Does Folk Medicine Work? A Randomized Clinical Trial on Patients With Prolonged Back Pain

Heikki M. Hemmilä, MD, Sirkka M. Keinänen-Kiukaanniemi, MD, PhD, Sinikka Levoska, MD, PhD, Pekka Puska, MD, PhD

ABSTRACT. Hemmilä H, Keinänen-Kiukaanniemi SM, Levoska S, Puska P. Does folk medicine work? A randomized clinical trial on patients with prolonged back pain. Arch Phys Med Rehabil 1997;78:571-7.

Objective: To determine whether traditional bone-setting or continuous light exercise therapy could ease back pain and improve function better than ordinary physiotherapy.

Design: Observer-blinded, randomized clinical trial with a 6-month follow-up.

Setting: An outpatient institution for folk medicine research.

Patients: Of 147 back pain patients recruited from local health centers and by newspaper announcements, 132 were found eligible (non-retired, no contraindications to manipulation) and entered. A final 114 (one dropout) with back pain for longer than 7 weeks were included in this intent to treat analysis.

Interventions: Bone-setting, guidance for continuous light back movements or physiotherapy for up to ten 1-hour sessions during 6 weeks.

Main Outcome Measures: Spinal mobility and muscular performance. Back pain assessed by visual analog scales (VAS).

Results: The physical measures changed only modestly, from one tenth to half of standard deviation, while the VAS was halved. The thoracolumbar side-bending, the modified Schober, and the VAS were significantly better improved by bone-setting than by exercise but not better than by physiotherapy.

Conclusion: Neither bone-setting nor exercise differed significantly from physiotherapy, but bone-setting improved lateral and forward bending of the spine and back pain more than did exercise.

BACK PAIN IS A GROWING challenge for scientific medicine. Three quarters of all Finnish adults report a lifetime experience of low back pain and one out of ten suffer from it continuously.[1] In spite of intensive research, Nachemson's statement still holds: "From the multitude of methods to treat back pain only few have demonstrated a positive effect in scientific studies."[2]

The effectiveness of physiotherapy on chronic low back pain has been studied extensively, but the evidence of its beneficial effect is still inconclusive, mainly because of the methodological shortcomings of the trials.[3]

Chronic back pain seems best treated by intensive fitness training.[4-9] Less strenuous or less time consuming exercises appear less effective.[8] A fitness training program taught to patients had a minor effect when compared to the same regimen performed in a controlled setting.[5] Immobilization has been proven in animal experiments to be harmful to the spinal structures, including intervertebral discs.[10] There is also some evidence of a "J-shaped" response of disc degeneration to physical loading in humans.[11] Nachemson[2] reports that "the least possible amount of movement needed to preserve or increase strength and to stimulate healing of different tissues is not known. For discs and cartilage it seems that, according to animal experiments, 30 minutes of daily jogging is good. More does not give extra benefit." Five weekly hours of vigorous exercise improved muscle force and spinal mobility synchronously with pain and disability.[9] Could the pain be alleviated with a similar amount of movement, but with less vigor?

Muscle stretching has had a positive effect on back pain and spinal mobility whether provided by a physiotherapist[12] or by the patient.[13] Autostretching can be taught to patients with an illustrated guide,[14] but its use as a home exercise alone or in combination with other therapies has not been evaluated.

Public dissatisfaction with medical treatment for back pain has resulted in many alternative therapies, including traditional bone-setting, which is common in Finland. According to a national survey,[15] 17% of adult Finns have consulted a bone-setter. Of those, 96% reported benefit, in comparison with only 85% of the medical doctors' patients. Finnish bone-setting resembles manipulative therapies, such as chiropraxis or osteopathy. Several studies have suggested that manipulative therapies are effective in treating back pain; however, most of those studies had methodologic flaws.[16] There is agreement on a positive short-term effect on acute conditions, but no consensus on a long-term effect, nor on a preventive action against relapses.[16,17] So far, there are no prospective studies on the clinical effectiveness of bone-setting, not withstanding its popularity.

The main purpose of this study was to determine whether traditional bone-setting, or a combination of light exercise and autostretching therapies, has clinically measurable effects on patients with prolonged back pain in comparison with regular physiotherapy plus autostretching.

MATERIAL AND METHODS

Subjects

The study patients were referred by colleagues in a local health center or recruited by articles and announcements in newspapers. The inclusion criterion was reported back pain between the shoulders and the buttocks. The exclusion criteria were retirement, pregnancy, malignancy, rheumatic diseases, severe osteoarthritis, cauda equina syndrome, back operation, or vertebral fracture in the past 6 months or any condition that would prevent or contraindicate any of the therapies. None of the study treatments were allowed during the previous month.

