Effect of intensive acupuncture on pain-related social and psychological variables for women with chronic neck and shoulder pain— an RCT with six month and three year follow up

Dong He, Arne T Høstmark, Kaj Bo Veiersted, Jon Ingulf Medbø

Abstract

Objectives This study examines whether intensive acupuncture treatment can improve several social and psychological variables for women with chronic pain in the neck and shoulders, and whether possible effects are long-lasting. The effects on pain have been reported elsewhere.

Methods Twenty-four female office workers (47±9 years old, mean ± SD) who had had neck and shoulder pain for 12±9 years, were randomly assigned to a test group or a control group. Acupuncture was applied 10 times during three to four weeks either at presumed acupuncture points for pain (test group) or at sham points (control group). In addition, acupressure was given to patients between treatments, at either real or sham points. Questionnaires for social and psychological variables were completed before each treatment, just after the course, and six months and three years later.

Results The pain-related activity impairment at work was significantly less in the test group than the controls by the end of treatment (P<0.04). Also there were significant differences between the groups for quality of sleep, anxiety, depression and satisfaction with life (P<0.05). At six months and three years follow ups the acupuncture group showed further improvements in most variables and was again significantly different from the control group.

Conclusion Intensive acupuncture treatment may improve activity at work and several relevant social and psychological variables for women with chronic pain in the neck and shoulders. The effect may last for at least three years.

Keywords

Acupuncture, neck pain, shoulder pain, sleep, work, depression, quality of life.

Introduction

Chronic neck and shoulder pain is a common medical and social problem, especially among women. A survey showed that 13% of the Norwegian working population had reported moderate or severe work-related neck and shoulder pain during the preceding two weeks,1 and in 2002 neck and shoulder pain cost the national insurance NOK 1625 million (ca £150m, € 200m) in sickness benefit.2,3 This kind of chronic pain may affect the ability to work, and has not only physical but also psychological and social effects that can reduce the quality of life. Patients with chronic pain often experience pain-related depression, irritability, and loss of mobility and their daily activities are inhibited.4–5

Acupuncture treatment is commonly used in the treatment for chronic neck and shoulder pain.6 Nevertheless, only a few studies have examined possible effects of acupuncture on chronic neck and shoulder pain, and few of these have examined whether acupuncture may improve activities, the quality of sleep and consequently tiredness, pain-related quality of life, and other psychological parameters that may be related to chronic pain.7,8 No study seems to have evaluated possible correlations between reduced pain and the pain-related social variables mentioned above with respect to acupuncture treatment. Moreover, most of the studies lack a long-term follow up after the treatment.
We have already reported the results of a six month and a three year follow up study on the effects of intensive acupuncture treatment on pain in sedentary women with chronic neck and shoulder pain. The current report focuses firstly on whether acupuncture treatment can improve pain-related activity impairments at work and at home, pain-related quality of sleep and other psychological parameters like self-reported frequency of depression, the degree of tiredness, irritability and satisfaction with life for women with chronic neck and shoulder pain. Secondly, we have looked at whether there were possible relationships between the effects of acupuncture on reduced pain and pain-related social variables. Finally, we have examined whether possible effects were long lasting.

Methods

Subjects

Altogether 24 female office workers with chronic pain in the neck and shoulder region volunteered for the study. The patients were recruited from five large companies in Oslo by the occupational physicians who applied our inclusion criteria. The participants received information about the purpose of the study and the treatment procedure. We recruited women between 20 and 50 years old who worked in sedentary occupations or in light repetitive activities. Their perceived pain in the neck and shoulder region had to be so severe that their work and spare time activities were affected, but none of the patients were on sick leave at the start of the study. Their ‘chronic pain’ had to have been experienced for at least three months during the previous year. People with diabetes, neurological, rheumatologic or other diseases were excluded, as were pregnant and breastfeeding women. It was also required that none of the patients received any other form of treatment for chronic pain or any other acupuncture treatment during the period of our treatments. The Ethics Committee for Health Region II in Norway approved the study design.

The patients were divided by complete randomisation (ie randomisation by drawing with replacement) into two groups, referred to as the test group (TG) and the control group (CG). The general characteristics of the patients are shown in Table 1.

