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Effectiveness of Ayurvedic Massage (*Sahacharadi Taila*) in Patients with Chronic Low Back Pain: A Randomized Controlled Trial

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Abstract

Objectives: Ayurveda is one of the oldest comprehensive healthcare systems worldwide. Ayurvedic massage and physical therapy are frequently used to treat patients with chronic pain syndromes and disorders of the musculoskeletal system. This study aimed to evaluate the effectiveness of Ayurvedic massage in nonspecific chronic low back pain by means of a randomized clinical trial.

Design: Sixty-four patients (mean age, 54.8 years; 49 women and 15 men) with chronic low back pain who scored >40 mm on a 100-mm visual analogue scale (VAS) were randomly assigned to a 2-week massage group with 6 hours of Ayurvedic massage and external treatment ($n = 32$) or to a 2-week local thermal therapy group ($n = 32$). The study observation period was 4 weeks, consisting of a 2-week intervention phase followed by a 2-week follow-up phase.

Outcome measures: Primary outcome measure was the change of mean pain (VAS) from baseline to week 4. Secondary outcomes included pain-related bothersomeness, the Roland Disability Questionnaire, quality of life (Medical Outcomes Study 36-Item Short Form), the Hanover Functional Ability Questionnaire for measuring back pain–related disability, and psychological outcomes. Outcomes were assessed at baseline and after 2 and 4 weeks.

Results: Mean back pain (primary outcome) at week 2 was significantly reduced from 53.4 ± 18.5 to 21.6 ± 18.2 in the massage group and from 55.3 ± 12.9 to 41.8 ± 19.8 in the standard thermal therapy group (mean group difference, −18.7; 95% confidence interval, −28.7 to −8.7; $p < 0.001$). While beneficial effects on pain-related bothersomeness and psychological well-being were also apparent, the Ayurvedic intervention did not improve function or disability in the short-term observation period. Both programs were safe and well tolerated.

Conclusions: Ayurvedic external treatment is effective for pain-relief in chronic low back pain in the short term. Further studies with longer observation periods are needed to evaluate the long-term effects of the Ayurvedic external treatment approach on function and disability.

Keywords: chronic low back pain, Ayurveda, Ayurvedic massage, randomized trial

Introduction

Low back pain is a common public health problem. More than 70% of the population in western societies experience low back pain in a given year.[1] Chronic low back pain can affect quality of life and has a high comorbidity with depression and burnout syndrome. Furthermore, it is the most costly ailment among people of working age, with an estimated €10 billion spent annually on medical costs in Germany and more than $30 billion in the United States.[2,3] A multitude

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of treatments for chronic low back pain exist, including education, analgesics, exercise, injections, massage and manual therapies, acupuncture, and, in treatment-resistant cases, surgery and minimally invasive treatments. However, evidence to support most of these treatments is still unsatisfactory.

Because patients with low back pain are often dissatisfied with their medical care, they frequently use complementary and integrative treatment methods.[4,5] In the context of modern globalized medicine, there is increasing use of traditional whole medical systems, such as traditional Indian medicine, with its main branch, Ayurveda. Ayurvedic medicine is well established in the public healthcare of India and other South Asian countries. With its migration into European and western healthcare settings, it is frequently applied for chronic pain conditions. Ayurvedic medicine comprises lifestyle modification, nutritional therapy, botanical medicine, mind–body techniques, and complex external and physical treatment, including sophisticated massage, thermotherapy, and manual techniques. These external treatments have become increasingly popular in Europe and are commonly used to treat chronic back pain. However, no clinical studies have evaluated the effectiveness of Ayurvedic medicine in the treatment of chronic back pain.

Given the widespread use and the promising empirical evidence of the Ayurvedic treatment in chronic back pain, there is a clear need for randomized clinical trials. Therefore, the present randomized controlled trial was designed to evaluate the effectiveness of an external Ayurvedic treatment approach in chronic low back pain. The study hypothesis was that external Ayurvedic therapy over 2 weeks leads to better pain relief after 4 weeks than does a standard local thermal therapy.

Materials and Methods

This study was designed as a randomized controlled clinical trial. All study participants gave their informed consent. The study protocol was reviewed and approved by the Ethics Committee of the University Hospital Essen, Germany. All study procedures and collection of data were carried out at the outpatient department of the University Hospital Essen, Department of Internal and Complementary Medicine.