From the Folk Medicine Centre, Kaustinen (Dr. Hemmilä); the Department of Public Health Science and General Practice, University of Oulu, and Unit of General Practice, Oulu University Hospital (Drs. Keinänen-Kiukaanniemi, Levoska); and the National Public Health Institute (Dr. Puska), Finland.

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Reprint requests to Heikki Hemmilä, MD, Folk Medicine Centre, Pajalantie 24, 69600 Kaustinen, Finland.

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The patients were excluded, also, if the initial pain score was less than 25mm on the 100-mm visual analog scale (VAS).

Of the 147 patients who contacted our center between February and June 1994, 132 were found eligible and were randomized and followed up. One patient (bone-setting) was operated on for a herniated disc soon after randomization and missed the therapy and control visits. Eighteen patients (10 physiotherapy, 3 bone-setting, and 5 exercise) had acute conditions. The Quebec Task Force criteria of chronicity, back pain of at least 7 weeks' duration,[18] was originally ment for a subgroup analysis, but because the majority of the patients had longer histories of back pain, this analysis was restricted to the remaining 113 chronic cases.

Study Design

During the first visit, a nurse registered and interviewed the patients, obtained an informed consent, and admonished them to not take any other than the randomized therapies during the treatment period. After completing the initial questionnaires on back pain and disability, the patients were examined by a general practitioner (GP), who made the final decision of inclusion. Immediately after the examination, the patients were randomized by drawing lots, and the first therapy session was booked. The GP was blinded to the therapies. After the 6-week treatment period, the physical examination was repeated and the questionnaire re-presented. Three months later a postal inquiry was made, and after 6 months the patients were seen again by the GP. Ethical approval for the study was obtained from the Ethics Committee of the university's medical faculty.

Therapy Options

The randomized therapy options were regular physiotherapy, treatment by bone-setters, and a home exercise regimen with individual training by a physiotherapist. A maximum of ten 1-hour sessions of each therapy option was offered at our center during the 6-week follow-up period for a total charge of approximately $30.

The pysiotherapy consisted of a combination of manual, thermal, and electrotherapy. The therapist was free to choose a suitable method within these categories and to use the facilities at his disposal: hot/cold packs, infrared heat, ultrasound, shortwave diathermy, and transcutaneous electric nerve stimulation. In addition to massage, he also employed specific mobilizations and manual traction according to the GP's prescription, but no manipulations with impulse. Individual autostretching exercises[14] were added if tightness of the pelvic or femoral muscles was noted at the initial examination.

The bone-setting was administered by four folk-healers aged 40 to 70 years with a practical experience of up to 30 years, but with no formal medical education. The bone-setters were free to choose the methods from their repertoires. The method they most commonly applied was gentle mobilization of the spine. The patient sits on a stool with the therapist behind him. The therapist first uses his fingers to find out if the spinous processes are in line or "dislocated" up or down or on either side. If a vertebra is found to be "out of alignment," the patient is asked to bend forward and slowly straighten up while the therapist holds his thumbs against the transverse processes of the next lower vertebra, thus presumably mobilizing the upper facet joints. The method is applicable from the sacroiliac joint up to the neck. Another common method is simply to rub the "misaligned" spinous processes gently from all sides to "negotiate" them into a "correct position." Massage is regarded as a less sophisticated treatment entity, and it was hence only applied occasionally. No direct and forceful, "chiropractic," manipulations were used. The patients randomized for bone-setting were allowed to choose between the four folk healers to avoid possible personal conflicts and to assure a more generalizable outcome from their variable therapy repertoires.

All exercise patients were taught a constant program: to bend their low back rhythmically from side to side and back and forth as well as to rotate from side to side, ten times in each direction every 15 minutes, whenever sitting, standing, or lying still (eg, watching TV, driving a car) or at least before getting up in the morning and after lying down in the evening. The program also included 10 sit-up, 10 arch-up, and 10 trunk rotation exercises twice a day. The rotatory exercises were performed standing with the feet apart, with small weights on both hands, rotating the upper body as far and as fast as possible. Autostretching exercises were added individually when appropriate. Repeated training sessions were booked only to ensure correct performance.

Compliance to the exercise therapy was monitored on a questionnaire after 3 and 6 months; patients were generally asked how closely (0%, 25%, 50%, 75%, or 100%) the program was adhered to during and after the treatment period. The treatment contamination was controlled on the same questionnaires by asking which treatments the patients had taken after the study therapies.

