes	122 (77·2%)	100 (67·6%)	
Had low-back pain in bed throughout follow-up			0·064
No	44 (27·8%)	57 (37·7%)	
Yes	114 (72·2%)	94 (62·3%)	
Had low-back pain on rising throughout follow-up			0·008
No	36 (22·8%)	55 (36·7%)	
Yes	122 (77·2%)	95 (63·3%)	
More intense pain in bed with more time in it throughout follow-up			0·087
No	73 (51·8%)	89 (61·8%)	
Yes	68 (48·2%)	55 (38·2%)	
Degree of improvement			
Median (range) pain while lying in bed on VAS	3·35 (–10 to 10)	4·0 (–5·0 to 9·20)	0·276
Median (range) pain on rising on VAS	4·0 (–7 to 9)	4·0 (–3 to 10)	0·053
Median (range) disability on RMQ	3·0 (–10 to 19)	4·0 (–14 to 19)	0·008

*Only partners who had pain while lying in bed on entering study. †Only partners free from pain while lying in bed on entering study.

Table 2: **Results of assessment at 90 days**

For personal use. Only reproduce with permission from The Lancet publishing Group.

	Odds ratio (95% CI)	p
Variable		
Improvement of pain while lying in bed on VAS*	2·36 (1·13–4·93)	0·023
Improvement of pain on rising (VAS)†	1·93 (0·97–3·86)	0·061
Improvement of pain-related disability (RMQ)	2·10 (1·24–3·56)	0·006

RMQ=Roland Morris questionnaire. *Adjusted by perceived firmness of new mattress, pain on rising at baseline, pain while lying in bed at baseline. †Adjusted by perceived firmness of new mattress and VAS on rising at baseline.

Table 3: **Results of multiple logistic regression model for intention-to-treat analysis**

medium-firm mattress than in the firm mattress group (81·9% *vs* 68·3%, 2·10 [1·24–3.56], p=0·005). After installing the new mattresses, worsening was observed in some patients for pain in bed (firm mattresses 17·1%, medium-firm mattresses 9·0%), pain on rising (firm mattresses 12·7%, medium-firm mattresses 6·5%), and disability (firm mattresses 24·1%, medium-firm mattresses 9·0%). However, none of the patients requested a change of the mattress during the course, or after completion of, the study.

In the multivariate analysis, to avoid collinearity-related difficulties, we eliminated the variable height-to-length bed ratio, and centred the variables fat coefficient and minutes spent in bed by subtracting their means.[23] Intensity of basal pain while lying in bed, pain on rising, and perceived firmness of the new mattress were confounding variables for intensity of pain in bed. Intensity of basal pain on rising and perceived firmness of the new mattress were confounding variables for improvement of pain on rising. After adjustment for these variables, the final model showed that patients who received the medium firmness mattresses were around twice as likely to improve than were patients with firm mattresses for low-back pain while lying in bed, low-back pain on rising, and disability (table 3).

For the per-protocol analysis, we did not include data for the three patients lost to follow-up. This exclusion did not change the direction of results, although it increased the differences between the groups, and intensity of pain on rising became significant in the crude and multivariate analyses (data not shown).

Discussion

In patients with chronic low-back pain, mattress conditions affect the degree of pain-related disability and the intensity of pain while lying in bed and on rising. The substitution of old mattresses with firm and medium-firm new ones was associated with more frequent discontinuation of drug treatment and relevant improvements in pain and disability than other strategies for chronic low back pain.[13]

The design of this study does not permit us to quantify the Hawthorne and placebo effects on the observed improvement. However, the double-blind design of the trial allows us to conclude that beyond such effects, the use of a mattress of medium firmness improves the clinical course of low-back pain in a higher proportion of patients than the use of a firm mattress. In fact, although the mean differences between groups for some quantitative variables were small, all the differences favoured the use of a mattress of medium firmness.

The underlying mechanisms explaining the results of this trial are probably related to the duration of exposure to the mattress, which represents roughly a third of a person's life, and to the effect of its firmness on pressure distribution and muscular function when lying in bed.

Side-effects were rare. The installation of a firm or medium-firm mattress was associated with a reduction in the number of partners with low-back pain while lying in bed. Pain in bed, however, occurred in nine of the 134 partners who did not have it previously.

We focused on low-back pain while lying in bed and on rising, and on the potential effect on back pain throughout the day, which was explored by a simple question related to its presence during the study period. Because of the low sensitivity of this method, the differences in favour of the medium-firm mattress were only close to significance. In addition, there were clinical and significant differences in favour of a medium-firm mattress in disability. Accordingly, the beneficial effect of the characteristics of the mattress seems to carry on beyond the time when the patient is lying in bed or immediately after rising. This possibility should be further explored in future trials.

