

# Efficacy, effectiveness, safety and costs of acupuncture for chronic pain – results of a large research initiative

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## Abstract

**Background** The aim of the ‘Acupuncture Model Project of the Techniker Krankenkasse’ was to determine efficacy, effectiveness, safety and cost effectiveness of acupuncture treatment in standard medical care.

**Methods** We evaluated a total of 304 674 patients (34.5% men, aged 53.1±13.8 and 65.5% women, aged 49.5±14.2) who were in the care of over 10 000 physicians and received on average 10±3 acupuncture treatments for chronic pain (osteoarthritis of the hip or knee, low back pain, neck pain, headache) during a period of three months.

**Results and conclusions** Our findings demonstrate that for the diagnoses examined, acupuncture in addition to usual care was an effective and safe treatment. Whether the effects of acupuncture can be attributed primarily to specific or nonspecific mechanisms appeared to depend on the diagnosis, and should be investigated in further studies. Using acupuncture as an adjunctive treatment was more expensive than usual care alone, but was cost-effective according to internationally accepted threshold values.

## Keywords

*Acupuncture, safety, cost effectiveness, chronic pain, randomised controlled trial (RCT).*

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## Introduction

Patients frequently make use of acupuncture,<sup>1-3</sup> although it is not clearly evidence based. There is a particular shortage of data for the effectiveness of acupuncture in standard medical care.

In 2000 the German Federal Committee of Physicians and Health Insurers proposed that large research initiatives on acupuncture could be conducted by health insurance companies for several pain syndromes.<sup>4</sup>

As one of these research initiatives, we designed the present model project with the aim of evaluating efficacy, effectiveness, safety and cost of acupuncture treatment in patients with one of the following chronic medical complaints: pain due to osteoarthritis of the knee or hip, low back pain, neck pain or headache.

The following article outlines the concept and methodology of the project, introduces the main results, and discusses important implications. Based

in part on the results of this model project, the German Federal Committee of Physicians and Health Insurers proposed in April 2006 that acupuncture will be provided as a routine medical option in the treatment of pain due to osteoarthritis of the knee or chronic low back pain.

## Methods

In order to evaluate efficacy, effectiveness, safety and costs of acupuncture the model project consisted of three parts which complemented each other in content and methodology (see Figure 1).<sup>5</sup> The overall design of the model project included the following three parts:

### *Acupuncture Randomised Trials (ART)*

These studies determined the efficacy of acupuncture and were performed in cooperation with the Center for Complementary Medicine Research of the Technische Universität München, Munich, Germany

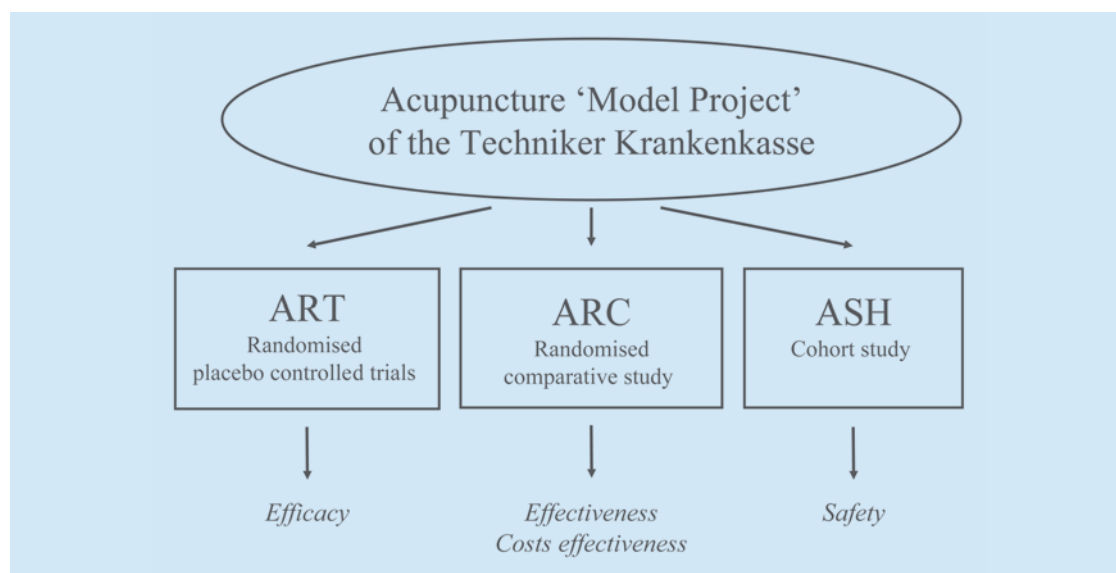


Figure 1 The design of the model project acupuncture: ART = Acupuncture Randomised Trial; ARC = acupuncture in Routine Care Studies; ASH = Acupuncture Safety and Health Economic Studies.