Outcome Assessments

A single GP, blinded for the therapies, carried out all the physical examinations: before the randomization and 6 weeks and 6 months later, following the guidelines recommended for occupational health controls.[19,20] The measures of back mobility included modified Schober, thoracolumbar side-bending, and lumbar extension. The modified Schober test and side-bending were measured with a tape.[19] Lumbar extension was measured with a single bubble goniometer. The instrument was placed against the spinous process of T12, zeroed when the patient was lying prone, and read after he extended his back maximally by leaning on his hands. The passive straight leg raising (SLR) test was measured with a goniometer as well. A liner was placed on the femur to get a stable measuring base. The analyses are based on the mean of left and right measurements.

Back pain in the past 3 days was recorded initially and 6 weeks, 3 months, and 6 months after the baseline measurement on a 100-mm VAS, which the patients filled in unassisted. The pain provocation score (PPS) was calculated from reactions to 13 tests of spinal and lower limb mobility, piriformis provocation tests, and sacroiliac springing tests. Piriformis provocation was performed prone as a resisted external rotation of the thigh. Sacroiliac springing test was performed by applying pressure on the lower part of sacrum and one posterior superior iliac spine simultaneously. The patients were asked if they had back pain after each test. In addition to these tests, the patient's pain reaction was observed during walking. Thus, a maximum of 18 points could be obtained.

The pressure pain thresholds[21] (PPTs) were measured with a commercial dolorimeter that has been found to give consistent results.[22] The measuring points were the back extensors 2cm lateral from the spinous processes of TXII and LIV. The device was placed perpendicular to skin and the pressure was increased by 1Kp per second. Only one reading was obtained. An average of all four measurements was computed for the analysis. Muscular performance was assessed with a single sit-up test and repeated sit-up, arch-up, and squatting tests.[20]

The reliability of the physical measurements was assessed on ten healthy individuals by the GP and the physiotherapist. The intraclass correlation coefficients (ICC)[23] were satisfactory for all but the back extension (table 1).

Table 1: Reproducibility of Physical Measurements: Mean (SD)

	HH 1 (N = 10)	JK (N = 10)	HH 2 (N = 10)	Intraobserver ICC	Interobserver ICC
Modified Schober (mm)	81 (9.7)	73 (14)	80 (11)	.89	.63
Side-bending (mm)*	225 (27)	213 (34)	215 (30)	.89	.94
Extension (degrees)	50.2 (8.1)	40.7 (9.6)	53.9 (8.4)	.63	.31
Straight leg raising (degrees)*	91.7 (17)	88.7 (14)	93.5 (14)	.85	.88
PPT (N/m^2)*	88.2 (30)	74.5 (32)	80.0 (30)	.91	.85

Abbreviations: HH1, first assessment of reliability (by GP); JK, second assessment (by physiotherapist); HH2, third assessment (by GP); ICC, intraclass correlation coefficient[23]; PPT, pressure pain threshold measured 2cm lateral from L IV.
* Means of right and left.

Statistical Analyses

The statistical analyses were performed on a microcomputer with the SPSS for Windows 6.1 software package. All outcome measurements were analyzed as intent to treat, but in addition, the exercise group was reanalyzed according to compliance and all groups were reanalyzed after exclusion of treatment contamination during the follow-up. The within-group changes were analyzed with Wilcoxon matched-pairs signed rank sum test. The onset values and change scores of continuous variables were compared between groups with Kruskal-Wallis one-way analysis of variance (ANOVA) and tested further by Mann-Whitney U test if significant differences were found. For categorical data, the χ^2 test was applied.

RESULTS

The study subjects were working-age people (mean 41.9yr, range 17-64yr) with a slight male preponderance (65/49) and a long history of back trouble (mean 7.5yr, range 60d-40yr). The distribution of education and occupations was representative of the local statistics. There were no statistically significant differences in the background variables between the therapy groups (table 2).

The mean number of therapy sessions was 9.9 (SD = 0.7) for physiotherapy, 8.1 (SD = 2.7) for bone-setting, and 4.5 (SD = 2.2) for exercise. Half of the exercise patients reported having done at least three quarters of the required home exercises during the 6-week treatment period. After 3 months 32 exercise patients (80%), and after 6 months 19 (54%), still reported having continued the exercises, while 4 (11%) had had physiotherapy and 8 (23%) bone-setting therapy. Twelve bone-setting patients (27%) had continued on bone-setting and 3 (7%) had received physiotherapy. One patient (3%) from the physiotherapy group had consulted a physiotherapist and 8 (24%) a bone-setter. During follow-up one patient from the exercise group was operated on for a herniated disc and one from the bone-setting group was referred to a rehabilitation center. Altogether, 41% of the physiotherapy, 58% of the bone-setting, and 44% of the exercise patients took some form of therapy during the follow-up ($p = .28$, χ^2 test). No complications were reported from the treatments or measurements.

