Effectiveness of massage therapy for subacute low-back pain: a randomized controlled trial

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Abstract

Background: The effectiveness of massage therapy for low-back pain has not been documented. This randomized controlled trial compared comprehensive massage therapy (soft-tissue manipulation, remedial exercise and posture education), 2 components of massage therapy and placebo in the treatment of subacute (between 1 week and 8 months) low-back pain.

Methods: Subjects with subacute low-back pain were randomly assigned to 1 of 4 groups: comprehensive massage therapy (n = 25), soft-tissue manipulation only (n = 25), remedial exercise with posture education only (n = 22) or a placebo of sham laser therapy (n = 26). Each subject received 6 treatments within approximately 1 month. Outcome measures obtained at baseline, after treatment and at 1-month follow-up consisted of the Roland Disability Questionnaire (RDQ), the McGill Pain Questionnaire (PPI and PRI), the State Anxiety Index and the Modified Schober test (lumbar range of motion).

Results: Of the 107 subjects who passed screening, 98 (92%) completed post-treatment tests and 91 (85%) completed follow-up tests. Statistically significant differences were noted after treatment and at follow-up. The comprehensive massage therapy group had improved function (mean RDQ score 1.54 v. 2.86–6.5, $p < 0.001$), less intense pain (mean PPI score 0.42 v. 1.18–1.75, $p < 0.001$) and a decrease in the quality of pain (mean PRI score 2.29 v. 4.55–7.71, $p = 0.006$) compared with the other 3 groups. Clinical significance was evident for the comprehensive massage therapy group and the soft-tissue manipulation group on the measure of function. At 1-month follow-up 63% of subjects in the comprehensive massage therapy group reported no pain as compared with 27% of the soft-tissue manipulation group, 14% of the remedial exercise group and 0% of the sham laser therapy group.

Interpretation: Patients with subacute low-back pain were shown to benefit from massage therapy, as regulated by the College of Massage Therapists of Ontario and delivered by experienced massage therapists.

Low-back pain affects a considerable proportion of the population.[1,2] In a methodological review of prevalence studies of low-back pain,[3] a mean point prevalence of 19.2% and a mean 1-year prevalence of 32.7% were estimated. Research on the effectiveness of treatment of subacute low-back pain has yielded inconsistent results,[4-6] and studies often contain methodological flaws[6-9] such as inadequate randomization procedures and lack of a placebo control. Flaws in studies employing massage include not using a registered massage therapist and making no attempt to ensure fidelity to a treatment model.[8] Researchers have compared massage to other treatments of low-back pain but have used nonspecific massage as a control.[9] No studies were found that specifically evaluated massage therapy as a treatment for low-back pain.

This study compared the effectiveness of comprehensive massage therapy, 2 separate components of massage therapy (soft-tissue manipulation and remedial exercise with posture education) and a placebo of sham laser therapy for the treatment of subacute low-back pain. Outcome measures were function, pain, anxiety and lumbar range of motion.

Research

Recherche

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Methods

This study was conducted at the Health and Performance Centre, University of Guelph, Guelph, Ont., which offers multidisciplinary services such as sports medicine, physiotherapy and chiropractic manipulation. Treatments were provided and outcome measures were obtained at this centre. Ethics approval was obtained from the University of Guelph Ethics Review Committee, and all subjects gave informed consent.

Subjects were recruited through university email, flyers sent to family physicians and advertisements in the local newspapers between November 1998 and July 1999. Potential subjects aged 18 to 81 years were screened by telephone according to the following criteria: existence of subacute (between 1 week and 8 months) low-back pain; absence of significant pathology, such as bone fracture, nerve damage or severe psychiatric condition, including clinical depression as determined by a physician; no pregnancy; and stable health. The screening process relied on self-reported criteria plus information concerning the existence of medical conditions, medication use and the possibility of serious injury. Any doubt of appropriateness for inclusion was verified by the potential subject's physician. Having a history or previous episode of low-back pain and a positive radiograph finding of mild pathology were not reasons for exclusion.