(Dieter Melchart, Klaus Linde) and investigated whether acupuncture was more effective than a) penetrating sham (minimal) acupuncture, and b) no acupuncture (waiting list control).<sup>6,7</sup> In four randomised, controlled, partially blinded studies we included patients with the following chronic diagnoses: low back pain, pain due to osteoarthritis of the knee, migraine and tension headaches.

Treatment for the acupuncture group involved deep needling of specific points following the principles of traditional Chinese medicine; for the non-acupuncture group it involved superficial needling of non-acupuncture points (for each group a total of 12 treatments over a period of two months). The waiting list control patients did not receive any acupuncture treatment until two months (three months in headache study) after randomisation. Assessment occurred at baseline, 2, 6 and 12 months (baseline, 12 weeks and 6 months in the headache study). The primary outcome measures for the clinical efficacy were assessed using the following validated questionnaires or methods:

- Low back pain: average pain during the last seven days measured on a visual analogue scale.<sup>8</sup>
- Osteoarthritis of the knee: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).<sup>9,10</sup>

- Tension-type headache or migraine: number of headache days documented in a diary.

#### Acupuncture in Routine Care Studies (ARC)

Four pragmatic randomised controlled studies with additional cohort studies evaluated the effectiveness of acupuncture in addition to usual care compared to usual care alone.<sup>11</sup>

Patients visiting their physician because of chronic low back pain, headache, pain due to osteoarthritis of the knee or hip, neck pain, who fulfilled predefined diagnosis-specific criteria and agreed to randomisation, were randomised into an acupuncture or a control group. Patients who rejected randomisation were included in a third non-randomised group. The patients in the acupuncture and non-randomised groups received acupuncture immediately (on average 10 sessions), the patients in the control group did not receive acupuncture until after three months. All patients were allowed to receive usual medical care. The patients completed standardised questionnaires at baseline, 3 and 6 months.

The primary outcome measures for the clinical efficacy (relative to each diagnosis) were assessed using the following validated questionnaires or methods:

- Low back pain: Hanover Functional Ability Questionnaire.<sup>12</sup>

- Headache: days with headache in the last four weeks.
- Osteoarthritis of the knee or the hip: WOMAC Index.<sup>9,10</sup>
- Neck pain: Neck Pain and Disability Scale.<sup>13</sup>

Additionally, all patients completed a questionnaire on their general, health related quality of life (short form, SF-36)<sup>14</sup> and adverse effects. The physicians documented medical history, diagnoses and adverse effects.

We evaluated overall cost effectiveness from a social perspective (cost data were provided by the social health insurance funds). The quality adjusted life years (QALYs) were calculated from the SF-36 data.<sup>15</sup> The incremental cost effectiveness relationship (cost per QALY gained) was expressed in Euros per QALY and resulted from the difference of the mean costs (direct and indirect, of both acupuncture and control groups), divided by the difference between the mean QALYs of both groups three months after the study began.

#### *Acupuncture Safety and Health economics studies (ASH)*

The aim of this prospective observational study was primarily to investigate safety on a large number of patients.<sup>11</sup> The safety evaluation consisted of two stages. In the first stage, all patients completed a standardised questionnaire on adverse effects at the end of the acupuncture treatment. In cases where adverse effects occurred, those patients progressed to a second stage and completed a detailed, standardised questionnaire.

#### **Results**

A total of 304 674 patients treated by over 10 000 physicians in the period from December 2000 to March 2005 were included in the studies and analysed (ART: 1164; ARC: 43 351; ASH: 260,159). This total comprised of 34.5% men (average age  $53.1 \pm \text{SD } 13.8$ ) and 65.5% women ( $49.5 \pm 14.2$  years). The acupuncture patients received on average  $10 \pm 3$  acupuncture treatments within three months.