The measurements of back mobility did not differ significantly between the groups at the onset (table 3). Side-bending was increased significantly by bone-setting ($p = .002$, Wilcoxon signed rank sum test), and the increment was still significant after 6 months ($p = .02$) and, moreover, differed significantly from that of exercise ($p = .01$, Mann-Whitney U test). The modified Schober test actually showed a decrease in lumbar flexion after exercise at 6 weeks ($p = .05$) and only showed significant increase in the bone-setting group at 6 months ($p = .008$), but the differences between groups were insignificant ($p = 0.1$, Kruskall-Wallis test). Physiotherapy did not induce significant changes in either side-bending or forward-bending. Lumbar extension increased significantly, first in the physiotherapy ($p = .001$) and the bone-setting groups ($p = .005$), but after 6 months the exercise patients also had a significant change ($p = .002$). The increase of extension was not significantly different between the therapies.

The results of the muscular performance tests were neither significantly different at the onset, nor differently affected by the therapies (table 4). The dynamic back extensor test only showed a significant improvement ($p = .04$ for physiotherapy, .000 for bone-setting, and .002 for exercise). After 6 months the bone-setting patients could still perform more arch-ups than at start ($p = .002$).

The VAS and the PPS initially indicated slightly more pain in the bone-setting than in the physiotherapy or exercise groups (fig 1), but the differences were statistically insignificant ($p = 0.5$, and 0.3, respectively, Kruskall-Wallis test). The decrease of the VAS was uniformly significant in all groups at 6 weeks ($p = .000$ within physiotherapy and bone-setting, .003 within exercise group, and $p = 0.2$ between groups). After 6 months the improvement scores of the VAS became significantly different ($p = .02$, Kruskal-Wallis test, bone-setting better than exercise, $p = .003$, Mann-Whitney U test). The PPS was also lowered by all the therapies ($p = .004$ for physiotherapy, .001 for bone-setting and .02 for exercise), and remained low at the 6-month follow-up ($p = .001$, .000, and .007, respectively) with no difference between the groups ($p = 0.6$). The PPT was only elevated in the physiotherapy group after the 6-week therapy period ($p = .03$) and in the exercise group after the 6-month follow-up ($p = .02$). The change scores of PPT were not different between the groups at any time.

A secondary analysis on exercise patients, who reported having done at least three quarters of the required home exercises during the therapy period, revealed that subjects with good compliance (17 of 35) had a slightly larger reduction of the VAS ($p = .13$, Mann-Whitney U test), a slightly larger increase of the side-bending ($p = .08$), and a significantly greater improvement in the repeated sit-up test ($p = .04$) at 6 weeks, and a significantly greater increase of the PPT ($p = .03$) at 6 months than the less compliant (fig 1). Substituting the exercise group for those with good exercise compliance reduced all the differences in the measures of pain and physical outcome to a nonsignificant level at both the 6-week and the 6-month assessments. The patients who reported still exercising at 6 months (19 of 35) showed greater improvements in the SLR ($p = .02$) and the PPT ($p = .02$) after 6 months than those who did not, but the change scores of the VAS were equal.

Because many patients changed therapy, an alternative analysis was performed on the 26 physiotherapy, 40 bone-setting, and 20 exercise patients who had refrained from other than the randomized therapies during the follow-up (tables 3 and 4). The change scores of the VAS were still significantly different after 6 months ($p = .02$, Kruskall-Wallis, bone-setting better than exercise). The compliant physiotherapy patients had significant changes in the VAS ($p = .000$), PPS ($p = .001$), and range of back extension ($p = .000$), while the bone-setting patients improved in the VAS ($p = .000$), PPS ($p = .000$), modified