Although patients were unaware of the type of mattress they were receiving, they generally perceived correctly the firmness of their mattress. The general belief that "harder means better" reduced the positive effect of the medium-firm mattress in the crude analysis, which in turn is consistent with the importance of cognitive and psychosocial factors in the course of chronic low-back pain.[26–28] This finding, together with the degree of improvement in the two groups, suggesting a contribution from the Hawthorne and placebo effects, strongly shows the need for using adequate methods (masked randomised controlled trial) in studies aimed at investigating mattress-related backache effects. Most previous controlled studies on the effects of the mattress were not blinded adequately for mattress characteristics,[4,6,9–11] which may have undermined the validity of their results. One previous study used a double-blind design, but the follow-up period was only 1 night, and it focused on the quality of sleep and not on the evolution of low-back pain.[5]

The medium-firm mattress was associated with an improvement in disability related to low-back pain. This effect is particularly important since, although some cognitive and psychosocial interventions slightly improve the degree of disability, very few medical or physical interventions have achieved this objective.[13,29,30] Several of the items in the Roland Morris questionnaire might be affected by stiffness in bed or on rising, which might account for such a result. The results of this study also suggests that, although psychosocial factors have an effect on disability,[26–28] some biomechanical factors that were not previously considered may also have an effect and should be taken into consideration for future studies.

The external validity of our results might be limited by several factors. This study was done in patients with chronic low-back pain and no referred pain, and the effect of the firmness of the mattress on referred pain as well as on an acute exacerbation of backache is unknown. Psychosocial factors affect the degree of disability associated with low-back pain and might be specific to each setting, which might alter slightly the generalisability of findings on this variable. Finally, we used mattresses of two different firmnesses but they were spring mattresses. Although the firmness scale is independent of the composition of the mattress, the results might differ with other kinds of mattresses. For ethical reasons, we offered patients any mattress for free after 90 days in case their low-back pain had worsened with the one installed during the study. This action limited follow-up to that period, and further studies should assess long-term effects of the mattress.

Our findings stress that recommendations for daily living, such as what kind of mattress to use, may have a

For personal use. Only reproduce with permission from The Lancet publishing Group.

relevant effect on the clinical course of low-back pain. The effects should be assessed with sound methods similar to those used for other medical treatments.

Contributors

F M Kovacs and M Gestoso designed the study, recruited patients, coordinated study execution, wrote the report, scientifically reviewed the paper, and approved the final draft. V Abraira reviewed the study design, planned and did the statistical analysis, reviewed the scientific content, and approved the final draft. A Muriel and J Zamora did the statistical analysis and approved the final draft. A Peña, J G Martín-Rodríguez, Manuel Sánchez-Vera, E Ferrer, D Ruano, P Guillén, M T Gil del Real, and N Mufraggi reviewed the design of the study, supervised coordination of the study, reviewed the report drafts, and approved the final version.

Conflict of interest statement

None declared.

Acknowledgments

This study was done and financed by the Kovacs Foundation, a non-profit Spanish research institution with its own funding resources that promotes evidence-based health care in clinical practice. FLEX, a Spanish bedding company, provided and installed the mattresses used in the trial without charge; nobody from that company participated in study design or in the collection, analysis, and interpretation of data. We thank Marta Pulido for editing the report and for editorial assistance.