Study procedures

Participants were recruited by means of a press release offering participation in a study for chronic low back pain. Potential participants were screened for eligibility by telephone interview, and eligible candidates were scheduled for enrollment visits. A study physician performed the candidates' physical examinations, and measures were administered by trained and blinded research staff. Thereafter, each eligible participant was randomly assigned to a 2-week external Ayurvedic therapy group with a total of 6 sessions of Ayurvedic treatment or to 6 sessions of standard physical therapy with application of a local heat pack and slight standard massage. The study observation period was 4 weeks, consisting of a 2-week intervention phase and a 2-week follow-up phase.

The written study information emphasized that both treatments might be useful for treatment of chronic low back pain. Patient recruitment took place between November and December 2008. Study procedures and outcome assessment were performed between January 2009 and February 2010.

Study participants

Patients of both sexes were eligible if they were age 18–70 years, had a minimum score of greater than 40 mm on a visual analog scale (VAS) for nonspecific chronic low back pain, and had had a self-reported restriction of lumbar spine mobility for at least 3 months. Nonspecific back pain was defined as back pain without identification of a specific underlying cause.

Patients were excluded if they had undergone invasive treatment within the last 6 weeks or had planned to do so within the next 4 weeks and those whose low back pain was complicated (e.g., spinal stenosis, herniated vertebral disk) or attributable to specific underlying diseases (e.g., congenital anomalies in the lumbar spine area, fractured bones, manifest osteoporosis, spondylolisthesis). Diagnosis of unspecific low back pain had to be confirmed by a board-certified orthopaedic physician, rheumatologist, neurosurgeon, or pain specialist. Patients were also excluded if they had coexisting serious comorbidities or were participating in another study.

Randomization

Patients were randomly allocated to a treatment group by a nonstratified block randomization with varying block lengths and by preparing sealed, sequentially numbered opaque envelopes containing the treatment assignments. Randomization was based on the ''ranuni'' pseudo-random number generator of the SAS/Base statistical software (SAS Inc., Cary, NC), and the envelopes were prepared by the study biostatistician. When a patient fulfilled all enrollment criteria, the study physician opened the lowest-numbered envelope to reveal that patient's assignment.

Interventions

Patients were randomly assigned to a 2-week external Ayurvedic treatment group with 6 treatments or to a group receiving standard local physical therapy. All treatments were applied by trained nurses and physical therapists. Six treatment sessions were chosen because this is a common prescription standard in Germany, with coverage of the cost by most health insurance companies.

Ayurvedic massage therapy. All patients received 6 treatments over 2 weeks; each treatment lasted 35 minutes, after which patients rested for 30 minutes. The patient was supine in a warm room with a pleasant and comfortable atmosphere. The massage techniques included the application of warm oil (*Sahacharadi Taila*) and light manual pressure. Special hand-size cotton bags (*Kizhi*) were applied on the lower back and gluteal region with rhythmic movements. After the *Kizhi* application, the therapist performed gentle Ayurvedic massage of the low back, gluteal region, and pain areas. Excess oil was then removed from the body. Finally, the patient took a hot shower and rested for an additional 30 minutes.

Physical therapy. Participants in the control group received a local heat pack that contained an additional ginger preparation (Zapp Sack). After 20 minutes of local heat therapy, slight standard massage techniques were applied. Patients then rested for 30 minutes after the treatment.

Outcomes

All participants were asked to complete standardized questionnaires at the outset of the study (baseline) and after 2 and 4 weeks.

Primary outcome. The primary outcome measure was the group difference of the change of mean pain (VAS) from baseline to week 4, as assessed by a 100-mm VAS asking for the mean pain during the last 48 hours.

Secondary outcomes. The secondary outcomes included validated instruments to assess functional impairment and disability. The Roland Disability Questionnaire (RDQ)[6] is the most commonly used and recommended outcome measure for assessing the disabling effects of lumbar spinal disorders. The score of the RDQ is the total number of items checked (i.e., from a minimum of 0 to a maximum of 24); greater levels of disability are reflected by higher numbers on a 24-point scale. To evaluate the functional effectiveness, the Hannover Functional Ability Questionnaire for measuring back pain-related disability (FFbH-R) was used.[7] The FFbH-R is a short German self-administered questionnaire that especially focuses on daily activities limited by back problems and contains 12 activities of daily living. Patients are asked to rate their ability on each activity on a 3-step scale.