Subjects were randomly assigned with the use of a random-numbers table to 1 of 4 groups: comprehensive massage therapy (soft-tissue manipulation, remedial exercise and posture education), soft-tissue manipulation only, remedial exercise with posture education only or a placebo of sham laser treatment. Upon arrival for the first appointment, patient characteristics and health information, informed consent and baseline measures (function, pain, anxiety and lumbar range of motion) were recorded. All subjects received 6 treatments within about 1 month. Post-treatment measures were obtained after 1 month of treatment, and follow-up measures were obtained 1 month after treatment ended. Subjects were asked not to seek additional therapy for their backs for the 2 months that they were involved in the study. The 6 subjects (1 in the comprehensive massage therapy group, 2 in the soft-tissue manipulation group, 1 in the remedial exercise group and 2 in the sham laser group) who reported that they took acetaminophen or anti-inflammatory medication for back pain were asked to refrain from doing so on test days until they had completed all the outcome measures.

Treatment variables

For subjects in the comprehensive massage therapy group various soft-tissue manipulation techniques such as friction, trigger points and neuromuscular therapy were used to promote circulation and relaxation of spasm or tension. The exact soft tissue that the subject described as the source of pain was located and treated with the specific technique indicated for the specific condition of the soft tissue (e.g., friction for fibrous tissue and gentle trigger points for muscle spasm). The duration of the soft-tissue manipulation was between 30 and 35 minutes. For each treatment, stretching exercises for the trunk, hips and thighs, including flexion and modified extension, were taught and reviewed to ensure proper mechanics. Stretches were to be within a pain-free range, held for about 30 seconds in a relaxed manner, and performed twice on one occasion per day for the related areas and more frequently for the affected areas. Subjects were encouraged to engage in general strengthening or mobility exercises such as walking, swimming or aerobics and to build overall fitness progressively. Compliance was recorded; 6 subjects (3 from the comprehensive massage therapy group and 3 from the remedial exercise group) had low compliance with performing the remedial exercise on their own. Education of posture and body mechanics, particularly as they related to work and daily activities, was provided. The exercise and education segment took about 15-20 minutes.

Subjects in the soft-tissue manipulation group received the same soft-tissue manipulation as the subjects in the comprehensive massage therapy group and no other treatment. Those in the remedial exercise group received the same exercise and education components of treatment as subjects in the comprehensive massage therapy group. The control group received sham low-level laser (infrared) therapy. The laser was set up to look as if it was functioning but was not. The subject was "treated" lying on his or her side with proper support to permit relaxation. The instrument was held on the area of complaint by the treatment provider, so the subject was attended for the duration of the session (about 20 minutes) to control for the effects of interpersonal contact and support.

Two treatment providers were hired to deliver treatments, but it became necessary for the principle investigator, who is also a registered massage therapist, to provide treatment when the other providers experienced personal distress (e.g., death of a family member). The 2 providers hired for this study underwent training to enhance treatment delivery and similarity of delivery techniques; they also underwent process checks. Two of the treatment providers were massage therapists with more than 10 years' experience each; they provided treatment for the comprehensive massage therapy and soft-tissue manipulation groups. The third was a certified personal trainer and certified weight-trainer supervisor who, with one of the massage therapists, provided treatment for the remedial exercise and sham laser groups. The one objective measure, the range of motion test, was conducted by 3 physiotherapists who were blind to which group each subject was allocated.

Outcome measures

Two primary outcome measures were functionality and pain relief. The Roland Disability Questionnaire[10] (RDQ), an adaptation of the Sickness Impact Profile, was used to measure subjects' level of functioning when performing daily tasks. Scores can range from 0 to 24 based on responses to 24 questions to which subjects answer Yes or No. A score of 14 or more is considered a poor outcome.[10] This questionnaire has shown reliability, validity and sensitivity[10,11] and has been used in trials of the treatment of low-back pain.[6,12,13]

The McGill Pain Questionnaire[14] consists of 2 indexes. The Present Pain Index (PPI) measures intensity of pain; the score ranges from 0 (no pain) to 5 (excruciating pain). The Pain Rating Index (PRI) measures quality of pain and is the sum total of 79 qualitative words the subject chooses to describe the pain. These indexes have shown reliability and validity.[15-17]

Two secondary outcome measures were anxiety and lumbar range of motion. The State Anxiety Index[18,19] (SAI) comprises separate self-report scales to measure state (at this moment) anxiety. Scores can range from 20 (minimal anxiety) to 80 (maximum). The norms of state anxiety for working adults are considered to be 35.7 (standard deviation [SD] 10.4) for men and 35.2 (SD 10.6) for women. This index has shown reliability, validity and internal consistency[18,19] and has been widely used in research[20]

in a variety of disciplines including psychology and medicine.[21,22]

Lumbar range of motion was measured with the Modified Schober test,[23] and the norm is about 7 cm (SD 1.2).[24] It has shown intraobserver (r = 0.99) and interobserver (r = 0.97) reliability[25] and has been used in studies of the effectiveness of treatment for subacute low-back pain.[4,12]

With a level of significance of 0.05 and a power of 0.80, minimum samples of 20 subjects per group[26] were required to detect a proportional reduction of pain of 50%. Outcome data were analysed by intention to treat and group means compared with ANOVA, and subsequently Scheffé (post hoc). Minimal, insignificant differences between groups at baseline with near normal distributions permitted analysis without adjustment.