#### *Efficacy – ART*

In the Acupuncture Randomised Trials the acupuncture groups of all four diagnoses

demonstrated significant superiority ( $P < 0.001$ ) in the primary outcome measure compared with the waiting list control.

A significant difference between the acupuncture and the sham acupuncture group was only found for osteoarthritis,<sup>16</sup> not for lower back pain,<sup>17</sup> migraine,<sup>18</sup> or tension-type headache (Table 1).<sup>19</sup> After 6 and 12 months there were no significant differences between the acupuncture and the sham acupuncture groups in any of the four trials.

#### *Effectiveness – ARC*

In the ARC studies for all diagnoses patients who received acupuncture in addition to usual care showed significantly greater improvement ( $P < 0.001$ ) in the primary outcome measure after three months compared to those who only received usual care.<sup>20-23</sup> (Table 2) The improvement of the acupuncture group after three months persisted up to six months. After a three month waiting period, the patients of the control group received acupuncture and showed similar improvement after six months compared with that of the acupuncture group. The non-randomised acupuncture group was consistently comparable to the acupuncture group. The health related quality of life was significantly higher in the acupuncture groups of all diagnoses as compared with the control groups ( $P < 0.001$ ) after three months.

#### *Cost effectiveness – ARC*

A total of 8496 patients were included in the economic analysis. The total overall costs (all costs were calculated independently of the study diagnoses) in the acupuncture group increased significantly within three months for all examined diagnoses from a social perspective, in comparison with the control group. As acupuncture treatment was associated both with higher costs and improved quality of life, additional cost effectiveness analyses were carried out. The cost effectiveness relationship lay between €10 526 per QALY (low back pain) and €17 845 per QALY (osteoarthritis of the knee or the hip) (see Figure 2).

#### *Safety – ASH*

In the ASH study, 22 126 (8.5%) of the 260 159 patients included in the study reported a total of 27 134 adverse effects. Side effects requiring medical

Table 1 Acupuncture Randomised Trials (ART), primary results on efficacy

Diagnoses	Baseline mean±SD	Follow-up 8 weeks/12 weeks mean±SD	P value‡ AC vs WL	P value‡ AC vs MA
<b>Low back pain<sup>17</sup></b>				
<b>VAS</b>			<0.001	0.260
- AC (n=147)	63.3±13.2	34.5±28.5		
- sham (n=75)	66.6±15.7	43.7±29.8		
- WL (n=79)	66.1±13.6	58.6±29.1		
<b>Osteoarthritis of the knee<sup>16</sup></b>				
<b>WOMAC Index</b>			<0.001†	0.0002†
- AC (n=149)	50.8±18.8	26.9±1.4*		
- sham (n=75)	52.5±18.6	35.8±1.9*		
- WL (n=70)	51.6±18.8	49.6±2.0*		
<b>Migraine<sup>18</sup></b>				
<b>Days with moderate to severe headache</b>			<0.001	0.960
- AC (n=145)	5.2±2.5	2.8±2.3		
- sham (n=81)	5.0±2.4	2.6±2.4		
- WL (n=76)	5.4±3.0	4.3±2.2		
<b>Tension type headache<sup>19</sup></b>				
<b>Days with headache</b>			<0.001	0.580
- AC (n=132)	17.5±6.9	9.9±8.7		
- sham (n=63)	17.7±6.7	10.8±8.3		
- WL (n=75)	17.3±6.9	16.3±7.4		

AC = acupuncture group, sham= sham (minimal) acupuncture group, WL = waiting list group.  
‡Student *t* test for differences baseline - 8 weeks (12 weeks), if not other stated, †covariance analysis adjusted for baseline values,  
\*estimated mean from covariance analysis adjusted for baseline

Table 2 Acupuncture in Routine Care Studies (ARC) primary results on effectiveness

