ORIGINAL ARTICLES

A RANDOMIZED CONTROLLED CLINICAL TRIAL OF STAY-ACTIVE CARE VERSUS MANUAL THERAPY IN ADDITION TO STAY-ACTIVE CARE: FUNCTIONAL VARIABLES AND PAIN

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ABSTRACT

Objectives: To compare the effect of manual therapy in addition to the stay-active concept versus the stay-active concept only in low back pain patients.

Study Design: A randomized, controlled trial during 10 weeks.

Methods: One hundred sixty outpatients with acute or subacute low back pain were recruited from a geographically defined area. They were randomly allocated to a reference group treated with the stay-active concept and, in some cases, muscle stretching and an experimental group receiving manual therapy and, in some cases, steroid injections in addition to the stay-active concept. Pain and disability rating index were used as outcome measures.

Results: At baseline, the experimental group had somewhat more pain, a higher disability rating index, and more herniated disks than the reference group. After 5 and 10 weeks, the experimental group had less pain and a lower disability rating index than the reference group.

Conclusions: The manual treatment concept used in this study in low back pain patients appears to reduce pain and disability rating better than the traditional stay-active concept. (J Manipulative Physiol Ther 2004;27:431-41)

Key Indexing Terms: *Low Back Pain; Disability Rating; Manipulation; Mobilization; Stay-Active Care*

INTRODUCTION

Low back pain is a major diagnostic and therapeutic problem, causing much suffering and large costs.[1,2] Since 1987, at least 12 randomized controlled trials on manipulation therapy versus reference therapies in subacute low back pain have been published. In 5 of these studies,[3-7] the treatment was given as a single tool, and the results regarding pain and functional measures were in favor of manual therapy. In the remaining 7 trials,[8-14] a pragmatic treatment approach was used; in 5 of these trials,[8,9,11,13,14] manual therapy was superior to the reference treatment.

The results are thus in favor of manipulation therapy. The beneficial effects have been acknowledged in literature reviews and national guidelines.[2,15] However, because the recommended treatment approach in 11 national guidelines still is the "stay-active concept,"[15] there is a need for trials of manipulation therapy versus the stay-active concept or the stay-active concept versus manipulation therapy combined with the stay active concept.

In a previous randomized controlled trial performed in Säter, Sweden,[8] we used a design with a pragmatic combination of manual treatment modalities in addition to the stay-active concept. The evaluated treatment was found

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Table 1. *Treatment content in the two groups*

	Reference therapy		Experimental therapy			
	Physiotherapist		Physician		Physiotherapist	
	%	95% CI	%	95% CI	%	95% CI
Mobilization/manipulation						
Sacroiliac mobilization	—		72.7	63.2-82.2	50.6	39.7-61.4
Lumbar mobilization	—		75.0	65.8-84.2	45.9	35.1-56.7
Lumbar manipulation (thrust techniques)	—		19.3	10.9-27.7	4.7	0.1-9.3
Thoracic mobilization/ manipulation	—		8.0	2.2-13.7	10.6	3.9-17.3
Cervical mobilization	—		2.3	−0.9-5.4	4.7	0.1-9.3
Muscle stretching/treatment						
Muscle stretching	80.6*	67.0-94.1	52.3	41.6-62.9	88.2	81.2-95.2
Home exercises for muscle stretching	78.4*	64.5-92.3	29.5	19.8-39.3	69.4	59.4-79.4
specific mobilization	—		6.8	1.4-12.2	30.6	20.6-40.6
Massage/soft tissue treatments	7.5	1.0-13.9	14.8	7.2-22.3	15.3	7.5-23.1
Deep frictions	—		3.4	−0.5-7.3	8.2	2.3-14.2
Steroid injections/ligament stretching						
Sacroparacoccygeal structures stretching	—		9.1	3.0-15.2	1.2	−1.2-3.5
steroid injections	—		4.3†	−1.7-10.2	—	
Piriformis/gl. med./min. steroid injections	—		21.3†	9.1-33.4	—	
Other steroid injections	—		17.0†	5.9-28.2	—	
Traction						
Autotraction	—		2.3	−0.9-5.4	30.6	20.6-40.6
Nonspecific traction	46.3	34.0-58.5	—		—	
Physical training						
Low back pain school training	1.5	−1.5-4.5	0		0	
Medical training therapy	9.0	1.9-16.0	1.1	−1.1-3.4	16.5	8.4-24.5
Other back exercises	—		3.4	−0.5-7.3	12.9	5.7-20.2
Sequential training	19.4	9.7-29.1	0		0	
Plunge-bath training	6.0	1.5-11.8	1.1	−1.1-3.4	4.7	0.1-9.3
Active movement therapy	34.3	22.7-46.0	0		0	
Active back exercises	58.2	46.1-70.3	0		0	
Relaxation training	13.4	5.1-21.8	0		0	
Body awareness training	9.1	2.0-16.2	0		0	
Postural exercises	25.4	14.7-36.1	0		0	
Ergonomic advice	74.6	63.9-85.3	0		0	
Heat and different electric treatment						
Ultrasonic waves	19.4	9.7-29.1	0		0	
TNS	49.3	37.0-61.5	0		0	
Heat (steam-pack)	11.9	4.0-19.9	0		0	
Electric stimulation	1.5	−1.5-4.5	0		0	
Corsets						
Pelvic corset (CAMP)	—		3.4	−0.5-7.3	8.2	2.3-14.2
Corset	3.0	−1.2-7.2	1.1	−1.1-3.4	1.2	−1.2-3.5