Results

Of the 165 potential subjects who responded to the advertisements, 107 (65%) met the inclusion criteria. Potential subjects were most commonly excluded because their low-back pain was beyond the 8-month subacute cut-off (15 subjects), they were not currently experiencing low-back pain (13), or they indicated a diagnosis of complex health problems such as multiple sclerosis (9).

Of the 107 subjects who met the inclusion criteria (Table 1), 5 dropped out before treatment (3 before randomization, 1 from the comprehensive massage therapy group and 1 from the remedial exercise group), and 4 subjects dropped out before the end of the treatment (2 from the soft-tissue manipulation group, 1 from the remedial exercise group and 1 from the sham laser group). These 4 subjects appeared typical at baseline. Because each group experienced a similar number of dropouts and results are based on comparisons of group means, these 4 subjects were excluded from analysis. One subject dropped out because she experienced a motor vehicle accident after screening, 5 dropped out because they were "too busy" and 3 subjects could not give a clear reason.

Ninety-eight subjects (92%) completed the treatment: 25 received comprehensive massage therapy, 25 soft-tissue manipulation, 22 remedial exercise and 26 sham laser treatment. Follow-up measures were completed by 91 subjects (85%).

The 4 treatment groups exhibited similar demographic characteristics (Table 2). The mean age of all subjects was 46 years, most (68%) were married or in a relationship with a partner, and most (70%) had at least a college education. The mean body mass index (kg/m2) was 25.5, which is considered overweight.[27] Previous episodes of low-back pain were experienced by 60% of the subjects, and the average duration of the present episode of pain was greater than 3 months. The most common reasons for low-back pain were identified by the subjects as bending or lifting injuries, work-related mild strains, sports injuries and unknown. There were no significant differences between the groups at baseline.

The post-treatment and follow-up outcome measures appear in Table 3. Statistically significant differences were found between the groups on self-reported measures of function, pain and state anxiety. There was no difference between the groups in lumbar range of motion.

Post hoc testing (Scheffé, significance at $p < 0.05$) for post-treatment scores indicated that the comprehensive massage therapy group had significantly better scores than the remedial exercise and sham laser groups on measures of function (RDQ), intensity of pain (PPI) and quality of pain (PRI) and significantly better scores than the soft-tissue manipulation group on the PPI. At follow-up the comprehensive massage therapy group continued to have significantly improved scores over the sham laser group on the RDQ, PPI and PRI and had significantly better scores than the remedial exercise group on the RDQ and PPI.

At the end of treatment the soft-tissue manipulation group had significantly better scores than the remedial exercise and sham laser groups on the RDQ and significantly better scores than the sham laser group on the PPI. At follow-up the soft-tissue manipulation group was not distinguishable from the exercise group; both group means were statistically better than the mean for the sham laser group on the RDQ.

At the end of treatment and at follow-up the comprehensive massage therapy group had significantly better scores

Table 1: Profile of study of effectiveness of massage therapy for subacute low-back pain involving 104 subjects who met the eligibility criteria and were randomly assigned to 1 of 4 treatment groups

	Treatment group, no. of subjects			
Stage of trial	Comprehensive massage therapy	Soft-tissue manipulation	Remedial exercise and posture education	Placebo (sham laser treatment)
Randomly assigned to group but did not receive treatment	1	0	1	0
Started but did not complete treatment	0	2	1	1
Received and completed treatment*	25	25	22	26
Withdrawn and lost to follow-up†	1	3	1	2
Completed trial‡	24	22	21	24

*Completed treatment and completed post-treatment tests.
.†Completed treatment and completed post-treatment tests but not follow-up tests.
‡Completed treatment, completed post-treatment tests and follow-up tests.

than the sham laser group on state anxiety, whereas no other group did. The mean scores on the pain indexes for all of the groups was lower at the end of treatment than at baseline. All subjects' reported levels of pain in the comprehensive massage therapy group decreased in intensity from baseline to post treatment, which did not occur in any other group. At the 1-month follow-up, 63% of the subjects in the comprehensive massage therapy group reported no pain, as compared with 27% in the soft-tissue manipulation group, 14% in the exercise group and 0% in the sham laser group.