Outcome measures

Three questionnaires, A, B and C, were used to collect baseline information and evaluate the effects of the acupuncture treatment. In questionnaire A, completed at baseline, 25 questions focused on the personal background, wellbeing and history of pain. The participants received information about the purpose of the study and the treatment procedure. We recruited women between 20 and 50 years old who worked in sedentary occupations or in light repetitive activities. Their perceived pain in the neck and shoulder region had to be so severe that their work and spare time activities were affected, but none of the patients were on sick leave at the start of the study. Their ‘chronic pain’ had to have been experienced for at least three months during the previous year. People with diabetes, neurological, rheumatologic or other diseases were excluded, as were pregnant and breastfeeding women. It was also required that none of the patients received any other form of treatment for chronic pain or any other acupuncture treatment during the period of our treatments. The Ethics Committee for Health Region II in Norway approved the study design.

The patients were divided by complete randomisation (ie randomisation by drawing with replacement) into two groups, referred to as the test group (TG) and the control group (CG). The general characteristics of the patients are shown in Table 1.

Table 1  Baseline characteristics of the subjects in the test group (TG) and the control group (CG).

<table>
<thead>
<tr>
<th></th>
<th>TG</th>
<th>CG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Age, yr</td>
<td>49 ± 8</td>
<td>45 ± 10</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>63 ± 10</td>
<td>68 ± 9</td>
</tr>
<tr>
<td>Height, cm</td>
<td>165 ± 7</td>
<td>168 ± 4</td>
</tr>
<tr>
<td>Education, yr</td>
<td>12 ± 2</td>
<td>12 ± 3</td>
</tr>
<tr>
<td>Work, h/wk</td>
<td>36 ± 5</td>
<td>33 ± 6</td>
</tr>
<tr>
<td>Working on computer, h/d</td>
<td>5.8 ± 1.8</td>
<td>4.7 ± 1.6</td>
</tr>
<tr>
<td>Length of pain, yr</td>
<td>12 ± 8</td>
<td>12 ± 10</td>
</tr>
<tr>
<td>Total days of pain /wk</td>
<td>4.3 ± 0.7</td>
<td>4.5 ± 0.7</td>
</tr>
<tr>
<td>Exercise, h/wk</td>
<td>2.9 ± 2.8</td>
<td>2.2 ± 3.1</td>
</tr>
</tbody>
</table>

The values are means ± SD.
degree of tiredness, depression, and satisfaction with life were measured on a 10cm visual analogue scale (VAS). The depression and anxiety were self reported and not assessed by a physician.

The intensity and frequency of pain and headache were also scored, both since the last treatment and compared with the state before the first treatment. The patients’ cigarette consumption was also recorded since studies have shown that smoking is associated with chronic musculoskeletal pain.\textsuperscript{13,14} The patients also reported to what extent they carried out the ear acupressure described further below.

Questionnaire C, containing 17 questions, was answered at the two follow up visits. That questionnaire contained largely the same questions as questionnaire B, but it also included questions relating to pain and to the quality of life during the last month (six month follow up) or last six months (three year follow up).

\textbf{Interventions}

The acupuncture treatment was carried out by one of the authors (DH), who is a doctor of TCM educated in Beijing, with 15 years’ experience in acupuncture clinics in China and Norway. Besides clinical work, she has more than 10 years experience with acupuncture research.

The acupuncture used was based on Traditional Chinese Medicine (TCM).\textsuperscript{15-19} Chronic pain in neck and shoulders is defined as an ‘obstruction syndrome’ in TCM, and it is considered to be caused by invasion of pathological Cold, Wind and Dampness into the meridians, blocking the flow of qi.\textsuperscript{20} The acupuncture points used in the study were selected from the literature.\textsuperscript{16-18,20}

Both the literature and clinical experience suggest that the effect of acupuncture is stronger when combining different treatments, for example body acupuncture and ear acupressure.\textsuperscript{21} Therefore the acupuncture treatment used in this study was a combination of body acupuncture, body electrostimulation and ear acupressure.

Apart from the different point location and use of active electrostimulation, there were no differences in the treatment procedures between the two groups. The same acupuncture points were used for all patients in the TG, no matter whether the chronic pain was located in the neck, the shoulders, or both. Likewise the same sham points were used for all patients in the CG.

Each patient received three treatments per week to a total of 10 treatments over a period of three to four weeks. Each treatment lasted 45 minutes.