Table 2: Baseline Characteristics of Study Subjects

	Physiotherapy	Bone-setting	Exercise	Total	χ^2
N (males)	34 (19)	45 (25)	35 (21)	114 (65)	0.9
Mean age, years (SD)	42 (12)	42 (8.9)	41 (9.9)	42 (10)	0.9*
Body Mass Index, kg/m^2 (SD)	26 (3.9)	26 (3.7)	27 (4.7)	26 (4.1)	0.9*
Chronic diseases (%)	21	16	23	19	0.6
Aerobic exercises weekly (%)	68	47	49	54	0.1
Married (%)	76	73	66	72	0.6
Current smokers (%)	21	33	31	29	0.4
Folk medicine users (%)	77	85	63	75	.08
Education (%)					
Basic school	74	64	69	68	0.6
Secondary school	15	30	20	22	
High school	12	7	14	10	
Trade (%)					
Agriculture	24	36	34	32	0.4
Service	62	40	43	47	
Industry	15	24	23	21	
Current episode of back pain					
Duration (years), mean (SD)	7.0 (8.9)	8.5 (10.5)	6.8 (7.2)	7.5 (9.1)	0.6*
Diagnosis, Quebec-classification (%)					
1a-1c (local pain)	62	42	51	51	0.6
2a-2c (+ proximal radiation)	12	13	14	13	
3a-3c (+ distal radiation)	15	27	26	23	
4-6 (root compression)	9	11	9	10	
9 (operated disc hernia)	3	4	0	3	
10 (chronic pain syndrome)	0	2	0	1	
Actions for back during last 12 months (%)					
Sick listed	21	36	26	28	0.3
Consulted GP	59	56	54	56	0.9
Consulted specialist	18	38	14	25	.03
Visited naprapath	41	40	46	42	0.9
Visited bone-setter	56	78	63	67	0.1
Prescribed NSAIDs by GP	50	53	54	53	0.9
Prescribed physiotherapy by GP	18	33	40	31	0.1
Prescribed exercises by GP	35	44	43	41	0.7
Spinal x-ray examination	56	62	51	57	0.6

* Kruskall-Wallis one-way ANOVA.

Schober (p = .006), side-bending (p = .03), back extension (p = .000), and the repeated arch-up tests (p = .003). The exercise patients improved in the VAS (p = .01), PPS (p = .04), and the range of back extension movement (p = .007).

DISCUSSION

All the tested therapies seemed to improve the subjective measures of back pain. Neither of the tested therapies appeared better than physiotherapy, but bone-setting increased lateral and forward back mobility and decreased back pain assessed by VAS better than exercise. There were no statistically significant differences in the effects on muscular performance. Generally, the changes in the physical measurements were modest, from one tenth to half of standard deviation at best, while the indexes of pain were approximately halved.

The increase of lumbar side-bending and anteflexion ob-

Table 3: Measurements of Back and Leg Mobility

	Physiotherapy (N = 34)	Bone-setting (N = 44)	Exercise (N = 35)	Kruskal-Wallis Test
Modifier Schober (mm)				
At start	69 (SD = 1.0)	67 (SD = 1.2)	72 (SD = 1.2)	0.2
6 weeks	+0.8 (−1.4 to +3.0)	+0.1 (−2.4 to +2.7)	−2.4 (−4.6 to −0.2)	0.3
6 months	+1.5 (−1.2 to +4.2)	+3.6 (+0.9 to +6.3)	−1.1 (−3.7 to +1.5)	0.1
Alternative	+2.3 (−0.8 to +5.5)	+4.0 (+1.0 to +6.9)	−1.0 (−4.8 to +2.8)	0.2
Side-bending (mm)				
At start	183 (SD = 40)	188 (SD = 36)	193 (SD = 40)	0.4
6 weeks	+5.4 (−2.9 to +14)	+11 (+4.5 to +18)	−2.1 (−1.1 to +6.2)	.04
6 months	+3.6 (−4.9 to +12)	+9.3 (+2.7 to +16)	−2.7 (−12 to +6.5)	0.2
Alternative	+6.2 (−4.5 to +17)	+9.0 (+2.0 to +16)	−0.1 (−13 to +13)	0.7
Lumbar extension (degrees)				
At start	39 (SD = 10)	39 (SD = 12)	39 (SD = 7.7)	0.9
6 weeks	+3.6 (+1.2 to +5.9)	+3.7 (+1.3 to +6.2)	+1.9 (−0.5 to +4.4)	0.8
6 months	+6.8 (+4.1 to +9.5)	+5.4 (+3.0 to +7.8)	+4.3 (+1.9 to +6.8)	0.5
Alternative	+7.1 (+3.7 to +10)	+5.8 (+3.2 to +8.3)	+3.8 (+1.3 to +6.3)	0.4
Straight leg raising (degrees)				
At start	94 (SD = 14)	94 (SD = 12)	91 (SD = 12)	0.3
6 weeks	+1.9 (−1.4 to +5.2)	+1.1 (−1.1 to +3.3)	+3.4 (+1.3 to +5.6)	0.3
6 months	+1.6 (−1.4 to +4.6)	+2.4 (+0.3 to +4.5)	+1.8 (+0.03 to +3.7)	0.9
Alternative	+0.8 (−2.6 to +4.3)	+2.5 (+0.2 to +4.7)	+1.9 (−0.9 to +4.6)	0.6

At start = mean values (SD = standard deviation) before randomization, 6 weeks = mean change (95% confidence interval) from pretreatment to posttreatment, 6 months = mean change from pretreatment to follow-up. Alternative = alternative analysis at 6 months after exclusion of treatment contamination (N = 26 for physiotherapy, 40 for bone-setting, and 20 for exercise).

