Health-related quality of life in patients with musculoskeletal complaints in a general acupuncture practice: an observational study

Ineke van den Berg,1,2,3 Loek Tan,1 H van Brero,4 K Tinka Tan,5 A Cecile J W Janssens,1 M G Myriam Hunink1,2,6

ABSTRACT
Background Musculoskeletal complaints are associated with a large medical and societal burden. Although acupuncture is a frequently used therapy for musculoskeletal complaints, little is known about the effect on health-related quality of life (HRQoL).

Objectives The aim of this study was to (i) compare the HRQoL of patients undergoing routine acupuncture treatment for musculoskeletal complaints with a Dutch population sample; (ii) investigate changes in HRQoL during the course of acupuncture treatment.

Methods An observational study of 26 patients between 18 and 65 years of age in a single acupuncture practice was performed. HRQoL was measured on eight functional domains using a RAND-36 health survey at baseline and after six and 12 treatment sessions. Baseline RAND-36 scores were compared to data from a Dutch population sample (n=1063) using t test, and longitudinal data were analysed using repeated measurement analyses.

Results At baseline, patients had significantly lower RAND-36 scores compared to the Dutch population sample for three domains: role-physical limitations (51.9 vs 79.4; p<0.001), bodily pain (49.3 vs 79.5; p<0.001) and social functioning (75.5 vs 86.9; p=0.005). During the course of treatment, RAND-36 scores increased significantly for five domains: physical functioning (79.3 vs 97.4; p<0.001), role-physical functioning (51.4 vs 79.5; p<0.001), bodily pain (47.3 vs 95.7; p<0.001), social functioning (74.5 vs 92.0, p<0.001) and vitality (69.1 vs 85.7; p<0.001).

Conclusion The observed improvements in HRQoL suggest a subjective, clinically relevant, benefit of routine acupuncture therapy in treating musculoskeletal complaints.

INTRODUCTION
In Western countries, musculoskeletal complaints are an important cause of disability, morbidity,1 absence from work2 and increased healthcare costs.3 4 In a large population-based study in The Netherlands, 75% reported having had musculoskeletal complaints during the past year and 44% reported chronic musculoskeletal pain.1 About half of these people contacted a health professional for their symptoms, which indicates a large demand on healthcare services.

Although the number of patients using acupuncture in Western countries is growing,5–7 and musculoskeletal complaints are common in acupuncture practice,8 little is known about the outcome of acupuncture in a general acupuncture practice in treating musculoskeletal complaints and preventing its consequences. Several randomised controlled trials (RCTs) have demonstrated evidence for the reasonable efficacy of acupuncture in pain-relief and disease-specific outcomes for a variety of musculoskeletal conditions such as chronic lower back pain, chronic neck pain, knee and hip osteoarthritis.9–13 RCTs generally only collect limited data, but for clinical relevance it is also important to know whether patients’ lives improve.

Two German observational studies have demonstrated subjective beneficial effects of routine acupuncture practice for osteoarthritic pain and routine acupuncture practice by showing clinically relevant improvements in health-related quality of life (HRQoL) over time, that is, in general, patients are very satisfied, not only with the treatment, but also with the effects of the treatment.8 14 These studies, however, offer limited information on the additional benefit of acupuncture for musculoskeletal complaints in other countries, because in Germany, a non-conventional therapy such as acupuncture is reimbursed by statutory sickness funds.15

The purpose of this study was to investigate in an observational study the effect of acupuncture on HRQoL in treating musculoskeletal complaints. We compared HRQoL profiles of patients seeking acupuncture treatment for musculoskeletal symptoms with HRQoL profiles of a Dutch population sample before and after treatment, and investigated changes in HRQoL during the course of acupuncture treatment. We expected a lower HRQoL prior to the treatment compared to the general population and an effect of acupuncture on
HRQoL, but we had no prior hypotheses about the magnitudes of the effects.

METHODS
Patients
This observational study was performed in the Northwestern region of The Netherlands, between September 2002 and September 2003. Patients in this study visited the routine acupuncture clinic (http://www.acupunctuur-vanbrero.nl/) on their own initiative. All consecutive patients (age 18–65 years), who had musculoskeletal complaints eligible for acupuncture treatment, had no previous experience of acupuncture and gave written informed consent, were included. Excluded were pregnant or breastfeeding women, patients suffering from a terminal disease, patients receiving any other form of treatment for their complaints besides self-medication and patients participating in another clinical study. Patients were diagnosed and treated by the licensed acupuncturist (HvB) according to a Dutch social insurance classification system which is based on the 10th edition of the International statistical classification of diseases and related health problems (ICD-10) from the World Health Organization. Data were collected according to guidelines for registration of personal data.