Further secondary outcomes included quality of life, as measured by the Medical Outcomes Study 36-Item Short Form (SF-36),[8] and psychological well-being, as assessed by the Profile of Mood states (POMS) with its 4 dimensions of depression, anger/hostility, vigor, and fatigue.[9] The study also used patient ratings of pain-related bothersomeness (''Please rate the discomfort you have experienced from your low back pain in the last 7 days'') by means of a 100-mm VAS.[10,11]

To control for outcome expectation as one dimension of nonspecific treatment effects, patients were asked to rate their outcome expectation on a 5-point Likert scale ranging from 4 (expecting considerable pain relief) to 0 (expecting no pain relief) immediately after they had been informed of their randomly assigned treatment.

Adverse effects were assessed by prespecified lists to be filled in by the study physician. Additionally, patients were asked to keep a diary recording any adverse effects of their treatment and their use of oral rescue medication.

Sample size determination and statistical analysis

Data from previous trials on Ayurvedic external treatment and chronic low back pain did not exist for sample size calculations. On the background of the personally reported empirical experience of Ayurvedic experts in the unit, a superiority of Ayurvedic over standard treatment for the primary outcome, mean change of pain intensity, was assumed, with a moderate effect size of Cohen $d = 0.6$ and calculated a number of $n = 52$ completely documented patients given a power of 80% and a two-sided significance level of $\alpha = 5\%$. To account for a maximum dropout rate of 20%, a minimum of $n = 64$ patients were included.

All outcome criteria were analyzed by intention-to-treat, including all randomly assigned patients, regardless of whether they adhered to the protocol or gave a full set of data. For each outcome, a generalized estimation equation (GEE) analysis of covariance was fitted, which included treatment group (binary covariate), the respective baseline value (linear covariate), the patient's expectation (linear covariate), and time (repeated measurement factor) as independent variables. The within-patient correlation was assumed to be autoregressive of first order. Treatment effects

Table 1. Baseline Characteristics of Study Patients

Characteristic	*Ayurvedic massage group (n = 32)*	*Control group (n = 32)*	p-*Value*
Sociodemographic			
Age (yr)	55.4 ± 11.2	54.2 ± 13.8	0.979
BMI (kg/m^2)	25.8 ± 4.2	26.9 ± 4.4	0.444
Women/men (*n/n*)	26/6	23/9	–
Current pension process (%)	3.1	31.3	–
Taking medication (%)	56.3	43.8	–
Using CAM (%)	15.6	18.8	0.733
Mean SF-36 physical quality of life score ± SD	39.0 ± 9.5	36.7 ± 7.2	0.219
Mean SF-36 mental quality of life score ± SD	51.2 ± 9.3	48.2 ± 11.0	0.363
Low back pain			
Mean duration of low back pain (mo)	188.7 ± 156.7	119.6 ± 107.3	0.101
Mean low back pain intensity ± SD[a]	53.4 ± 18.5	55.3 ± 12.9	0.629
Bothersomeness of low back pain ± SD[b]	5.8 ± 1.7	6.0 ± 1.4	0.488
Treatments previously used (%)			
Acupuncture	71.9	59.4	0.292
Physical therapy	81.3	84.4	0.525
Injections	84.4	71.9	0.226

Control group received standard physical therapy with application of a local heat pack that contained an additional ginger preparation, plus slight standard massage.

[a]On visual analog scale of 0–100.

[b]On scale of 0–10.

BMI, body mass index; CAM, complementary and alternative medicine; SF-36, Medical Outcomes Study 36-Item Short Form; SD, standard deviation.

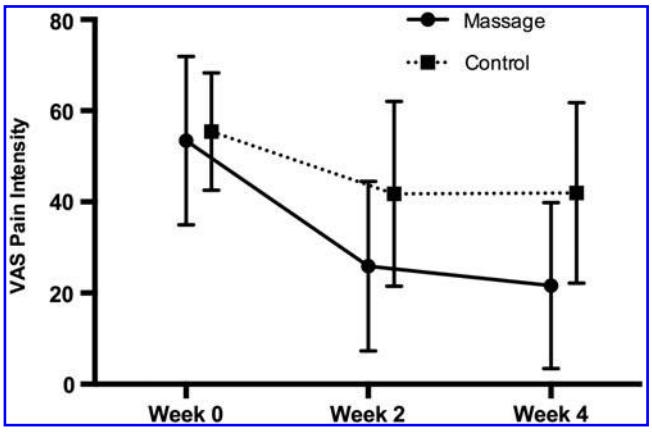

FIG. 1. Pain score. Mean ± standard deviation change of pain in both groups during the study ($p < 0.001$ for between-group difference after 4 weeks).

were estimated within these models and reported as adjusted group differences, including respective 95% confidence intervals (CIs) and *p*-values. The GEE technique considers the structure of missing values implicitly.