Altogether 16 body acupuncture points and six ear acupuncture points were used (Table 2). The TG received real acupuncture or electrostimulation treatment to points considered appropriate for chronic pain in the neck and shoulder region.\textsuperscript{16-18,20} First,

\begin{table}[h]
\centering
\begin{tabular}{|l|l|}
\hline
\textbf{Type of acupuncture} & \textbf{Acupuncture points (number used)} \\
\hline
Body electrostimulation & Jingjiaji (4), ExHN* \\
& Jianjing (2), GB21 \\
& Fengmen (1), BL12 \\
& Dazhui (1), GV14 \\
& Jianzhongshu (1), SI15 \\
& Jianwaishu (1), SI14 \\
\hline
Body acupuncture & Hegu (2), LI4 \\
& Quchi (2), LI11 \\
& Fengshi (2), GB31 \\
\hline
Ear acupressure & Shenmen (1) \\
& Neck (1) \\
& Cervical spine (1) \\
& Shoulder (1) \\
& Shoulder joint (1) \\
& Shoulder-back (1) \\
\hline
\end{tabular}
\caption{Acupuncture points (total number) used for the test group.}
\end{table}

\*Extra points at C4 and C5 level, 0.5 cun from midline.
stimulation was given through the flat electrodes of the instrument (JJ205; Shenzhen Star Technology and Shanxi Pingyao Poyi Instrument Manufacturer, Shanxi, China) placed on the acupuncture points of the neck and shoulder area. The pulse width was 100µs and the amplitude 170-200V, followed by a reversed current decaying exponentially over 10ms. The stimulation was given for 30 minutes at 5Hz. After starting electrostimulation, sterile acupuncture needles 25-40mm long and with a diameter of 0.25-0.35mm (Huatuo, needles for single use, Suzhou Medical Instruments Factory, Suzhou, China) were inserted bilaterally in three body points (see Table 2) to a depth of 10-30mm. The needles were retained for 30 minutes and rotated every 5 minutes. 13;14;16-18

After the electrodes and needles were removed, plant seeds (Wangbuliuxingzi, Beijing, China) were placed on six ear acupuncture points for acupressure. Each seed was kept in place by a piece of 6mm by 6mm tape until the next treatment. The patients were instructed to press on each of the ear acupuncture points 100 times, repeated four times per day. 17

The CG received sham acupuncture treatment. The electrostimulation pads were attached without applying any voltage; the instrument emitted short beeps giving an audible signal as if pulses had been sent. The body acupuncture was applied to points 10-40mm distal to the appropriate acupuncture points, and ear acupressure was applied on points 4-6mm below the appropriate acupuncture points. The sham acupuncture was thus not applied at any known acupuncture points.

**Statistical analysis**

The results are presented as mean (standard error of mean (SEM) unless otherwise stated explicitly. Univariate tests of statistical significance were carried out by Student's matched-paired (within group, denoted $P_w$) and two-sample t tests (between TG and CG, denoted $P_b$). Possible association in changes in scores of two parameters were examined by Pearson’s correlation coefficient.

**Results**

Altogether 24 women were enrolled in the study, and no one dropped out during the treatment period or at the two follow up observations. There were no statistical differences between the two groups (TG and CG) for any parameter measured before the first treatment. The patients smoked on average seven cigarettes daily, and there was no difference between the two groups ($P_b>0.6$) and no significant changes during the study period. None of the patients depended on health insurance contribution or applied for such support, and all earned their own living. The patients exercised on average two to three times monthly, but 10 out of the 24 patients reported that they did not train regularly. At the three year follow up, the patients in TG exercised 3.3 times monthly, but the patients in the CG exercised significantly less at 1.4 times per month ($P_b=0.05$).

There was no difference between the groups’ reported use of ear acupressure during the treatment period (TG 3.43±0.08 times/day, CG 3.58±0.07 times/day, $P_b=0.18$). During the three years follow up period five patients in the CG and three in the TG had once received other treatments (two CG patients had cupping, two physiotherapy and one psychotherapy; two in the TG had physiotherapy and one homeopathy). No patient received more than one treatment, and we believe that these treatments are unlikely to have influenced the outcome. It should also be noted that the patients in the CG received more treatments than those in the TG, which would tend to reduce the differences between the two groups.

The quality of sleep improved in the TG but only at the last two measurements during treatment (Figure 1a, $P_w<0.002$). In CG, quality of sleep remained constant through treatment ($P_w=0.94$). The scores differed between the two groups after the ninth treatment ($P_w<0.01$) and at the two follow ups ($P_w<0.03$).

The mean score for pain-related activity impairment at work (Figure 1b) improved in TG from 31% to 22% reduction during the first half of the treatment period and a further 12% by the end of the treatments ($P_w<0.001$). The improved state was maintained at both follow ups ($P_w<0.002$). The activity of the CG tended to improve during the latter half of the treatment period (to a 20% reduction; $P_w=0.06$), but the state returned to the pre-treatment level in the follow up ($P_w>0.2$). The value differed significantly between the two groups only at the follow up three years after treatment ($P_w=0.04$).