Controls
Data from a community survey were used to compare the health status of the study-population. The controls (1063 persons, age range 18–89) were randomly selected from the population register of a comparable area as the treated persons were participants of this population-based Dutch RAND-36 validation study.

Intervention
A licensed acupuncturist, with over 30 years of working experience, performed all acupuncture treatments. All participants were treated according to the principles of traditional Chinese medicine (TCM), meaning that the treatment frequencies as well as the number of needles and the used acupuncture points were determined individually for each patient and were adjusted to the patients’ TCM profile during the course of therapy. On average, eight needles were used with a range of two to 12 needles per session. The treatment end point was 12 individualised sessions.

Outcome measurement
HRQoL was measured using a validated Dutch language version of the RAND-36-item health survey 1.0 (RAND-36) which was adapted from the standardised short form (SF)-36 health survey. Physical and mental health summery scores were derived from the eight RAND-36 scales: physical functioning, role functioning limitations due to poor physical health, bodily pain, general health, vitality, social functioning, role functioning limitations due to mental and poor emotional health. The SF-36 is designed for use in populations, not for drawing conclusions about HRQoL status at the individual level, as MYMOP and NHQ are. HRQoL was measured before the start of the first acupuncture treatment (baseline measurement) and immediately after six and 12 treatment sessions. Additionally, patients were asked for the duration of their symptoms on the basis of which they were categorised into either acute (symptoms present <3 months) or chronic (symptoms present >3 months) patients. The Medical Ethics Committee Erasmus MC gave a declaration of no objection for publication (MEC-2009-422).

Statistics
Scores for each scale of the RAND-36 were computed from the raw data according to the Dutch language version RAND-36 guidelines. For each scale, responses to the corresponding survey-items were summed and converted to a 0–100 scale, in which 100 indicates the best possible functioning. Differences in age and sex distribution between the study sample and the general population sample were tested using t test and \( \chi^2 \) test. Mean baseline RAND-36 scores were compared with the Dutch population, and compared between patients with acute and chronic symptoms using t tests. To evaluate the clinical relevance of the mean RAND-36 changes, differences of >5 points were considered as clinically relevant.

To assess the course of HRQoL over time, the longitudinal data were analysed using a mixed model analysis for repeated measurements. With this procedure, the contribution of the within-subject variation was taken into account and participants with incomplete follow-up data were included in the analysis. We examined the overall course over time for each scale by comparing estimated means using a mixed model analysis with the number of treatment sessions (0, 6 and 12), age and sex as covariates. The estimated means at treatment 12 were compared to the Dutch population sample and tested using t tests.

We also explored differences in HRQoL between acute and chronic patients at baseline by comparing the mean RAND-36 baseline scores using t tests. We additionally performed an exploratory analysis of differences in HRQoL changes over time between chronic and acute patients by adding duration of symptoms and the interaction effect of duration of symptoms treatment in the repeated measurements analysis. Bonferroni correction was used to adjust for testing all eight scales of the RAND-36, resulting in the use of a significance level of \( p<0.006 \) (0.05/8) for all tests we performed. t Tests and \( \chi^2 \) tests were performed using SPSS V.11 and longitudinal analyses were performed using the SAS Proc Mixed procedure in SAS V.9.13.

RESULTS
Characteristics of the study population
In total, 26 patients who met the inclusion criteria agreed to participate in the study. All completed the first and second assessments and 23 patients (88.5%) completed the third assessment. No adverse events were reported. Seventeen patients (65%) received treatment for chronic symptoms.
and nine (35%) for acute symptoms. Table 1 shows that 58% of participants were women, and mean age of 42.6 years (range 22–62), which was not significantly different from the Dutch population sample (65% women, mean age 44.1 years, range 18–89). The mean treatment period was 6.9 weeks between baseline and the sixth treatment session and 8.4 weeks between the sixth and the 12th treatment session (table 1). Treatment consisted of 12 sessions with an average duration of 30 min, administered over an average period of 14 weeks.

### Health-related quality of life

At baseline, the total study sample had significantly lower scores on the RAND-36 scales role-physical functioning (51.9 vs 79.4; p<0.001), bodily pain (49.5 vs 79.5; p<0.001) and social functioning (75.5 vs 86.9; p=0.005) compared to the Dutch population sample (figure 1 and table 2). No significant differences between both populations were found for the other RAND-36 scales.