TNS, Transcutaneous nerve stimulation.
*Data for the reference subgroup in which muscle stretching was allowed (51%). The frequency of stretching in the entire reference group was 41%.
†Data for the experimental group in which steroid injections were allowed (52%).

to be more effective than stay active treatment, even though the study population was fairly small. We have now performed a new randomized controlled trial with a larger study population and with a factorial design by which the effect of 2 treatment modalities, stretching and steroid injections, may be evaluated in addition to the main study effects of the stay active concept and manipulation therapy added to the stay active concept. In this report, the main study effects on the outcome variables pain and disability rating are presented.

Table 2. *Treatment intensity and waiting time for treatment*

	Reference therapy		Experimental therapy	
	Mean	95% CI	Mean	95% CI
Appointments with physicians				
Waiting time for treatment (days)	2.9	2.5-3.4	3.3	2.9-3.8
Number of appointments	2.2	2.0-2.4	2.6	2.4-2.9
Treatment sessions	—		2.3	2.1-2.5
Appointments with no treatment	—		0.3	0.2-0.5
Telephone contacts	0.5	0.3-0.7	0.5	0.4-0.7
Appointments with physiotherapists				
Waiting time for treatment (days)	9.7	8.2-11.1	6.1	5.1-7.1
Number of appointments	6.0	4.8-7.2	5.8	4.9-6.6
Individual sessions	5.5	4.4-6.6	5.4	4.6-6.3
Group sessions	0.5	0.1-1.0	0.3	0.05-0.6

Table 3. *Baseline data and data on suspected and verified disk herniation in the two treatment groups; demographic data concerning previous low back pain infirmity*

	Reference therapy		Experimental therapy	
	Mean or %	95% CI	Mean or %	95% CI
Age, years	41.1	39.1-43.0	41.6	39.7-43.4
Females, %	35.2	24.1-46.3	50.6	40.2-61.0
Cigarette smokers, %	43.7	31.8-55.5	44.9	34.4-55.5
Current episode of low back pain				
Duration, days	30.4	24.0-36.8	24.9	19.7-30.2
On sick leave at baseline, %	66.2	54.9-77.5	70.8	61.2-80.4
Previous history of low back pain				
Previous similar low back pain, %	83.1	74.2-92.0	84.3	76.6-92.0
Time since the first episode of low back pain, years	8.6	6.8-10.3	10.3	8.6-12.0
Number of previous episodes	4.0	2.8-5.3	3.7	2.8-4.6
Mild chronic complaints, last 2 years, %	33.9	21.5-46.3	41.3	29.9-52.7
Mean VAS concerning chronic complaints, mm	22.2	18.3-26.2	21.5	16.4-26.6
Sick leave due to low back pain the last				
2 years, %	69.0	58.0-80.0	77.5	68.7-86.4
1-5 days, %	34.0	20.9-47.1	52.2	40.5-64.0
6-30 days, %	44.0	30.2-57.8	30.4	19.5-41.2
1-3 months, %	16.0	5.8-26.2	10.1	3.0-17.2
more than 3 months, %	6.0	−0.6-12.6	7.3	1.2-13.4
Radiograph because of previous low back pain, %	45.1	33.2-56.9	32.6	22.7-42.5
Suspected disk herniation at baseline or follow-up, %	22.5	12.6-32.5	19.1	10.8-27.4
Verified disk herniation at baseline or follow-up, %	5.6	0.1-11.1	11.2	4.5-17.9

VAS, Visual analogue scale concerning pain.

Methods

Design and Sampling

The study was performed in the province of Gotland, Sweden. The recruitment population segment consisted of the 19,000 persons who were 20 to 55 years of age, employed and with no threat of job loss, born in Sweden, and articulate enough not to jeopardize the verbal contact with the physicians and/or the physiotherapists.