Table 4: Measurements of Muscular Performance

	Physiotherapy (N = 34)	Bone-setting (N = 44)	Exercise (N = 35)	Kruskal-Wallis Test
Sit-up single effort (0-5 pts)				
At start	1.9 (SD = 1.5)	2.0 (SD = 1.4)	1.8 (SD = 1.5)	0.9
6 weeks	−0.2 (−0.5 to +0.1)	.00 (−0.2 to +0.2)	+.03 (−0.2 to +0.3)	0.6
6 months	−.03 (−2.9 to +0.2)	−.02 (−0.3 to +0.3)	+0.1 (−0.3 to +0.6)	0.5
Alternative	−.04 (−0.3 to +0.2)	+.08 (−0.2 to +0.4)	0.0 (−0.7 to +0.7)	0.7
Sit-up repeats				
At start	40 (SD = 14)	38 (SD = 14)	40 (SD = 16)	0.5
6 weeks	+3.2 (−0.5 to +6.9)	+0.7 (−3.0 to +4.5)	−0.4 (−2.9 to +2.0)	0.2
6 months	+2.5 (−1.3 to +6.4)	−0.5 (−4.4 to +3.4)	−0.2 (−1.9 to +1.5)	0.4
Alternative	+2.6 (−2.3 to +7.6)	−1.5 (−5.4 to +2.5)	+0.9 (−1.1 to +3.0)	0.2
Arch-up repeats				
At start	36 (SD = 16)	31 (SD = 14)	37 (SD = 13)	0.1
6 weeks	+3.1 (+0.1 to +6.1)	+7.2 (+4.2 to +10)	+4.7 (+1.9 to +7.4)	0.1
6 months	+3.4 (−0.7 to +7.6)	+6.2 (+2.6 to +9.8)	+1.5 (−2.0 to +4.9)	0.3
Alternative	+2.5 (−2.1 to +7.0)	+6.2 (+2.4 to +9.9)	−0.2 (−5.3 to +4.9)	0.2
Stand-up repeats				
At start	42 (SD = 12)	41 (SD = 12)	40 (SD = 12)	0.7
6 weeks	+0.3 (−1.6 to +2.2)	+0.8 (−3.6 to +5.3)	+1.2 (−1.4 to +3.8)	0.9
6 months	+0.3 (−4.2 to +4.9)	+0.4 (−4.8 to +5.5)	+2.8 (−0.9 to +6.5)	0.6
Alternative	+1.0 (−4.7 to +6.7)	+0.4 (−5.2 to +6.0)	+4.0 (−3.0 to +11)	0.8

At start = mean values (SD = standard deviation) before randomization, 6 weeks = mean change (95% confidence interval) from pretreatment to posttreatment, 6 months = mean change from pretreatment to follow-up. Alternative = alternative analysis at 6 months after exclusion of treatment contamination (N = 26 for physiotherapy, 40 for bone-setting, and 20 for exercise).

served in the bone-setting group may indicate an effect of treatment on the movement in facet joints, the restriction of which is one possible source of back pain. The theories behind manual medical procedures usually refer to restriction or locking of movement in various joints, which are thought to need manipulation to restore the normal function. Normalization of function would then abolish the pain connected to the dysfunction. It is interesting, that from a battery of measurements the tape-measured thoracolumbar side-bending has shown best correlation with back pain,[19,24] and its increase has shown best correlation with progress after therapy.[24]

The outset values of the modified Schober and side-bending were generally higher than those of the inpatients of the AKSELI project[4] or of the sick-listed patients in the study by Lindström et al,[7] but close to the normative values of working-age Finns.[19] The results of the performance tests were even better than the average Finnish normative values.[20] Hence, there was not much to gain in terms of mobility and muscular performance. One explanation could be that the patients already had exercised their back muscles, because exercise is commonly recommended as a self-remedy. Also, Alaranta et al's[20] study subjects with low-back pain without disability during previous year tended to have higher scores in endurance tests than people with back pain more than 12 months ago or subjects with never any pain. Only people with disabling pain were weaker. Another explanation for the good physical condition of the current study subjects could be the patient selection. Recruitment by advertisements probably brings in more active people than other methods to enlist volunteers.