The pain-related activity impairment at home (Figure 1c) improved in both groups during the treatment ($P_w<0.03$). While improvement was
Figure 1  (a, upper panel) Self-reported quality of sleep (b, middle panel) pain-related activity impairment at work and (c, lower panel) pain-related activity impairment at home at baseline (B), after each treatment (T1-T10) and six months (6mo) and three years (3yr) after the treatments for the test group (TG) and the control group (CG). The data are mean ± SEM for 14 (TG) and 10 (CG) patients; * denotes a statistically significant difference between the two groups.
Figure 2  (a, upper panel) Self-reported degree of anxiety and irritability, (b, middle panel), frequency of depression, and (c, lower panel) degree of satisfaction with life before the first treatment (B), after each treatment (T1-T10) and six months (6mo) and three years (3yr) after the treatments for the test group (TG) and the control group (CG). The data are mean ± SEM for 14 (TG) and 10 (CG) patients; * denotes a statistically significant difference between the two groups.
maintained at the follow ups for the TG (P<0.004), the value for the CG returned to the pre-treatment level after three years (P=0.66), at which point there was a significant difference between groups (P=0.03).

Anxiety and irritability scores (Figure 2a) reduced rapidly in both groups (P≤0.01). There was a difference between groups after the sixth treatment (P<0.02) and during the two follow up periods (P=0.02). The scores for depression improved for both groups (Figure 2b), with a significant difference between them during the latter part of the treatment period (P=0.04). The improvement was maintained in TG but not CG during follow up. The rating of satisfaction with life showed significant superiority in TG at the eighth treatment (Figure 2c) and at follow ups (P<0.01 at six months).

The patients in the TG reported that they felt significantly less tired than CG at six months and three years (P=0.008). They also reported less headache during the treatment period (P=0.02) and at the three years follow up (P<0.001).

The change in the frequency of pain correlated with the changes in headache, the quality of sleep, the satisfaction with life and the pain-related activity impairment at home, both after the treatments and at the six months follow up (r=0.47, P<0.03). The change in the pain-intensity correlated with the changes in the degree of anxiety and irritability, and the satisfaction with life (r=0.46, P≤0.03). At the two follow ups the changes in the quality of sleep correlated with most of the other variables, like the changes in the frequency of pain, the degree of headache, the degree of depression, the pain-related activity impairment at work and at home (P<0.02). Three years after the treatments the subjects’ working hours on computer correlated with most of the variables observed too (r=0.50, P≤0.02).

Discussion
The main finding in this trial is that intensive acupuncture treatment can improve the pain-related activity impairment at work for patients with chronic pain in the neck and shoulders (reported elsewhere). In addition, the group who received acupuncture scored significantly less on pain-related activity impairment at home at follow ups. Moreover, the treatment also recorded improvements in quality of life, such as the quality of sleep, the degree of tiredness, and the degree of anxiety, irritability and self-reported depression. The observed changes correlated positively, suggesting that there may be a common underlying cause. The effects either persisted to the follow ups, or they were first seen at the follow ups.

Earlier studies have found positive correlations between chronic pain and psychological distress and dysfunctional cognitions among patients. According to the theory of Traditional Chinese Medicine the physical state of a patient is always correlated with her or his psychological state, and our results are in line with these findings. Since the positive effects of our acupuncture treatment appear to have lasted for at least three years, acupuncture may reduce the burden of illness.

Few studies to our knowledge have looked at whether acupuncture treatment for pain may improve the patients’ activity at work and at home, the quality of sleep, the degree of tiredness and other social variables related to the quality of life. These issues are important since these variables are important for wellbeing. Our results are in line with some previous studies. Junnila used individual body acupuncture treatment for more than 300 patients with chronic pain, measuring possible long-term effects, and found that 87% of the patients with chronic pain in the neck and shoulder region experienced an improved working activity after the treatments. In particular, the 5% of the patients who were unable to work before treatments returned to work after the treatment period. Strauss reported that half of patients with chronic head and neck pain reported improved sleep after classic body acupuncture treatment on 6-10 acupuncture points, and one third of the patients reported normal sleep. Another study examining effects of acupuncture on chronic low back pain showed that acupuncture improved the return to work and the quality of sleep immediately after the treatment period and six months later. The control group who received mock transcutaneous electrical nerve stimulation (mock TENS) treatment showed no such effects. Sator-Katzenschlager et al found that the quality of sleep and the psychological wellbeing improved for chronic cervical pain patients who received both needle ear acupuncture and electrical ear acupuncture, but not for the patients who received only ear acupuncture treatment.