In Sweden, the National Social Insurance Offices handle all sick leave with a duration of 2 weeks or more. All patients sick-listed for low back pain who provisionally fulfilled the inclusion criteria were referred from the local National Insurance Office to the recruiting physician. In addition, Gotland general practitioners (GP) referred patients. The recruiting physician examined all patients, performed a physical examination, and made the final assessment whether or not they fulfilled the inclusion criteria. These were:

- Acute or subacute perceived low back pain with or without pain radiating to 1 or both legs, not requiring acute surgical or rheumatologic care. Patients with shown or suspected herniated disks were included if surgery was not indicated, as assessed by the recruiting

Table 4. *Pain variables in the two groups at baseline and at 5 weeks and 10 weeks, respectively*

	Baseline				At 5 weeks	
	Reference therapy		Experimental therapy		Reference therapy	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
Pain last 24 hours, mm	52.2	46.7-57.8	54.7	49.8-59.6	29.7	23.3-35.2
Pain last week, mm	54.5	49.4-59.7	53.5	49.0-58.1	36.1	30.6-42.7
Pain at rest, %	69.0	58.0-80.0	69.7	59.9-79.4	28.2	17.4-38.9
Pain influencing leisure time negatively, %	60.6	48.9-72.2	70.8	61.1-80.4	32.4	21.2-43.6
Difficulties falling asleep due to back pain, %	46.5	34.6-58.4	53.4	42.8-64.0	22.5	12.6-32.5
Waking up with back pain, %	71.8	61.1-82.6	67.4	57.5-77.3	34.3	22.9-45.7
Morning stiffness, %	81.7	72.5-90.9	74.2	64.9-83.4	67.6	56.4-78.8
Time to relief of morning stiffness, minutes	91.3	53.0-129.6	71.0	35.1-107.0	58.9	46.2-71.5
Taking painkillers or NSAIDs, %	60.6	48.9-72.2	67.4	57.5-77.3	32.4	21.2-43.6

These variables were measured on a visual analogue scale 100-mm long, where 0 mm means no pain and 100 the worst possible pain or by answering a yes or no question.

95% CI=95% confidence intervals, *p* value refers to test of difference in pain reduction over 10 weeks between reference and experimental therapy group, mm-millimeters.

* $P < .05$ at 5 weeks follow-up.

Table 5. *Mean disability measures in the two groups at baseline, at 5 weeks, and at 10 weeks, respectively*

	Baseline				At 5 weeks follow-up	
	Reference therapy		Experimental therapy		Reference therapy	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
"Heavy" disability rating index	70.0	65.3-74.8	78.3	74.0-82.5	45.0	37.9-52.1
Heavy physical work	75.6	70.5-80.7	81.8	77.2-86.3	49.0	41.3-56.8
Lifting heavy objects	80.0	75.5-84.4	84.9	81.0-88.9	55.7	47.6-63.8
Participating in exercise/sports	62.1	55.8-68.3	75.1	69.5-80.7	38.7	31.3-46.1
Running	62.6	55.7-69.4	71.2	65.1-77.3	37.2	29.7-44.6
"Less heavy" disability rating index	45.4	40.6-50.2	50.3	46.0-54.6	27.2	22.5-31.9
Dressing (without help)	41.0	34.1-48.0	46.0	39.8-52.2	24.0	18.7-29.3
Outdoor walks	36.4	29.8-43.0	44.3	38.4-50.2	22.5	17.0-27.9
Climbing stairs	41.4	35.2-47.6	43.2	37.7-48.7	23.3	18.3-28.2
Sitting for a longer time	56.3	49.7-62.8	57.4	51.6-63.3	40.2	33.7-46.8
Standing bent over a sink	57.2	50.3-64.1	58.9	52.7-65.0	33.8	27.2-40.5
Carrying a bag	41.7	34.9-48.5	49.2	43.1-55.3	25.1	19.4-30.8
Making a bed	56.1	49.0-63.1	62.5	56.2-68.8	31.7	25.4-38.1
Light physical work	40.8	34.1-47.5	50.1	44.2-56.1	23.0	17.8-28.2
Lying still	32.0	25.1-39.0	38.4	32.1-44.6	20.6	15.3-25.9
Car driving/car riding	44.4	37.1-51.6	50.2	43.7-56.7	26.6	20.7-32.5
Getting up from sitting	52.3	46.0-58.6	53.1	47.4-58.7	31.6	26.0-37.1
Mean all disability rating variables	52.0	47.4-56.6	57.8	53.7-61.8	31.9	26.8-37.0

P value refers to test of difference in disability rating over 10 weeks between reference and experimental therapy groups.