Diagnoses	Baseline mean±sd	Follow-up* 3 months mean±SE	P value† ACU vs CON
<b>Low back pain<sup>20</sup></b>			
<b>HFAQ</b>			<0.001
ACU (n= 1,451)	61.8±21.0	74.5±0.4	
CON (n= 1,390)	63.3±20.8	65.1±0.4	
<b>Neck pain<sup>21</sup></b>			
<b>NPAD</b>			<0.001
ACU (n= 1,753)	55.0±15.8	38.3±0.4	
CON (n= 1,698)	53.0±16.0	50.5±0.4	
<b>Osteoarthritis of the knee and the hip<sup>22</sup></b>			
<b>WOMAC Index</b>			<0.001
ACU (n= 322)	48.2±23.3	30.5±1.0	
CON (n= 310)	48.0±23.4	47.3±1.0	
<b>Headache<sup>23</sup></b>			
<b>Headache days/4 weeks</b>			<0.001‡
ACU (n=1,613 )	8.4±7.2	4.7±5.6§	
CON (n=1,569 )	8.1±6.7	7.5±6.3§	

SE = Standard error, ACU= acupuncture group, CON= control group. \*estimated mean from covariance analysis adjusted for baseline, if not other stated, †Covariance analysis adjusted for baseline, if not other stated, ‡Student *t* test, §unadjusted means

treatment were reported by 0.8% of patients. Two cases of pneumothorax were reported, one requiring hospitalisation. No life threatening side effects occurred.

### Discussion

Our model project demonstrated for all examined diagnoses a significant superiority for a treatment with acupuncture compared with a treatment

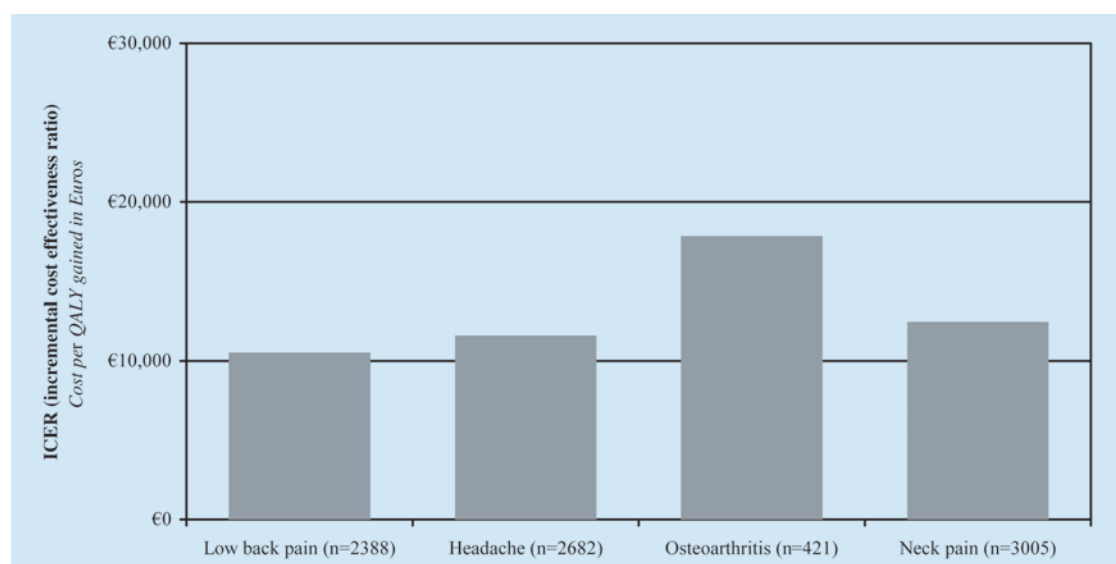


Figure 2 Acupuncture in Routine Care studies (ARC) primary results on cost effectiveness.

without acupuncture in standard care. However, a superiority of acupuncture compared with sham acupuncture was only detected for osteoarthritis of the knee but not for low back pain, migraine and tension-type headache. Adverse effects were rare, and in no case life threatening. Acupuncture treatment in usual care was related to higher costs; however, these were within internationally accepted thresholds.

The design of the ARC studies, the nationwide implementation of our project, with over 10 000 participating physicians (approximately 8% of all practising physicians, or 25% of all acupuncture physicians), and the involvement of the major acupuncture associations allows us to generalise the results to usual medical care in Germany.

One of the main advantages of this project is the fact that both randomised parts of the study (ART and ARC) complemented each other in content and method. The ART trials focused on determining – with high internal validity – the specific efficacy of acupuncture. The aim of the ARC studies, on the other hand, was to evaluate – with high external validity – the effectiveness of acupuncture within usual medical care.

