

Acupuncture in patients with tension-type headache: randomised controlled trial

Dieter Melchart, Andrea Streng, Andrea Hoppe, Benno Brinkhaus, Claudia Witt, Stefan Wagenpfeil, Volker Pfaffenrath, Michael Hammes, Josef Hummelsberger, Dominik Irnich, Wolfgang Weidenhammer, Stefan N Willich, Klaus Linde

Centre for Complementary Medicine Research, Department of Internal Medicine II, Technische Universität München, Kaiserstr 9, 80801 Munich, Germany

Dieter Melchart
director

Andrea Streng
researcher

Andrea Hoppe
researcher

Wolfgang Weidenhammer
biostatistician

Klaus Linde
epidemiologist

Institute of Medical Statistics and Epidemiology, Technische Universität München

Stefan Wagenpfeil
statistician

Department of Neurology, Technische Universität München
Michael Hammes
neurologist

Institute of Social Medicine, Epidemiology, and Health Economics, Charité University Medical Centre, Berlin, Germany
Benno Brinkhaus
internist

Claudia Witt
epidemiologist
Stefan N Willich
professor

Private practice, Munich

Volker Pfaffenrath
neurologist

Josef Hummelsberger
internist

Department of Anesthesiology, University of Munich, Munich
Dominik Irnich
anaesthetist

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Abstract

Objective To investigate the effectiveness of acupuncture compared with minimal acupuncture and with no acupuncture in patients with tension-type headache.

Design Three armed randomised controlled multicentre trial.

Setting 28 outpatient centres in Germany.

Participants 270 patients (74% women, mean age 43 (SD 13) years) with episodic or chronic tension-type headache.

Interventions Acupuncture, minimal acupuncture (superficial needling at non-acupuncture points), or waiting list control. Acupuncture and minimal acupuncture were administered by specialised physicians and consisted of 12 sessions per patient over eight weeks.

Main outcome measure Difference in numbers of days with headache between the four weeks before randomisation and weeks 9-12 after randomisation, as recorded by participants in headache diaries.

Results The number of days with headache decreased by 7.2 (SD 6.5) days in the acupuncture group compared with 6.6 (SD 6.0) days in the minimal acupuncture group and 1.5 (SD 3.7) days in the waiting list group (difference: acupuncture *v* minimal acupuncture, 0.6 days, 95% confidence interval -1.5 to 2.6 days, $P = 0.58$; acupuncture *v* waiting list, 5.7 days, 3.9 to 7.5 days, $P < 0.001$). The proportion of responders (at least 50% reduction in days with headache) was 46% in the acupuncture group, 35% in the minimal acupuncture group, and 4% in the waiting list group.

Conclusions The acupuncture intervention investigated in this trial was more effective than no treatment but not significantly more effective than minimal acupuncture for the treatment of tension-type headache.

Trial registration number ISRCTN9737659.

Introduction

Tension-type headache is essentially defined as bilateral headache of a pressing or tightening quality without a known medical cause.¹ Acupuncture is widely used for the treatment of tension-type headache, but its effectiveness is controversial.² In the acupuncture randomised trial in tension-type headache (ART-TTH), we investigated whether acupuncture reduced the frequency of headache more effectively than did minimal acupuncture (superficial needling at non-acupuncture points) or no acupuncture in patients with tension-type headache.

Methods

Protocol, design, and randomisation

ART-TTH was a randomised, multicentre trial comparing acupuncture, minimal acupuncture, and a no acupuncture waiting list condition. Minimal acupuncture served as a sham intervention. Patients were blinded to treatment in the acupuncture and minimal acupuncture groups. Two blinded evaluators analysed headache diaries. The methods of the trial have been described in detail elsewhere.³ After a baseline phase of four weeks, we randomised patients, stratified by centre, in a 2:1:1 ratio (acupuncture:minimal acupuncture:waiting list).

Participants

Inclusion criteria were a diagnosis of episodic or chronic tension-type headache according to the criteria of the International Headache Society,¹ at least eight days with headache a month in the previous three months and in the baseline period, age 18-65 years, duration of symptoms at least 12 months, completed baseline headache diary, and written informed consent.