Interpretation

A difference in RDQ scores of 2.5 has been considered to be minimally important in terms of clinical effects.[28] When this criterion was applied to the outcome measures at follow-up in the present study, clinical significance was demonstrated in the comprehensive massage therapy group in comparison with the remedial exercise group (difference 4.2) and the sham laser group (difference 5.0). Clinical significance was also evident in the soft-tissue manipulation

Table 2: Baseline characteristics of subjects who received treatment

Characteristic	Treatment group: Comprehensive massage therapy *n = 25*	Soft-tissue manipulation *n = 25*	Remedial exercise and education *n = 22*	Placebo (sham laser treatment) *n = 26*
Mean age, yr	47.9 (16.2)*	46.5 (18.4)	48.4 (12.9)	41.9 (16.6)†
Female, %	56	56	41	54†
Relationship status, %				
Partnered or married	68	64	73	69†
Single, divorced or widowed	32	36	27	31†
Education, %				
High school or less	36	32	27	23
College	20	24	27	20
University	44	44	45	57
Mean body mass index (kg/m^2)	25.0 (4.1)	25.5 (3.8)	26.5 (3.5)	25.0 (2.6)†
Occupational activity, %				
Not working or retired	32	28	27	15
Student	4	16	9	15
At desk mainly	12	24	9	19
At desk and movement	36	16	27	27
Physical labour	16	16	27	23
Duration of LBP, wk	12.0 (9.1)	14.8 (8.2)	13.2 (11.1)	13.3 (8.8)†
Previous episode of LBP, %	68	56	68	50†
Problem, %				
Not known	20	8	9	19
Mild strain (overworked)	8	40	14	35
Sports injury	16	12	18	12
Bending or lifting injury	36	28	45	27
Fall or accident	12	8	9	0
Stress related	8	4	5	8
Outcome measures‡				
RDQ score	8.3 (4.2)	8.6 (4.4)	7.2 (5.2)	7.2 (4.2)†
PPI score	2.4 (0.8)	2.2 (0.8)	2.2 (0.7)	2.0 (0.7)†
PRI score	12.3 (5.0)	10.6 (5.8)	10.2 (6.4)	11.1 (5.5)†
State Anxiety Index score	31.8 (9.8)	37.3 (10.3)	32.6 (7.5)	34.1 (8.4)†
Modified Schober test, cm	5.6 (1.3)	5.2 (1.8)	5.3 (1.1)	5.5 (1.2)†

Note: SD = standard deviation, LBP = low-back pain, RDQ = Roland Disability Questionnaire, PPI = Present Pain Index, PRI = Pain Rating Index.
*Figures represent mean (and SD), unless stated to be a percentage of the group.
†No significant difference between groups.
‡RDQ (score range 0–24) measures function (a lower score indicates less dysfunction); PPI (score range 0–5) measures intensity of pain (a lower score indicates less intensity); PRI (score range 0–79) measures quality of pain (a lower score indicates fewer qualitative symptoms); State Anxiety Index (score range 20–80) measures level of anxiety experienced at this moment (a lower score indicates less anxiety); modified Schober test measures lumbar range of motion in centimetres.

group at follow-up in comparison with the exercise group (difference 2.8) and the sham laser group (difference 3.6). Both the comprehensive massage therapy group and the soft-tissue manipulation group showed clinical significance for the improvement of function.

Self-reported levels of function and pain (intensity and quality) improved the most for patients with subacute low-back pain who had comprehensive massage therapy administered by experienced massage therapists. Soft-tissue manipulation was shown to have some benefit after treatment, but by follow-up there was no statistical difference between the soft-tissue manipulation group and the remedial exercise group. Comprehensive massage therapy was shown in this study to maintain statistical significance over the sham laser group on all 3 outcome measures and over the exercise group on 2 outcome measures. This did not occur for any other group. However, at follow-up there were no statistical differences between the comprehensive massage therapy group and the soft-tissue manipulation group. Soft-tissue manipulations were shown to have considerable benefit, and the addition of remedial exercise and posture education was shown to improve the clinical results moderately. Comprehensive massage therapy seemed to have the greatest impact on pain scores but was only marginally better than soft-tissue manipulation alone for improving function.