Some earlier studies that have employed vigorous physical activities have shown greater changes in the measures of back mobility and muscle strength,[4,7,9] whereas the studies testing the effect of manipulation[25,26,31] or less vigorous exercise programs[4,8,13] have achieved results comparable to ours. The change in the modified Schober test was comparable to the effect achieved by manipulation in a study by Pope et al,[25] although he found no significant differences between manipulation and the reference therapies. The increase of side-bending was of the same magnitude as in the AKSELI study group,[4] which did achieve a difference from the reference group. Meade et al[26] reported an increase of lumbar flexion by 8.5mm after chiropractic treatment, but the onset values were not published. The stretching maneuvers of Khalil et al[12] resulted in a striking increase in the ranges of lumbar motion, but the onset values were far lower than in this study and the number of patients was only 28. They did not publish the measurements from the comparison group.[12]

The modest changes in the physical measures are understandable on the basis of the study design. The increase of back mobility or muscle force was not a primary goal for any of the therapies. The aim was to relieve back pain by means of a correction of segmental vertebral dysfunction (bone-setting) or of an enchancement of metabolism in back tissues (physiotherapy and exercise). The muscular strain of the exercise program was planned so light that according to earlier studies[8] no changes in muscle forces should have occurred. The increase in the repeated arch-up test after all therapies could have resulted from mere relief of back pain and associated inhibition of movement.

The autostretching exercises were mostly confined to the iliopsoas and hamstring muscles. Autostretching could be responsible for the observed increase in the SLR in the exercise group, as only 10% of all the patients had signs of lumbar nerve root compression at onset, and in most patients the SLR was restricted by tight hamstring muscles.

The initial pain scores were of the same order of magnitude as in the earlier studies on chronic back pain. The VAS was about the same as in the AKSELI study,[4] or Deyo et al's[13] study on TENS and stretching exercises, or Malmivaara et al's[27] study on acute back pain. The pain assessed by the VAS declined to approximately half during the therapies and remained low for at least 6 months, which is in accordance with some other studies with remarkable results.[4,5,9]

The long-standing relief of pain may reflect the natural history of chronic, fluctuating back pain. Acute back pain has a strong tendency towards spontaneous cure,[28] and it currently seems that continuing the daily activities is the best choice of treatment.[27] The natural history of prolonged back pain is insufficiently studied.[29] Its spontaneous course cannot be predicted, and the results of different treatments may be confused by chance, especially as a credible placebo is seldom feasible and it is nearly impossible to select homogeneous groups of patients when we do not know the disease.

The proportional effect of placebo has seldom been evaluated in studies of back pain management. Koes et al[30] found detuned ultrasound and short-wave diathermy to give significantly