At 5 weeks		At 10 weeks				
Experimental therapy		Reference therapy		Experimental therapy		
Mean	95% CI	Mean	95% CI	Mean	95% CI	*P* after adjustments
20.8	16.0-25.7	21.1	16.2-26.0	16.2	11.8-20.6	ns*
29.0	24.1-33.9	27.5	22.3-32.8	19.5	14.8-24.2	<.05
23.6	14.6-32.6	25.7	15.2-36.2	19.5	11.0-28.0	ns
28.1	18.6-37.6	25.4	15.0-35.7	16.1	8.0-23.4	ns
14.6	7.1-22.1	11.3	3.7-18.8	5.8	0.8-10.7	ns
27.0	17.6-36.4	22.9	12.8-32.9	23.3	14.1-32.4	ns
62.9	52.7-73.1	64.8	53.4-76.2	52.9	42.2-63.6	ns
50.6	38.9-62.3	58.1	38.7-77.4	52.3	38.1-66.5	ns
32.6	22.7-42.5	25.4	15.0-35.7	18.4	10.1-26.7	ns

At 5 weeks follow-up		At 10 weeks follow-up				
Experimental therapy		Reference therapy		Experimental therapy		
Mean	95% CI	Mean	95% CI	Mean	95% CI	*P*
39.3	32.9-45.7	37.8	31.1-44.6	29.9	23.9-35.9	<.01
43.2	36.2-50.2	43.0	35.6-50.5	31.9	25.2-38.5	
47.4	40.1-54.7	51.1	43.1-59.2	39.1	32.0-46.2	
34.0	27.5-40.5	30.7	23.8-37.6	26.3	20.2-32.5	
31.4	24.6-38.1	27.1	20.6-33.7	23.7	17.8-29.6	
21.2	17.0-25.4	20.7	16.4-25.0	16.6	12.8-20.5	<.05
15.4	10.7-20.1	18.8	14.1-23.6	12.3	8.0-16.6	
16.7	11.9-21.6	18.1	13.3-22.8	13.9	9.6-18.2	
16.0	11.6-20.4	18.2	13.8-22.6	13.8	9.8-17.8	
30.0	24.0-35.9	31.8	25.5-38.2	23.5	17.7-29.2	
28.4	22.4-34.3	25.5	19.5-31.4	22.3	16.9-27.6	
24.7	19.6-29.9	20.8	15.8-25.9	16.8	12.2-21.4	
26.4	20.7-32.0	23.9	18.0-29.8	21.5	16.2-26.7	
17.6	12.9-22.2	19.4	14.9-24.0	12.9	8.7-17.0	
16.9	12.2-21.6	15.4	10.6-20.1	12.7	8.4-17.0	
18.4	13.1-23.7	17.2	12.3-22.1	15.7	11.3-20.2	
22.3	17.3-27.2	23.3	18.6-28.1	16.0	11.7-20.3	
25.8	21.2-30.4	25.0	20.2-29.7	20.1	15.9-24.3	<.05

physician. Low back pain was required to be the dominating symptom, but patients with other musculoskeletal symptoms not requiring treatment were allowed.
- Symptom duration of 3 months or less, preceded by at least 2 months of relative freedom from symptoms.
- Consent to treatment and follow-up for 10 weeks.
- Agreement not to consult therapists other than those participating in the study during the treatment period.
- Absence of other conditions or circumstances that might jeopardize completion of treatment and follow-up, such as pregnancy, malignant tumors, etc.
- No previous treatment of current complaints with specific mobilization or manipulation.
- No previous participation in the present study.

Of the 316 patients who were referred to the study, 111 did not fulfill the inclusion criteria and 45 declined participation. The remaining 160 patients were entered in the study. The most common reasons for failing to fulfill the inclusion criteria were too-long symptom duration (33 subjects), previous manual treatment for the current acute low back pain episode (28 subjects), and spontaneous recovery before the study start (12 subjects).

Patients who fulfilled the inclusion criteria received standardized information concerning the study, and those who gave informed consent to participation were included. When a patient had responded to questionnaires and undergone a physical examination, he or she was randomly allocated to one of the treatment groups by the study monitor, using sealed previously prepared envelopes with the group assignment derived from a random number table. The envelopes were inaccessible to anyone but the monitor. A weighted randomization procedure was used, aiming at random allocation of 45% of the patients to the reference therapy group and 55% to the experimental therapy group. The Research Ethics Committee of the Faculty of Medicine at Uppsala University approved the study.

Treatments

The treatment was provided individually, in groups, or both. In both groups, treatment modalities were chosen by physicians and physiotherapists after clinical assessment of the patients and according to need. The available treatment modalities and treatment contents in the 2 groups are presented in Table 1. Information on treatment content, diagnoses, the prescription of diagnostic imaging, and medication was obtained by questionnaire from the treating staff in both groups at 5-week and 10-week follow-up.