References

1 Deyo RA, Weinstein JN. Low back pain. *N Engl J Med* 2001; **344:** 363–70.
2 Pope MH, Wilder DG, Krag MH. Biomechanics of the lumbar spine: basic principles. In: Frymoyer JW, ed. The adult spine: principles and practice. New York, NY: Raven Press, 1991.
3 Lings S, Leboeuf-Y de C. Whole body vibration and low back pain: a systematic, critical review of the epidemiological literature 1992–1999. *Int Arch Occup Environ Health* 2000; **73:** 290–97.
4 Koul PA, Bhat MH, Lone AA, Koul AN, Wahid A. The foam mattress-back syndrome. *J Assoc Physicians India* 2000; **48:** 901–02.
5 Enck P, Walten T, Traue JC. Associations between back pain, quality of sleep and quality of mattresses: double-blind pilot study with hotel guests. *Schmerz* 1999; **13:** 205–07.
6 Scriver V, Crowe J, Wilkinson A, Meadowcroft C. A randomized controlled trial of the effectiveness of exercise and/or alternating air mattress in the control of back pain after percutaneous transluminal coronary angioplasty. *Heart Lung* 1994; **23:** 308–16.
7 Kovacs FM, Gestoso M, Gil del Real MT, López J, Mufraggi N, Méndez JI. Risk factors for nonspecific low back pain in schoolchildren and their parents: a population-based study. *Pain* 2003; **103:** 159–268.
8 Levy H, Hutton WC. Mattresses and sleep for patients with low back pain: a survey of orthopaedic surgeons. *J South Orthop Assoc* 1996; **5:** 185–87.
9 Garfin SR, Pye SA. Bed design and effect on chronic low back pain. a limited controlled trial. *Pain* 1981; **10:** 87–91.
10 Hagino C, Erfanian P. Before-after study to determine the effectiveness of an adjustable wood frame-foam and wool mattress bed system (The Natura Mattress System) in reducing chronic back pain in adults. *J Can Chiropract Assoc* 1997; **41:** 16–26.
11 Monsein M, Corbin TP, Culliton PD, Merz D, Shuck EA. Short-term outcomes of chronic back pain patients on an airbed vs innerspring mattresses. *MedGenMed* 2000; **2:** E36.
12 Jacobson BH, Gemmel HA, Hayes BM, Altena TS. Effectiveness of a selected bedding system on quality of sleep, low back pain, shoulder pain, and spine stiffness. *J Manipulative Physiol Ther* 2002; **25:** 88–92.
13 Van Tulder MW, Koes BW, Bouter LM. Conservative treatment of chronic low back pain: a meta-analysis of 80 randomized trials of 14 interventions. In: Van Tulder MW, Koes BW, Bouter LM, eds. Low back pain in primary care. Amsterdam: Institute for Research in Extramural Medicine, 1996.
14 Andersson GBJ. The epidemiology of spinal disorders. In: Frymoyer JW, ed. The adult spine: principles and practice, 2nd edn. New York, NY: Raven Press, 1997.
15 Agency for Health Care Policy and Research. Clinical practice guideline number 14: acute low back pain problems in adults. Rockville, MD: US Department of Health and Human Services, 1994.
16 Moses LE, Oakford RY. Tables of random permutations. Standford, CA: Standford University Press, 1963.
17 European Committee for Standarization. Domestic Furniture. Beds and mattresses: test method for the determination of functional characteristics. CEN/TC207/WG1/TG4. Brussels: Comité Européen de Normalisation, 1996.
18 Huskisson EC. Measurement of pain. *Lancet* 1974; **2:** 1127–31.
19 Kovacs FM, Llobera J, Gil del Real MT, et al. Validation of the Spanish version of the Roland-Morris questionnaire. *Spine* 2002; **27:** 538–42.
20 Lemeshow S, Hosmer DW, Klar J, Lwanga SK. Adequacy of sample size in health studies. Chichester, UK: John Wiley, 1990.
21 Abraira V, Zaplana J. PRESTA, un paquete de procesamientos estadísticos. Proceedings de la Conferencia Iberoamericana de Bioingeniería. 100. Asturias, Spain: Gijón, 1984.
22 Pocock SJ. Clinical trials: a practical approach. New York: John Wiley, 1983.
23 Kleinbaum DG, Kupper LL, Muller KE. Applied regression analysis and other multivariable methods, 2nd edn. Boston, MA: PWS-KENT, 1988.
24 Pronnett S. Le marathon, equilibre energetique, endurance et alimentation du coureur sur route. Paris: Vigot, 1983.
25 Belsley DA. Conditioning diagnostics: collinearity and weak data in regression. New York, NY: John Wiley, 1991.
26 Schmidt AJ. Cognitive factors in the performance level of chronic low back pain patients. *J Psychosom Res* 1985; **29:** 183–87.
27 Sandstrom J, Esbjornsson E. Return to work after rehabilitation: the significance of the patient's own prediction. *Scand J Rehabil Med* 1986; **18:** 29–33.
28 Waddell G, Somerville D, Henderson I, Newton M, Main CJ. A fear avoidance beliefs questionnaire (FABQ) and the role of fear avoidance beliefs in chronic low back pain and disability. *Pain* 1993; **52:** 157–68.
29 Kovacs FM, Abraira V, Pozo F, et al. Local and remote sustained trigger point therapy for exacerbations of chronic low back pain: a randomized, double-blind, controlled multicenter trial. *Spine* 1997: **22:** 786–96.
30 Kovacs FM, Llobera J, Abraira V, et al. Effectiveness and cost-effectiveness analysis of neuroreflexotherapy for subacute and chronic low back pain in routine general practice: a cluster randomized, controlled trial. *Spine* 2002; **27:** 1149–59.

For personal use. Only reproduce with permission from The Lancet publishing Group.