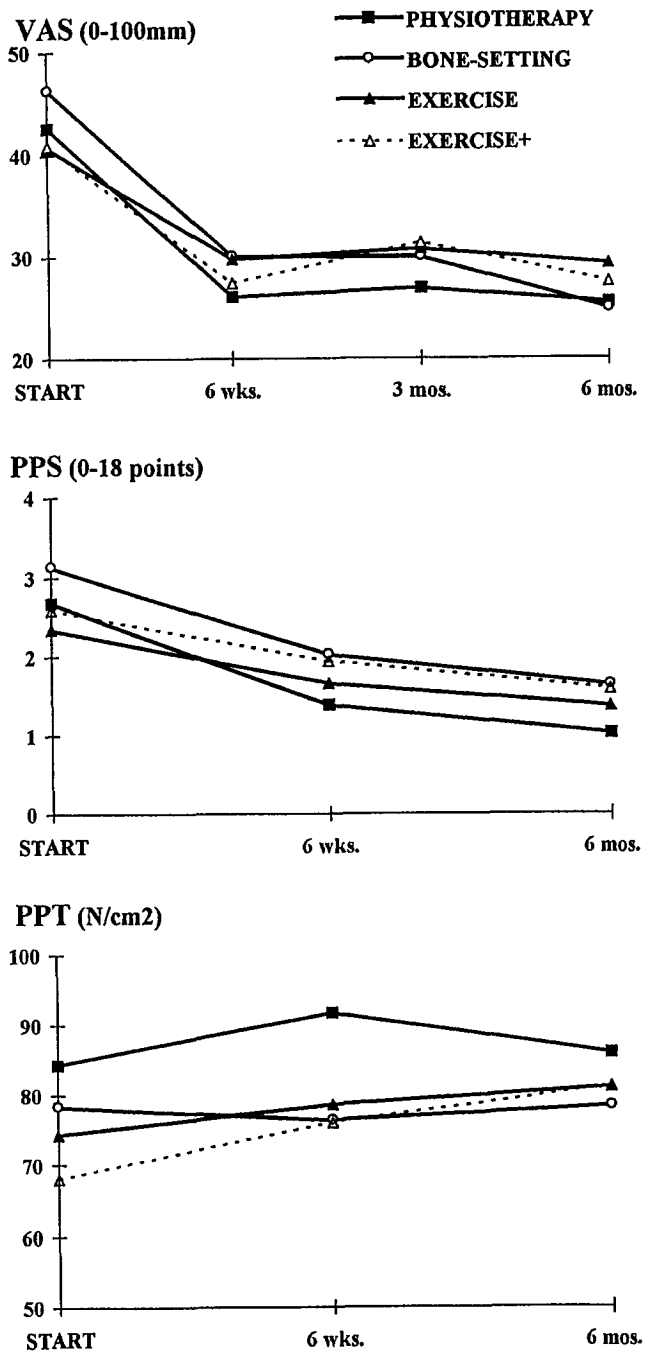

Fig 1. Assessments of back pain. VAS = Visual Analog Pain Scales, PPS = Pain Provocation Scores, PPT = Pressure Pain Treshold measurements. Exercise + = exercise patients reporting at least 75% compliance during the therapy period (N = 17).

greater pain relief than treatment by a general practitioner consisting mostly of a single visit with prescriptions for pain medication and advice on working postures and exercises. Bone-setting may have a strong placebo effect that could induce changes in measures of physical outcome in addition to subjective measures of pain and disability, but the mere placebo effect of bone-setting could hardly be larger than the combined true and placebo effects of physiotherapy. Koes et al[31] did not find a consistent pattern in the changes of cervical or lumbar mobility of their patients. After exclusion of the effects of co-interventions and dropouts they found the effect of placebo to be close to that of therapy by GP. The measures of physical function probably are more resistant to the effects of placebo than the subjective symptoms. The only significant differences in outcome in our study appeared between bone-setting and exercise, the placebo effect of which is probably smaller than that of the other two therapies, as it lacks the human touch component. A placebo effect would hardly endure for 6 months, either, so the measured changes in physical function appear true.

The possible confounding effect of the extra therapies taken by a considerable number of the patients must be considered, too. Both the exercise and the physiotherapy patients tended to switch over to bone-setting after the 6-week treatment period. Alternative analyses were carried out to examine the effects of treatment contamination and compliance. Exclusion of patients who changed therapy did not appreciably modify the results: the modified Schober and side-bending increased significantly by bone-setting only, and pain (VAS) reduced most by bone-setting, albeit the only significant differences were between bone-setting and exercise. Treatment contamination would, anyhow, decrease the observed differences in outcome and reduce the risk of type I error in the interpretation of results as illustrated by Koes et al.[30]

A subgroup analysis of the exercise compliant and non-compliant patients gave some evidence of a positive effect of the current exercise on back pain and function. Those patients who reported having done at least three quarters of all the exercises during the therapy period had a slightly larger relief of pain and significantly different effects in some physical outcome measures than the less compliant, but the observed differences may have other explanations. The back symptoms may have influenced the motivation to or the reporting of exercise. For example, the patients with more severe conditions may have been unable to exercise or, on the contrary, the cured patients may have ceased exercising. Regardless, the compliant exercise group did not improve more than the two other therapy groups.

The selection of study subjects was a necessary compromise. The original idea of recruiting patients from the local health centers would have taken too long, although all the eight patients recommended by GPs finally entered, which indicates no difficulty in motivating the patients to participate. The background variables of the study patients were not different from the local official sociodemographic statistics. Even the large number of patients having consulted a bone-setter earlier may reflect the local tradition. The exact proportion of bone-setting use by back pain patients is not known, but it may not be much different from the three quarters found in this sample. The patients in this study were relatively heavy users of health resources, as indicated by the frequency of visits to health centers and specialists and prescriptions for physiotherapy and non-steroidal anti-inflammatory drugs. More than half of them had been x-rayed before the study. They most probably were the typical back pain patients treated in the primary health care.

CONCLUSION

Bone-setting seems to have an effect on back mobility and pain, not larger than that of physiotherapy, but seemingly larger than that of the tested exercise therapy. This study is perhaps the first to demonstrate that actions by uneducated folk healers can have an effect on back pain and at presumably lower costs than physiotherapy. Our results also suggest that manual therapy could be useful for prolonged, in addition to acute, back pain. The concept of continuous light movements in the treatment of either acute or prolonged back pain deserves reassessment.

These results should be confirmed in other scientific studies with different populations and longer follow-up. The effects of

these therapies on further consequences of back pain and perceived disability, eg, sick leaves and the use of medical services, are the aims of subsequent research.

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