Limitations of the project were that blinding of both the waiting list control group of the ART trials, and the control group of the ARC studies was not possible, and that subjective parameters were used as primary outcome measures, although they were based on internationally validated questionnaires. In

addition the cost effectiveness analysis did not assess longterm effects.

In the ART trials, the comparison between acupuncture and sham acupuncture demonstrated inconsistencies for the different diagnoses. Although the responder rates were comparable in the acupuncture groups (approximately 50% of patients in all diagnostic groups reported pain reduction, or half the number of days with pain), the effect of sham acupuncture on the primary outcome was similar in the patients with migraine, tension-type headache and low back pain. It was not, however, for those suffering pain due to osteoarthritis of the knee. This finding indicates a high proportion of non-specific effects (eg through skin penetration at non-points – ie not classical acupuncture point locations; through the characteristics of the therapy setting and the role of expectations) on the overall effect of acupuncture.

Several reports of cases of pneumothorax following acupuncture were found in the literature.<sup>24-28</sup> The fact that in our study serious side effects were very rare, with a total of only two cases of pneumothorax (equivalent to one case per one million acupuncture treatments), showed that acupuncture is a safe treatment.

Economic analyses were a relevant part of the model project. Acupuncture demonstrated effectiveness for all examined diagnoses; however, it resulted in a cost increase. For this reason, additional cost effectiveness analyses using common health economics methods, were carried out.<sup>29-32</sup> The

incremental cost effectiveness relationship was between €10 000 and €18 000 per additional QALY. In some countries medical treatments are considered to be included into the health system up to threshold values of €50 000 or £30 000 per QALY.<sup>31,33-36</sup> To date, no such threshold values exist in Germany; however, applying these international threshold values to our studies, acupuncture is relatively cost effective. From a health policy point of view, the model project presents additional arguments for the reimbursement of acupuncture treatment within the framework of the social health insurance scheme.

Our findings demonstrated that, for the diagnoses examined, acupuncture in addition to standard care was an effective and safe treatment. Whether the effects of acupuncture can be attributed primarily to specific or non-specific mechanisms appeared to depend on the diagnosis, and should be investigated in further studies. Using acupuncture as an adjunctive treatment was more expensive than usual care alone, but was cost effective according to internationally accepted threshold values.

### Acknowledgments

We wish to thank all participating patients and physicians, as well as our scientific cooperation partners: Dr Dieter Melchart, Dr Klaus Linde, Dr Andrea Streng, Zentrum für naturheilkundliche Forschung (ZnF), II. Medizinische Klinik und Poliklinik, Klinikum rechts der Isar, Technische Universität München, Prof Dr A. Neiss, Dr Stefan Wagenpfeil, Institut für Medizinische Statistik und Epidemiologie, Technische Universität München, Prof Karl Wegscheider, Institut für Statistik und Ökonometrie, Fachbereich Wirtschaftswissenschaften, Universität Hamburg, the members of the steering committee: Dr Konrad Beyer, Deutsche Gesellschaft für Akupunktur und Neuraltherapie, Dr Josef Hummelsberger, Internationale Gesellschaft für Chinesische Medizin, Hardy Müller und Dr Bodo Liecker, Techniker Krankenkasse, Dr Albrecht Molsberger, Forschungsgruppe Akupunktur und traditionelle Chinesische Medizin, Dr Helmut Rüdinger und Dr Wolfram Stör, Deutsche Ärztesgesellschaft für Akupunktur, Dr Gabriel Stux, Deutsche Akupunktur Gesellschaft Düsseldorf, and the members of our study team Iris Bartsch, Margit Cree, Beatrice Eden, Susanne Jena, Elvira Krüger, Sigrid Mank, Karin Weber und Katja Wruck.

### Funding

The following social health insurance companies supported the pilot project: Techniker Krankenkasse, BKK Aktiv, Betriebskrankenkasse der Allianz Gesellschaften, Bertelsmann BKK, Bosch BKK, BKK BMW, DaimlerChrysler BKK, BKK Deutsche Bank, Ford Betriebskrankenkasse, BKK Hoechst, HypoVereinsbank Betriebskrankenkasse, Siemens-Betriebskrankenkasse, Handelskrankenkasse, Innungskrankenkasse Hamburg.

### Conflict of Interest Statement

The authors declare that no conflict of interest exists.

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