Results

Telephone screening after distribution of press releases yielded more than 120 calls from patients interested in study participation. Eighty-eight patients were invited to the study center. Of these, 64 fulfilled all entry criteria and were enrolled into the study. Thirty-two patients were randomly assigned to each group. After 2 weeks, 4 patients in the control group were lost because of unwillingness to return to the study center or time constraints. At week 4, an additional 3 patients in the control group did not complete the study. Five patients withdrew because of lack of perceived benefit of study intervention and 2 because of unwillingness to return to the study center due to time constraints. One patient in the Ayurvedic group did not complete the study because of unwillingness to return to the study center. The resulting dropout rates were 3% in the Ayurvedic group and 22% in the control group.

Baseline data

The patient ages ranged from 20 to 71 years. Baseline characteristics were well balanced between the groups (Table 1). Patients in the control group were nonsignificantly older than those in the Ayurvedic group. Mean duration of low back pain was about 13 years in both groups. Eighty-one percent of patients in the Ayurvedic group and 53% in the control group expected that the treatment would provide good or very good pain relief ($p = 0.052$).

Outcome measures

Primary outcome. Compared with the control intervention, the Ayurvedic treatment led to greater improvement of low back pain intensity at weeks 2 and 4 (Fig. 1). Mean low back pain score at week 4 was reduced from 53.4 ± 18.5 to 21.6 ± 18.2 in the Ayurvedic group and from 55.3 ± 12.9 to 41.8 ± 19.8 in the thermal therapy group, resulting in a significant mean adjusted group difference (−18.7; 95% CI, −28.7 to −8.7; $p < 0.001$).

Secondary outcomes. A significant group difference favoring Ayurvedic treatment over control treatment was also evident for bothersomeness of low back pain at weeks 2 and 4 (Table 2). Of note, the Ayurvedic treatment was also beneficial regarding pain relief for headache when patients also had that condition ($n = 58$) (Table 2).

Disability and functional impairment

The RDS only decreased nonsignificantly more in the Ayurvedic group than in the control group. Respectively,

TABLE 2. FUNCTIONAL DISABILITY, BOTHERSOMENESS OF PAIN, AND INSOMNIA IN BOTH STUDY GROUPS (UNADJUSTED VALUES), WITH GROUP DIFFERENCES FOR CHANGE ON TREATMENT (ADJUSTED VALUES)

Variable	*Baseline*	*Week 2*	*Week 4*
RDQ score (0–24)			
Ayurvedic massage (mean ± SD)	10.0 ± 4.3	7.8 ± 5.9	6.0 ± 4.7
Control (mean ± SD)	10.4 ± 4.5	10.1 ± 5.0	10.2 ± 6.0
Group difference (95% CI); *p*-value		−1.6 (−3.9 to 0.6); $p = 0.214$	−2.9 (−6.4 to 0.6); $p = 0.214$
FFbH-R score (0–100)			
Ayurvedic massage (mean ± SD)	65.7 ± 21.4	73.2 ± 20.5	74.5 ± 21.3
Control (mean ± or + SD)	63.6 ± 17.6	69.3 + 18.6	66.7 ± 20.4
Group difference (95% CI); *p*-value		4.0 (−2.7 to 10.7); $p = 0.241$	5.6 (−0.9 to 12.2); $p = 0.185$
Bothersomeness of low back pain (0–10)			
Ayurvedic massage (mean ± SD)	5.8 ± 1.7	3.2 ± 1.6	2.7 ± 1.8
Control (mean ± SD)	6.0 ± 1.4	4.5 ± 1.8	4.5 ± 1.9
Group difference (95% CI); *p*-value		−1.3 (−2.2 to −0.4); $p = 0.006$	−1.6 (−2.5 to −0.7); $p = 0.001$
Bothersomeness of headache (0–10)			
Ayurvedic massage (mean ± SD)	2.7 ± 3.1	0.6 ± 1.4	0.2 ± 0.6
Control (mean ± SD)	1.5 ± 2.3	0.9 ± 2.0	0.6 ± 1.6
Group difference (95% CI); *p*-value		−1.1 (−1.9 to −0.2); $p = 0.015$	−1.1 (−1.8 to −0.4); $p = 0.005$

RDQ, Roland Disability Questionnaire; CI, confidence interval; FFbH-R, Hannover Functional Ability Questionnaire for measuring back pain-related disability.