Reference Therapy

Two orthopedic surgeons at Visby Hospital and 8 physiotherapists treated the reference group patients. The stay-active concept, as described by Waddell[16] and evaluated by Indahl et al,[17] Torstensen,[18] Tortensen et al,[19] and Malmivaara et al,[20] was the basic management strategy. It includes encouraging patients to take part in physical and other activities to stay fit.[17,19] The operant conditioning behavioral approach was consistent with official recommendations for low back pain treatment in Sweden.[2] The reference therapy was similar to the pragmatic approach to low back pain as evaluated by Lindström et al.[21,22] The physicians were instructed to certify as short periods of sick leave as possible at each consultation and prescribe drugs when indicated. In accordance with the factorial study design, muscle stretching or matching home exercises or both was a treatment option in 51% of the reference group and 41% actually received muscle stretching.[23,24]

Experimental Therapy

Two GPs based at primary health care centers in Visby and 9 physiotherapists treated the experimental group. During the 2 months before the study, the GPs and the physiotherapists in the experimental treatment team received basic training for 12 days, corresponding to the basic course in manual therapy (Step 1). In addition, the 2 GPs completed their examinations for the Step 2 level 13 months after the study started. Two of the physiotherapists began their Step 2 course 1 year after the study started and graduated 6 months before the end of the study period.

The stay-active concept was the basic treatment strategy. In addition, manual therapy or muscle stretching, with or without matching home exercises, were provided.[23,24] The origins of Swedish manual therapy are the classic osteopathic techniques[25] and the continental tradition.[26,27] These techniques, as well as specific "locking techniques," have been further developed in Scandinavia,[23,24,28] and they formed an important part of the experimental treatment. Diagnostic items according to the Muscular Energy Technique (MET)[29] are incorporated in the physical examination. An essential therapeutic maneuver is mobilization for pelvic dysfunctions according to Kubis,[30] with the addition of an Evjent and Hamberg[23,24] locking technique and a strictly applied MET procedure in the treatment situation. Thus, the maneuver has become gentle.

All patients were treated with specific mobilization or lumbar thrust techniques (manipulation) or both by the 2 physicians. In addition, the physiotherapists treated 67% of the experimental patients with specific mobilization or manipulation. According to the factorial study design, steroid injections, in case of specific findings, were allowed in half of the patients. Steroids were often given in combination with "needling"[26] and local anesthetics. After parasacrococcygeal injections, the soft tissues were also stretched per rectum ad modum Midttun et al.[31] Because patients with shown or suspected herniated disks were admitted to the study, autotraction was allowed.[32,33]

