Clinical Area: Massage therapy for low–back pain (LBP)
Keywords: Massage, therapy, therapeutic, chronic, low back pain.

Study Type: Randomized controlled trial.

Outcomes:
- **Primary**: Symptoms, dysfunction.
- **Secondary**: Disability, utilization and cost, use of medication, and satisfaction with the care given.

Design
- **Number of subjects**: N=262
- **Description of study population**: Group Health Cooperative patients, 20-70 years old, (mean 44.9±11.5 years). 58% were women, 84% white, 84 % employed, and almost 80% had some college education. Two thirds of the patients (66%) had LBP for at least 90 days in the 6 months prior to the study. 80% sought medical care more than one year before the study, more than two thirds (68%) used medications for treatment, 16 % had a previous massage for the pain, 6 % had surgery, and 3 % previous acupuncture.
- **Inclusion criteria**: Group health patients, 20-70 years old, with persistent low-back pain (at least six weeks duration).
- **Exclusion criteria**: Symptoms of sciatica, acupuncture or massage for LBP in the year before the study, back care from a specialist or CAM (complementary and alternative medical therapy) provider, severe clotting disorders, anticoagulant therapy, cardiac pacemaker, underlying disease, pregnancy, lumbar surgery in the past 3 years, severe neurologic deficits, recent vertebral fracture, inability to speak English, and bothersome of back pain rated <4 (scale 0-10).
- **Power**: 80% power to detect a 2.5 point difference between the acupuncture and massage therapy on the Ronald Disability Scale, and 1.5 point difference on the Symptom Bothersome Scale.
- **Method of randomization**: Used a computer generated random sequence.
- **Intervention**: 94 patients received 10 sessions each, of Traditional Chinese Medical (TCM) acupuncture from 7 licensed, experienced acupuncturists. The techniques allowed were needling, electrical stimulation and manipulation of the needles, cupping, infrared heat, indirect moxibustion, and exercise recommendations.

78 patients had up to 10 visits for massage therapy provided by 12 licensed experienced therapists. The techniques permitted were the Swedish therapy, deep tissue, neuromuscular, trigger and pressure point therapies. Those resembling acupuncture were not allowed, as well as those that do not involve physical contact.

There were 90 patients in the self-care group. They were given educational material on chronic back pain, containing information on self-management and control of the pain.
- **Blinding**: Patients and providers were not blinded. The interviewers who conducted the telephone interviews to assess the outcomes were blinded to the treatment group.
Source of outcome data (e.g. patient self-report, doctor report, lab results): Patient interviews and automated utilization data. The scales used to measure outcome were Symptom Bothersome Scale (score 0-10), Modified Ronald Disability Scale (score for number of positive answers to 23 questions), National Health Interview Survey questions, and SF-12 Physical and Mental Health Summary scales.

Length of follow-up: 12 months.

Completeness of follow-up: Follow-up data were complete for 95% of the patients.

Validity

- Is the study type appropriate for the questions being asked? Yes.
- Was the study population typical of patients with this disease? Yes.
- Were the treatment/control groups comparable at baseline? Yes.
- Was the intervention compared to placebo and/or best accepted intervention? Yes.
- Was there compliance with the intervention? Yes.
- Was there equal intensity of observation of study and control subjects? Yes.
- Was the process of observation likely to affect the outcome? Probably, due to the unblinding of the patients.
- Intention to treat analysis? Yes.

Conclusions regarding validity of methods:
The study is well conducted and there do not appear to be any significant methodological flaws. However, the patients and providers were not blinded, which may be difficult in a study like this, yet there is a concern about a possible bias especially when the outcomes are based on subjective measures. Moreover, the study lacked a no treatment control group.
Results:

**Symptom Bothersome Scale and Roland Disability Scale Scores***
*At Baseline, 4 Weeks, 10 Weeks, and 1 Year*

<table>
<thead>
<tr>
<th>Scale scores</th>
<th>Treatment group</th>
<th>p value unadjusted</th>
<th>p value adjusted</th>
<th>p value pairwise</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acupuncture</td>
<td>Massage</td>
<td>Self-care</td>
<td></td>
</tr>
<tr>
<td>Symptom Bothersome Scale score</td>
<td>( n=94 )</td>
<td>( n=78 )</td>
<td>( n=90 )</td>
<td></td>
</tr>
<tr>
<td>Roland Disability Scale score</td>
<td>6.2 (5.8-6.5)</td>
<td>6.2 (5.8-6.6)</td>
<td>6.1 (5.7-6.5)</td>
<td>.96</td>
</tr>
<tr>
<td></td>
<td>12.8 (11.7-13.8)</td>
<td>11.8 (10.8-12.7)</td>
<td>12.0 (10.9-13.0)</td>
<td>.39</td>
</tr>
<tr>
<td><strong>At 4 weeks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom Bothersome Scale score</td>
<td>4.3 (3.7-4.9)</td>
<td>4.5 (4.0-5.1)</td>
<td>4.9 (4.3-5.5)</td>
<td>.31</td>
</tr>
<tr>
<td>Roland Disability Scale score</td>
<td>9.1 (7.8-9.9)</td>
<td>7.9 (6.9-9.0)</td>
<td>9.3 (8.0-10.6)</td>
<td>.28</td>
</tr>
<tr>
<td><strong>At 10 weeks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom Bothersome Scale score</td>
<td>4.0 (3.4-4.9)</td>
<td>3.6 (3.0-4.2)</td>
<td>4.6 (3.9-5.3)</td>
<td>.11</td>
</tr>
<tr>
<td>Roland Disability Scale score</td>
<td>7.9 (6.5-9.3)</td>
<td>6.3 (5.1-7.5)</td>
<td>8.8 (7.4-10.2)</td>
<td>.04</td>
</tr>
<tr>
<td><strong>At 1 year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom Bothersome Scale score</td>
<td>4.5 (3.8-5.2)</td>
<td>3.2 (2.5-3.9)</td>
<td>3.8 (3.1-4.5)</td>
<td>.04</td>
</tr>
<tr>
<td>Roland Disability Scale score</td>
<td>8.0 (6.6-9.3)</td>
<td>6.8 (5.5-8.1)</td>
<td>6.4 (5.1-7.7)</td>
<td>.22</td>
</tr>
</tbody>
</table>

* Data given as means ((95% CI). Higher scores indicate more severe symptoms or dysfunction.
** Adjusted for baseline Symptom Bothersome, Roland Disability Scales values as well as other covariates.
‡ M for massage, S self-care, A for acupuncture.

Adverse effects:

No serious side effects were reported for any of the treatments given.

Cost:

<table>
<thead>
<tr>
<th></th>
<th>Acupuncture</th>
<th>Massage</th>
<th>Self-care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean(SD) cost/patient</td>
<td>$352 ($138)</td>
<td>$377 ($139)</td>
<td>$ 50</td>
</tr>
</tbody>
</table>
Authors’ Conclusions:
The authors concluded that the results of the study indicate that, “Massage is an effective short-term treatment for chronic low-back pain, with benefits that persist for at least one year.” The authors noted that the effect of the self-care material provided to the patients was almost similar to that of massage by the end of the year. They pointed out that the protocol of the study limited the acupuncturists to using only one form (TCM) of therapy, thus the effect of other treatments was not studied. Another limitation the authors pointed to, was that the study did not compare the treatments provided to “no treatment.”

The authors also listed several elements through which massage therapy could produce its effect, and recommended further research to determine these components, as well as the effects of other forms of acupuncture.

Reviewer’s Conclusions:
Agrees with the authors’ conclusion. One issue of note is the non-blinding of patients and providers, which may be a potential source of bias.