Table 3. Quality of Life and Psychological Well-Being Assessed by Profile of Mood States in Both Study Groups (Unadjusted Values), with Group Differences for Change on Treatment (Adjusted Values)

Variable	*Baseline*	*Week 2*	*Week 4*
POMS fatigue			
Ayurvedic massage (mean ± SD)	1.7 ± 1.3	1.1 ± 0.9	1.0 ± 0.8
Control (mean ± SD)	2.1 ± 1.2	1.9 ± 1.0	1.9 ± 1.2
Group difference (95% CI); *p*-value		−0.5 (−0.9 to −0.2); $p = 0.003$	−0.7 (−1.1 to 0.3); $p < 0.001$
POMS anger/hostility			
Ayurvedic massage (mean ± SD)	1.2 ± 1.3	0.6 ± 0.7	0.5 ± 0.7
Control (mean ± SD)	1.1 ± 1.2	0.9 ± 1.1	1.2 ± 1.4
Group difference (95% CI); *p*-value		−0.4 (−0.8 to −0.1); $p = 0.023$	−0.7 (−1.1 to −0.3); $p = 0.004$
POMS depression			
Ayurvedic massage (mean ± SD)	0.9 ± 1.1	0.5 ± 0.6	0.4 ± 0.6
Control (mean ± SD)	1.1 ± 1.1	0.8 ± 1.0	0.9 ± 1.2
Group difference (95% CI); *p*-value		−0.1 (−0.4 to 0.2); $p = 0.611$	−0.3 (−0.7 to 0.0); $p = 0.130$
POMS vigor			
Ayurvedic massage (mean ± SD)	3.4 ± 1.0	3.3 ± 1.1	3.4 ± 1.0
Control (mean ± SD)	3.2 ± 0.8	3.3 ± 0.9	3.2 ± 0.9
Group difference (95% CI); *p*-value		−0.2 (−0.5 to 0.2); $p = 0.786$	0.1 (−0.2 to 0.5); $p = 0.786$
SF-36 physical quality of life			
Ayurvedic massage (mean ± SD)	39.0 ± 9.5	39.5 ± 8.7	41.9 ± 9.8
Control (mean ± SD)	36.7 ± 7.2	38.2 ± 9.3	37.6 ± 9.8
Group difference (95% CI); *p*-value		−1.2 (−4.8 to 2.4); $p = 0.678$	1.7 (−1.8 to 5.3); $p = 0.678$
SF-36 mental quality of life			
Ayurvedic massage (mean ± SD)	51.2 ± 9.3	53.1 ± 9.2	52.4 ± 9.7
Control (mean ± SD)	48.2 ± 11.0	50.5 ± 10.9	49.8 ± 12.8
Group difference (95% CI); *p*-value		0.2 (−3.7 to 4.2); $p = 1.000$	−0.3 (−4.8 to 4.2); $p = 1.000$

POMS, Profile of Mood States.

back pain–related disability as assessed by the FFbH-R showed only nonsignificant improvements from the Ayurvedic treatment compared with the control treatment (Table 2).

Psychological outcomes and quality of life

Some of the assessed psychological outcomes significantly improved in the Ayurvedic treatment group compared with the control treatment: fatigue ($p < 0.001$) and anger/hostility ($p = 0.004$) as assessed by the POMS. No group differences were found for the other dimensions of the POMS or for, the psychological and physical sum score of quality of life. In the subdimensions of quality of life there was a trend for better physical function with Ayurvedic treatment and a significant improvement of vitality ($p < 0.001$) (Table 3).

Safety

There were no serious adverse events in either group. All treatments were well tolerated in both groups, without any reported side effects.

Discussion

Chronic low back pain is the most common medical condition and an increasing public health problem in Germany, Europe, and the United States.[1] This trial evaluated the effectiveness of one of the components of the whole medical system of Ayurveda, external manual treatments and massage, in the short-term treatment of low back pain. Compared with standard thermal/manual therapy, the 2-week Ayurvedic external treatment series led to a greater treatment effect on the primary outcome, mean change in back pain. Among the secondary outcomes, the Ayurvedic treatment approach reduced pain-related bothersomeness after 2 and 4 weeks. Although some beneficial effects on mood and psychological well-being were additionally apparent, the Ayurvedic intervention did not improve function or disability in the short-term observation period.

The observed pain relief was of clinical relevance, with a mean within-group pain reduction after 4 weeks of about 60% and a net between-group pain reduction of 35%.