The cost of treatment per subject in the comprehensive massage therapy group was $300 (6 sessions at $50 per treatment) and $240 for the soft-tissue manipulation group. The estimated cost of treatment per subject in the remedial exercise and sham laser groups was $90. Thus, comprehensive massage therapy had the most benefit but cost $60 more per subject than soft-tissue manipulation alone.

Limitations of the study included the use of a single setting, the use of a specific form of massage therapy provided by only 2 massage therapists, unmeasured provider effects on the validity of outcome measures and the confines of the protocol (e.g., a set number of treatments regardless of the severity or complexity of the problem and short-term follow-up). The treatment was provided by therapists with clinical experience and continuing education that focused on physiology. It is likely that massage therapists with similar education and training based on physiology, as opposed to reflexology or craniosacral therapy, would provide similar treatment. Only in British Columbia and Ontario is massage therapy regulated, although most other provinces, except Quebec, have similar training.

This is the first randomized controlled trial of the effectiveness of massage therapy for subacute low-back pain. Replication of this study, comparisons with other forms of treatment and external evaluation are required to help ascertain which types of low-back problems with which types of complicating factors (e.g., levels of stress and activity) will respond best to massage therapy. Massage therapy that is based on physiology and emphasizes the soft-tissue manipulation component of treatment was found to be effective in the nonpharmacological management of subacute low-back pain.

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Table 3: Outcome data

Variable	Comprehensive massage therapy Mean (and 95% CI)	SD	Soft-tissue manipulation Mean (and 95% CI)	SD	Remedial exercise and posture education Mean (and 95% CI)	SD	Placebo (sham laser treatment) Mean (and 95% CI)	SD	*p* value
Primary outcomes									
Post treatment	*n = 25*		*n = 25*		*n = 22*		*n = 26*		
RDQ score	2.36 (1.2–3.5)	2.8	3.44 (2.3–4.6)	2.8	6.82 (4.3–9.3)	5.6	6.85 (5.4–8.2)	3.5	< 0.001
PPI score	0.44 (0.17–0.71)	0.6	1.04 (0.76–1.3)	0.7	1.64 (1.3–2)	0.8	1.65 (1.3–2)	0.8	< 0.001
PRI score	2.92 (1.5–4.3)	3.4	5.24 (2.9–7.6)	5.7	7.91 (5.2–10.6)	6.1	8.31 (6.1–10.5)	5.4	0.001
Follow-up (1 mo)	*n = 24*		*n = 22*		*n = 21*		*n = 24*		
RDQ score	1.54 (0.69–2.4)	2.0	2.86 (1.5–4.2)	3.1	5.71 (3.5–7.9)	4.8	6.50 (4.7–8.3)	4.2	< 0.001
PPI score	0.42 (0.17–0.66)	0.6	1.18 (0.52–1.8)	1.5	1.33 (0.97–1.7)	0.8	1.75 (1.5–2)	0.6	< 0.001
PRI score	2.29 (0.5–4.0)	4.2	4.55 (2.0–7.1)	5.7	5.19 (3.3–7.1)	4.3	7.71 (5.2–10.3)	6.0	0.006
Secondary outcomes									
Post treatment	*n = 25*		*n = 25*		*n = 22*		*n = 26*		
State Anxiety Index score	23.96 (22.4–25.5)	3.8	28.96 (25.5–32.4)	8.4	30.91 (27.9–34.0)	6.9	32.54 (29.4–35.7)	7.8	< 0.001
Modified Schober test, cm	6.36 (5.8–6.9)	1.2	5.87 (5.2–6.5)*	1.5	5.86 (5.3–6.4)	1.3	5.98 (5.5–6.5)	1.2	0.51
Follow-up (1 mo)	*n = 24*		*n = 22*		*n = 21*		*n = 24*		
State Anxiety Index score	23.79 (22.2–25.4)	3.8	30.73 (26.4–35.1)	9.8	28.81 (25.6–32)	7.1	32.63 (29.5–35.7)	7.4	< 0.001
Modified Schober test, cm	6.47 (6.0–7.0)	1.2	5.93 (5.3–6.6)†	1.4	5.39 (4.8–6.0)†	1.4	5.50 (4.8–6.1)	1.5	0.04

Note: CI = confidence interval.

*$n = 24$.

†$n = 20$. Some range of motion tests were missed because of scheduling difficulties.

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