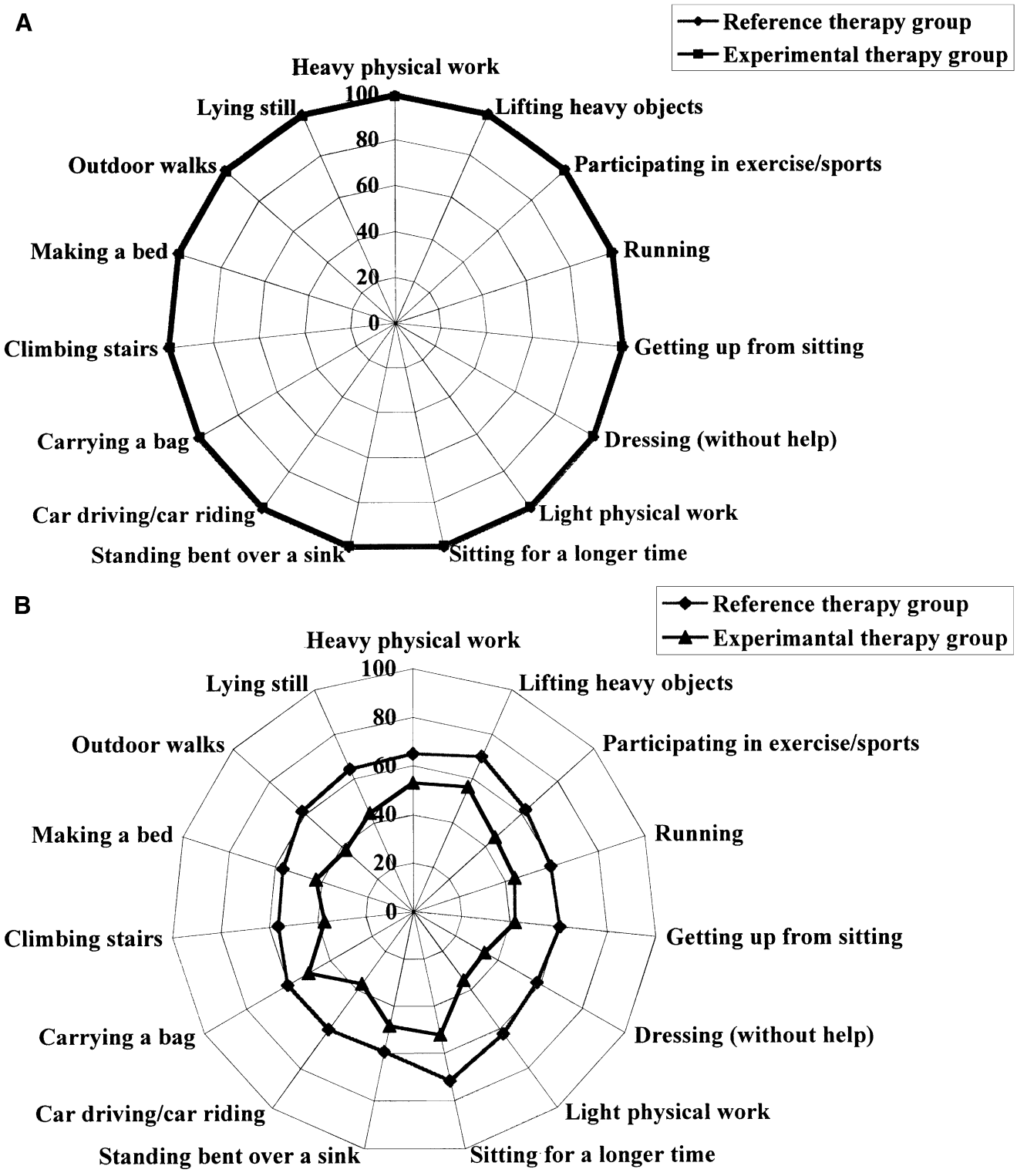

Fig 1. *Adjusted levels of 15 disability measures in the experimental and reference groups at baseline (**A**), 5 weeks (**B**), and 10 weeks (**C**), expressed as percentages of the group means at baseline. The baseline values were set to 100% and 0% indicates complete improvement.*