This appears to be the first study to evaluate the effectiveness of Ayurvedic treatments in chronic low back pain.[12–16] Therefore, the results cannot be compared with other data with regard to Ayurvedic medicine. However, standard massage and thermal therapies were previously evaluated by randomized controlled trials and are well established nonpharmacologic therapies for chronic low back pain.[17–22] In this context, the present Ayurveda-induced effect of 60% and 35% for reduction of pain intensity and of 54% and 28% for reduction of pain-related bothersomeness compares well.

Because Ayurvedic medicine is a multimodal treatment approach, several mechanisms might be responsible for the observed treatment effect. First, bodily oriented therapies, such as manual and massage therapies, induce neurobiological mechanisms at the level of the peripheral nociceptor and the spinal chord, for example by modulating nociceptor sensitivity and stimulating of A and C fibers; it can be expected that they involve the spinothalamo-cortical pain pathways.[23] Second, Ayurvedic external treatments use medicated oils that may

also have local and systemic pharmacologic effects. Finally, manipulation of skin and connective tissue is mostly perceived as being pleasurable. Thus, these techniques are highly likely to induce emotional and attentional processes on the cortical level, fostering relaxation and inducing beneficial effects on pain perception on a systemic level.[23] Furthermore, such techniques may act via enhanced distribution of endogenous opioids.

Of note, differences in responsible mechanisms between different types of massages may be relevant for differential effects. For Ayurvedic external treatments, the use of medical oil (*Sahacharadi Taila*) and the intensive traditional manual techniques seem to be the most obvious differences compared with standard naturopathic and manual techniques, with their respective primary spino-thalamic and neurobiological effects.

For the interpretation of the data, several limitations have to be considered. First, the interventions in both study groups were restricted, meaning that the Ayurvedic treatment consisted only of external manual treatments but not the other components of Ayurveda as a whole medical system (e.g., diet, herbs, lifestyle advice). The control treatment consisted of a moderate-intensity thermal treatment and a few standard massage techniques but was not an extended physical or functional treatment. Furthermore, both treatment approaches were provided in only 6 therapy sessions in 2 weeks, which is less than commonly performed in Ayurvedic practice. However, this quantity was selected because 6 manual/thermal treatments are a common prescription standard in Germany, the cost of which is typically covered by public health insurance. To allow a comparison with the standard therapy, the number of treatment sessions was equalized for both groups. Thus, the study did not evaluate Ayurvedic medicine as a whole medical system but rather only one treatment component of Ayurveda.

Second, patients in the Ayurvedic treatment group received some additional treatment time and attention compared with that provided in the control group. Thus, nonspecific effects may have been greater in the Ayurvedic treatment group than in the control group. Third, the study had a short observation period of only 4 weeks and thus could not allow estimation of longer-term effects for both interventions.

The uncertainties associated with these limitations make it difficult to determine the true magnitude of the benefits of Ayurvedic treatment observed in this trial. However, the trial also has strengths, including a sufficient sample size, inclusion of an active control group, and outcome assessment with validated tools.

In the results, the dissociation between the pronounced highly significant pain-relieving effect and the only nonsignificant improvement of function and disability is noteworthy. Most likely, the lack of effect on function and quality of life was due to the study design, with short treatment and observation periods. An alternative explanation could be that Ayurvedic manual treatments beneficially affect nociception without having a short-term functional effect on the locomotor system. However, a trend toward an increasing effect on function and quality of life was apparent after 4 weeks and indicates the short observation period to be the cause for the only small effect on these secondary outcomes. Clearly, further studies with longer observation periods are needed to evaluate the long-term effects of the Ayurvedic manual treatment approach on function and disability.

The clinical value of the Ayurvedic treatment must be assessed in relation to the time, effort, and cost of the interventions. While the induced pain relief is of clinical relevance, the time, effort, and cost of the 6 hours of individual manual and massage treatment seem comparatively high.

In the treatment of chronic low back pain, several complementary medicine treatments have already proven effective, including acupuncture, meditation, exercise, yoga, and further movement therapies. The data reported here indicate that Ayurvedic medicine might be a further promising treatment approach for chronic low back pain.

In conclusion, Ayurvedic external treatment is effective for pain relief in chronic low back pain in the short term. Further trials on Ayurvedic treatments in chronic low back pain are warranted. These studies should include longer-term follow-up and also integrate the broader approach of Ayurvedic medicine as a whole medical system and use study designs enabling comparative effectiveness research.

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Author Disclosure Statement

No competing financial interests exist.

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