Five out of eight RAND-36 scales showed significantly higher scores after treatment compared to baseline (table 2) physical functioning, role-physical functioning, bodily pain, social functioning and vitality. The mean RAND-36 scores after treatment were higher than the Dutch population sample scores for all eight RAND-36 scales (figure 2). The difference was statistically significant for the physical functioning (p<0.001), bodily pain (p<0.001), general health (p<0.001) and mental health scores (p=0.001).

### Acute versus chronic patients

Baseline RAND-36 scores for acute patients were 15 points lower for bodily pain on role-physical functioning scores compared to chronic patients, but differences between acute and chronic patients were only statistically significant for the differences in bodily pain scores (p<0.05). The improvement in the five out of eight RAND-36 scales reported in table 2 was observed in both acute and chronic patients.

### DISCUSSION

We compared HRQoL of patients undergoing routine acupuncture treatment for musculoskeletal complaints to the normal population and described the perceived changes in physical and mental health during the course of acupuncture treatment. Patients with musculoskeletal complaints had lower RAND-36 scores on role-physical functioning, bodily pain and social-functioning at baseline, significantly improved HRQoL during treatment on five out of eight scales and had higher RAND-36 scores at follow-up on all scales compared to controls.

Before discussing our results, two important methodological issues need to be addressed. First of all, it is important to keep in mind that the design of this study does not permit any causal inferences concerning the effect of acupuncture itself, since no control group of patients was evaluated longitudinally to assess the impact of possible placebo effects, as patients went to the acupuncture clinic on their own initiative, likely with a prior open view regarding the effectiveness of acupuncture.

Second, the small number of patients provided us with insufficient statistical power to incorporate possible confounding factors in our model or compare the age and sex distribution between groups in more detail. Also, we had limited statistical power for the exploratory analyses of differences between acute and chronic patients and for other clinically interesting comparisons. While the statistical power increased by using the repeated measurement procedure with three measurements per patient, still the possibilities for subgroup analyses were limited.

Our study demonstrated that the HRQoL of patients seeking acupuncture treatment for musculoskeletal symptoms differed significantly from the normal population. At baseline, HRQoL of both acute and chronic patients was lower on the RAND-36 role-physical functioning, bodily pain and social functioning scales compared to the Dutch population sample. The difference was most prominent for the physical health dimensions (role-physical functioning and bodily pain). These findings are similar to results from a previous study in patients suffering from...
**Table 2** Health-related quality of life in a general acupuncture practice at baseline and after 6 and 12 treatments

<table>
<thead>
<tr>
<th>RAND-36 scales</th>
<th>Baseline (SE)</th>
<th>After 6 treatments (SE)</th>
<th>After 12 treatments (SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td>79 (2.3)</td>
<td>93 (1.5)</td>
<td>97 (0.9)</td>
</tr>
<tr>
<td>Role-physical functioning</td>
<td>51 (6.8)</td>
<td>81 (5.6)</td>
<td>94 (5.3)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>47 (4.3)</td>
<td>84 (2.9)</td>
<td>96 (1.7)</td>
</tr>
<tr>
<td>General health</td>
<td>83 (3.7)</td>
<td>85 (4.0)</td>
<td>86 (3.5)</td>
</tr>
<tr>
<td>Mental health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitality</td>
<td>69 (4.9)</td>
<td>81 (3.9)</td>
<td>86 (4.3)</td>
</tr>
<tr>
<td>Social functioning</td>
<td>75 (4.9)</td>
<td>91 (4.3)</td>
<td>92 (4.6)</td>
</tr>
<tr>
<td>Mental health</td>
<td>84 (2.9)</td>
<td>87 (3.2)</td>
<td>89 (3.7)</td>
</tr>
<tr>
<td>Role-emotional functioning</td>
<td>96 (4.2)</td>
<td>97 (4.3)</td>
<td>95 (4.9)</td>
</tr>
</tbody>
</table>

Values are mean RAND-36 scores, as estimated by SAS Proc Mixed analyses, with standard errors.