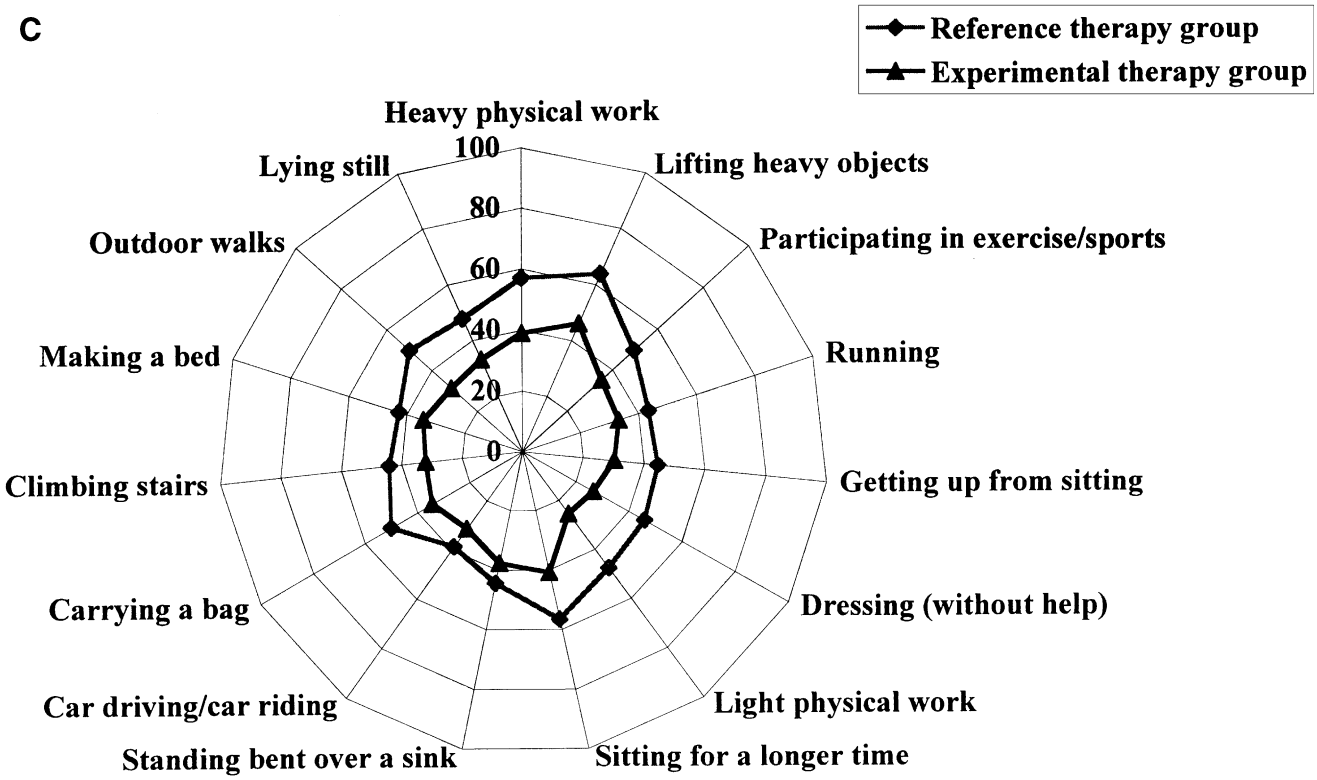

Fig 1. (*continued*)

Treatment Intensity

Treatment intensity data are given in Table 2. The waiting time for physiotherapy was significantly shorter in the experimental group. Physiotherapy was offered to all patients in this study. However, mainly because of complete recovery after randomization, 8% of the experimental group and 6% of the reference group did not see a physiotherapist.

Outcome

Pain scores and 15 disability rating variables were measured with visual analogue scales, 100-mm long, and ranging from no pain or disability (0 mm) to maximum pain or disability (100 mm). Baseline data were obtained by questionnaire and interview, and outcome variables were obtained by questionnaire at baseline and after 5 weeks and 10 weeks of treatment.

Twelve of the 15 disability rating variables form the Disability Rating Index instrument, evaluated with regard to validity as well as reliability by Salén et al.[34] The remaining 3 items, lying still, car driving or car riding, and getting up from sitting, have been used previously[8] and provide additional daily activities. In addition, drugs consumed were asked for in the questionnaire.

Masking and Parallel Treatment

All information on outcome was kept inaccessible to anyone but the study monitor and was thus masked, or blinded, to the treatment staff. Information on contamination by parallel treatment provided by external therapists was obtained at the 10-week follow-up by questionnaire and was also asked for and reported by the participating physicians and physiotherapists.

Statistical Considerations

All analyses were performed according to the intention-to-treat concept. During the first 10 weeks of follow-up, only 1 patient (0.6%) dropped out and did not return the last questionnaire. The partial nonresponse rate (missing data in returned questionnaires) was less than 2%.

Data were analyzed with the JMP[35] and SAS[36] statistical program packages (SAS Institute, Cary, NC). Summary statistics, such as mean values and measures of dispersion, were computed using standard parametric methods. Differences between the groups at baseline were tested with analysis of variance and the chi-square test. For the analyses of outcomes, change in the outcome variables (pain and disability rating scores) from baseline to the end of the

treatment period was analyzed in the 2 treatment groups by analysis of variance.

Only 2-tailed tests were used. P values less than 5% were considered to indicate statistical significance.

Results

Baseline Data

Some baseline data concerning the reference and experimental therapy groups are presented in Table 3. There were no significant differences between the groups in these variables. Approximately one third reported mild chronic low back pain during the previous 2 years. More than one third had previously undergone radiograph examinations because of low back pain infirmity, and 10 patients had been admitted to the hospital because of low back pain, 4 of whom underwent back surgery. Herniations were verified in 11% of the experimental group and 6% of the reference group.

Pain Variables

Pain variables are shown in Table 4. The scores for pain during the last 24 hours and pain during the last week were fairly similar in the 2 groups at baseline. They decreased significantly over time in both groups, but there were no significant differences between the groups. The variables measuring pain or the effect of pain in various situations all improved significantly during the treatment period in both groups, but there were no significant differences in rate of decrease between the groups.

However, because the experimental group tended to be somewhat more affected than the reference group by low back pain at baseline but less so at 5 and 10 weeks, an adjustment for the initial differences in outcome variables, verified disk herniations, and differences in age and sex distribution was made. After this adjustment, the experimental group had a faster rate of decrease of pain for the last week than the reference group ($P < .05$) and a faster decrease of pain during the last 24 hours after 5 weeks of follow-up ($P < .05$) but not at 10 weeks of follow-up. For all other pain variables, the rate of decrease tended to be nonsignificantly faster in the experimental group than in the reference group, except for waking up with back pain, where the nonsignificant rates tended to be reversed.

The use of painkillers or nonsteroidal anti-inflammatory drugs decreased as well in both groups, but there were no significant differences in decrease rate between the groups. The most frequently used painkillers at baseline were light analgesics and antipyretics (53.8%), light opoids (41.9%), nonsteroidal anti-inflammatory drugs (21.4%), and muscle relaxants (12.5%). At 10 weeks follow-up, the most frequently used painkillers were light analgesics and antipyretics (15.2%), light opoids (12.7%), nonsteroidal anti-inflammatory drugs (12.0%), and muscle relaxants (3.8%).