On the other hand, Karst et al found no effect on
the quality of life for their patients when using acupuncture treatment for tension-type headache. However, the treatment group showed a higher pain threshold six weeks after the acupuncture treatments. In a study of acupuncture for patients with chronic low back pain, Kerr et al reported that the quality of life improved after six sessions of mock TENS, whereas there were no other significant differences between acupuncture and mock TENS groups. As discussed in more detail elsewhere, it may be that the treatments given were not of sufficiently high frequency and intensity to be effective.

The time course of acupuncture’s effect and possible placebo effects

Several of the effects of acupuncture, for example on pain-related activity impairment at work, were not significantly different from the CG until towards the end of treatment, and in many cases they were greater at the six months and three years follow ups. One interpretation of this is that the placebo effects (common to both groups) may have lasted up to several weeks, even up to about six months after the treatments.

Another interpretation is that acupuncture has cumulative effects, and changes are not seen until an adequate course of treatment has been given. For example, quality of sleep, which was reduced in all of our patients because of their pain in the neck and shoulders, was not improved until eight acupuncture treatments had been given. These considerations suggest that at least 10 treatments should be given within three to four weeks to get an improvement on this parameter. Clinical experience from China in acupuncture treatment for insomnia suggests that patients require at least 15-20 treatments and in some cases as many as 30 treatments to get positive effects.

Psychological variables like depression, the degree of anxiety and irritability, and satisfaction with life showed a similar pattern concerning the effect of the acupuncture treatment. More specifically, it took at least six to seven treatments before there were any differences between the two groups, and the largest differences between the groups were seen at the two follow ups. It thus appears that a possible placebo effect on these psychological variables in the control group disappeared within six months, and it was not as strong as that seen for the pain-related activity impairment.

Most studies on the possible effects of acupuncture treatment, no matter what kind of diseases or problems that have been addressed, lack a follow up of several years. We addressed earlier the importance of a long-term follow up. There may have been a placebo effect for several of the parameters in the present study. If so, that further emphasises the importance of long-term follow up.

A proposed model for the effect of acupuncture

The changes in the reported pain correlated with the changes in their patients’ daily activity, with their overall satisfaction with life. This suggests that acupuncture may have a cumulative effect, and that an adequate course of treatment is necessary to achieve significant improvements.

Figure 3  Proposed model for how acupuncture may improve the subjects’ daily activity and reduce their reported depression.
changes in the degree of depression, anxiety and irritability, with their satisfaction with life, and also with their quality of sleep. Correlations indicate an association, not necessarily a cause-and-effect-relationship. We therefore propose the following model for how acupuncture may improve the patients’ state (Figure 3).

More specifically, we suggest that acupuncture given at acupuncture points for pain reduces the intensity and frequency of pain, particularly in the neck and shoulder region, and also the degree of headache. Reduced pain may lead to less experience of depression, and that may again improve sleep, and enable the patients to do more work. It may also be that, once a patient’s activity at work and at home is increased and the sleep is better, they become less depressed, and that improved state can again feed back, leading to a reduction in perceived pain. This model may perhaps explain why the beneficial effects seen for the TG could last for at least three years after the last treatment. The acupuncture treatment given may in other words have broken a vicious cycle accompanying chronic pain, thereby counteracting depression and a reduction in the patients’ activities.

**Methodological questions**

The acupuncturist was aware of what kind of treatment each patient was given, but the patients were not, and the study was thus ‘single blind’ in that respect. Apart from the different acupuncture points (TG) or sham points (CG) used for the two groups, all patients were treated as equally as possible in the treatment procedures used (time of each treatment, the number of points used and so on), and in the communications with the acupuncturist. The lack of ‘double blinding’ in this study may not be a big problem. Other issues of the experimental design, such as the treatment intensity and number of acupuncture points used have been addressed elsewhere.

**Conclusion**

Our results, even though based on a relatively small group, suggest that intensive acupuncture treatment for women with chronic pain in the neck and shoulders may improve the pain-related activity impairment at work and at home (reported elsewhere), the quality of sleep, and several important variables of wellbeing and quality of life, and the effect may last for three years.

**Acknowledgments**

He Dong has had a PhD scholarship from the Norwegian Research Council. We thank doctors John Berg, Charite Bonnevie, Helle Laier Johnsen, Unni Gunvaldsen, and Geir Riise who recruited patients for the study. We thank Doctor Zhang Bao Jian for his recommendations on the acupuncture treatment and Professor Zhang Qi Yuan for her advice when preparing the manuscript. We finally thank Ingvild Dalen for her statistical advice.

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*Acupunct Med* 2005 23: 52-61
doi: 10.1136/aim.23.2.52

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