The longitudinal findings of this study showed that the HRQoL of patients seeking routine acupuncture improved significantly during the course of treatment. This improvement in physical and mental health during the course of acupuncture treatment concerned the dimensions physical functioning, role-physical functioning, bodily pain, social functioning and vitality. The observed improvements were most pronounced in the course of the first six treatments for both acute and chronic patients. Although it is unusual that both acute and chronic patients require the same number of treatments, the researcher chose this fixed number in both groups for statistical reasons to deal with the small number of patients in the treatment group. For all RAND-36 scales, the observed improvement was larger than the five points considered clinically relevant.

The most distinct improvements were observed with regard to the scales role-physical functioning, bodily pain and social functioning, indicating that the largest improvements were symptom-related. Importantly, for these RAND-36 scales—in which a lower score compared to the Dutch population sample was found at baseline—the scores after treatment were higher than the scores of the Dutch population sample. In the Dutch population sample the age was older and therefore might reduce their HRQoL scores. However, given that the mean age is the same and that the very old are only a small part of the total sample, we think it is unlikely that the differences are only explained by an effect of age. Considering the normal baseline results compared to the population sample, the observed improvements with regard to the RAND-36 scale physical functioning was significantly higher than the mean score of the Dutch population sample. It should be noted that the better health on all scales compared to the general population may be due to response shift, which is defined as an adaptation to changing health, a beneficial mental process that can help in adapting to a new situation. Response shift is more likely to occur when the disease experience is new, intense or pervasive. Two-thirds of our population had long lasting musculoskeletal complaints, who may no longer expect improvement of musculoskeletal pain who did not visit an acupuncturist for their symptoms, suggesting that patients who seek acupuncture treatment are not a subgroup with particular HRQoL profiles, neither physically nor mentally.
their symptoms. All the patients were treated by the same acupuncturist what might affect the generalisability of our findings.

The understanding of the holistic model of acupuncture treatment embedded in Chinese medicine is limited by a lack of inquiry into the dynamics of the process where “the whole is greater than the sum of the parts.”28-31 Paterson and Britten22 found that treatment effects were perceived as changes in symptoms, changes in energy and changes in personal and social identity. After treatment, the study population had a significantly higher score on the RAND-36 scales for general health and mental health as compared to the general population. The longitudinal results of this study suggest that patients experience acupuncture as relevant for their recuperation, also supported by the fact that the majority of the study population completed the full course of 12 treatment sessions, even though acupuncture is often only partially reimbursed after prescription and often leads to private expenses.

Our findings support the view that acupuncture therapy has beneficial effects in patients with musculoskeletal complaints. This is in concordance with the findings of two previously mentioned observational studies that reported beneficial effects of acupuncture on HRQoL8 14 and with a variety of RCTs on the efficacy of acupuncture in treating musculoskeletal complaints.9 10 12 13 33 34 In order to obtain a more accurate and robust evidence for the role of acupuncture in daily practice with regard to musculoskeletal complaints and its consequences, more extensive randomised controlled research is needed. For instance, we suggest conducting a large controlled study on the usefulness of acupuncture across multiple acupuncture practices and for specific musculoskeletal complaints. Also, the characteristics of patients that seek acupuncture treatment for musculoskeletal complaints need to be addressed in detail. Furthermore, it seems necessary to assess whether the apparent benefit patients obtain from acupuncture treatment also translates to less disability, morbidity and absence from work and healthcare expenses in the long term.

In conclusion, this study demonstrated that patients who sought acupuncture treatment for musculoskeletal complaints in an out-patient acupuncture clinic showed a lower HRQoL at baseline, mainly with respect to physical domains. During the course of acupuncture treatments, patients experienced significant, clinically relevant improvement in HRQoL. Therefore, acupuncture should be considered as treatment option for patients with musculoskeletal complaints in general practice.

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Competing interests None.

Patient consent Obtained.

Ethics approval This study was conducted with the approval of the Medical Ethics Committee Erasmus MC who gave a declaration of no objection for publication (MEC-2009-422).

Summary points

- Standard assessments of quality of life include eight dimensions
- Twenty six patients with musculoskeletal disorders showed significant deficits in three dimensions
- Five dimensions showed improvement after a course of acupuncture

Provenance and peer review Not commissioned; externally peer reviewed.

Contributors HvB and KTT are the principal investigators of the study; they designed the protocol supervised its progress, and were involved in the acquisition of the data. HvB was involved in the planning of the study and the acquisition of the data. ACWJ and LT were responsible for the statistical analysis. HvB, ACWJ and LT drafted the manuscript. All authors contributed to the interpretation of the data, revisions of the paper, and read and approved the final manuscript.

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