Disability Rating

The 15 disability rating variables are shown in Table 5. At baseline, the experimental group tended to have higher scores than the reference group in all 15 variables. However, at 5 weeks and 10 weeks, the experimental group tended to have lower scores than the reference group in all variables. The rate of improvement was significantly faster in the experimental treatment group than in the reference treatment group for disability rating index ($P < .05$) including 12 variables and all 15 variables ($P < .05$). The same was true for the "heavy" variables ($P < .01$), as well as for "less heavy" variables ($P < .05$).

Levels for all 15 disability rating score variables at baseline, 5 weeks, and 10 weeks adjusted for the initial differences in outcome variables and for differences in verified disk herniations and age and sex distribution are shown in Figure 1. At baseline, all levels were set to 100%. In both groups, the levels, expressed as percentages of the initial value, decreased, but the experimental therapy group had consistently lower levels than the reference group for all variables at 5 weeks as well as at 10 weeks of follow-up.

Discussion

The experimental treatment thus improved pain measured as pain during the last week and everyday function in acute and subacute cases of low back pain better than stay active treatment only. The methods used in this study are all well established and evaluated. The visual analogue scale has been used for decades, as has the Disability Rating Index instrument.[34] The 3 variables that were added to the Disability Rating Index instrument did not affect the results. A potential confounder in this study could be the shorter waiting time for visits to the physiotherapists favoring the experimental group. However, the 4 days prolonged waiting time for physiotherapy is an unlikely explanation for the differences in outcome at 5 weeks and 10 weeks. The data loss caused by dropout and partial nonresponse was minimal. We, therefore, have no reason to believe that the data should be biased to such an extent that the results would be affected.

Since 1987, some 12 randomized clinical trials on manual therapy versus various reference treatments in low back pain patients have been published. A variety of study designs and treatment methods were used, which makes the comparison of results between trials difficult. In 5 studies, the treatment was given as a single tool treatment,[3-7] and in 7 trials, a pragmatic approach was used.[8-14] The manual

therapy was more effective than the reference treatment in all the single-tool trials and in 5 of the pragmatic approach trials.[8,9,11,13,14] The results of the present study, thus, are in line with these earlier studies.

Most clinical trials in other fields are performed as single-tool trials where one specific treatment is compared with another specific treatment. It is claimed to be the most unbiased method to evaluate specific treatment effects. However, during the past decades, the pragmatic approach has become more common, not the least in drug trials where the study drugs may be combined with other specified drugs if the treatment goal is not achieved.

Because the patient group affected by low back pain probably is a heterogeneous one regarding cause, the pragmatic treatment approach provides an opportunity to use the most suitable treatment option from a specified list in each of the treatment groups. The treatment situation is from this point of view closer to a clinical situation than the single tool trial. The criticism against the pragmatic approach is mainly based on the potentially confounding effect caused by the number of treatment modalities. However, the fewer the number of treatment modalities, the smaller the potential confounding effect will be. The possibility to evaluate the effect of separate treatment modalities is diminished by the pragmatic design unless a factorial design is used,[37] as in the present study.

The cause of low back pain is still largely unknown.[2] However, several hypotheses have been presented.[38] Johansson et al,[39] Djupsjöbacka,[40] and Heikkilä et al[41] have proposed that low back pain may have its origin within the proprioceptive system. An increased muscle spindle sensitivity might affect the proprioceptive system to erroneous signaling. Furthermore, studies performed on the gamma-muscle-spindle indicate that a possible cause for this erroneous signaling could be that the proprioceptive system adapts to an impaired stretch reflex and thereby enhances the muscular stiffness.[42,43] The muscular fatigue will then reduce the natural stretch reflex amplitude,[44] and the exercises performed will not be as effective as they were before.

Both manipulation and mobilization maneuvers have been shown to produce an attenuation of the alpha-motor neuron excitability with regard to the Hoffmann reflex in the gastrocnemius muscle[45] and electromyelographic activity in back muscles.[46] Thus, the manipulation or mobilization maneuvers might expand the muscle spindle significantly for a period long enough to reset the input to the proprioceptive system.

Manual therapy in low back pain has thus been found more effective than the reference treatments in the majority of trials. However, the mechanism by which the effect is mediated is still largely unknown, even though some clues have been reported. More research is needed to refine the treatment model and to get more insight into the mechanism by which the effect is mediated.

Conclusion

The manual therapy concept was more effective than the standardized but optimized stay-active concept in acute and subacute low back pain patients regarding pain reduction and improvement of everyday function. Despite the fact that the mechanism by which the effect is mediated is still unknown, the results are sufficiently convincing for the method to be used as one of several treatment options in patients with acute and subacute low back pain.

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