Interventions

Trained physicians experienced in acupuncture delivered the interventions. Both the acupuncture and minimal acupuncture treatments consisted of 12 sessions of 30 minutes, given over eight weeks.

Acupuncture patients were treated at "basic" points bilaterally; additional points could be chosen individually (see bmj.com). We instructed physicians to achieve "de qi" (an irradiating feeling considered to be indicative of effective needling) if possible and to stimulate needles manually at least once during each session. The total number of needles was limited to 25 per session.

The number, length, and frequency of the sessions in the minimal acupuncture group were the same as for the acupuncture group. Physicians needled at least five out of 10 predefined distant non-acupuncture points bilaterally and superficially using fine needles (see bmj.com). Physicians avoided "de qi" and manual stimulation of the needles.

Patients in the waiting list control group did not receive any prophylactic treatment for their headaches for a period of 12 weeks after randomisation. After that time, they received 12 sessions of the acupuncture treatment described above.



Trial centres are listed on bmj.com



This is the abridged version of an article that was posted on bmj.com on 29 July 2005: <http://bmj.com/cgi/doi/10.1136/bmj.38512.405440.8F>

All patients were allowed to treat acute headaches as needed. Treatment was supposed to follow current guidelines⁴ and had to be documented in the headache diary.

Outcome measurement

Patients filled in headache diaries in the four weeks before randomisation and during weeks 1-12 and 21-24 after randomisation. We asked patients to fill in a pain questionnaire before treatment, after 12 weeks, and after 24 weeks.⁵ The primary outcome measure was the difference in number of days with headache between baseline and weeks nine to 12 after randomisation. To test blinding and credibility of the different treatment methods, patients filled in a credibility questionnaire after the third acupuncture session.⁶

Statistical methods

We based confirmatory testing of the primary outcome measure and all main analyses on the intention to treat population and used all available data (see bmj.com).

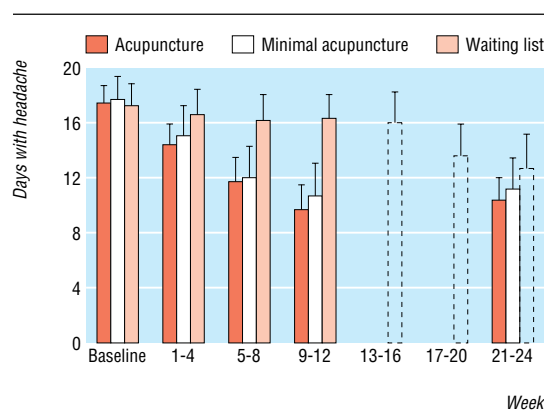
Results

Participants and blinding

Between March 2002 and January 2004, 2700 patients with headache expressed interest in participating in the study; 524 entered the four week baseline period, and 296 patients recruited in 29 outpatient centres were randomised. We excluded one trial centre with 26 patients, owing to repeated severe protocol deviations and the suspicion of data manipulation in some patients, leaving 270 patients in the intention to treat population (132 acupuncture, 63 minimal acupuncture, 75 waiting list). Treatment groups were comparable at baseline (see bmj.com). After three sessions, patients rated the credibility of acupuncture and minimal acupuncture very highly and very similarly. At the end of the study, patients' guesses as to their treatment allocation did not differ significantly between groups, but patients in the acupuncture group guessed their allocation correctly slightly more often than did patients in the minimal acupuncture group.

Effectiveness

From baseline to weeks 9-12, the number of days with headache decreased by 7.2 (SD 6.5) days in the acupuncture group compared with 6.6 (SD 6.0) days in the minimal acupuncture group and 1.5 (SD 3.7) days in the waiting list group (difference: acupuncture *v*



Mean (95% confidence interval) number of days with headache. Patients in the waiting list group received acupuncture after week 12 (dotted bars)

minimal acupuncture, 0.6 days, 95% confidence interval -1.5 to 2.6 days, $P=0.58$; acupuncture *v* waiting list, 5.7 days, 4.2 to 7.2 days, $P<0.001$) (fig). The proportion of responders (at least 50% reduction in headache days) was 46% in the acupuncture group, 35% in the minimal acupuncture group, and 4% in the waiting list group (exploratory P values 0.163 for acupuncture *v* minimal acupuncture and <0.001 for acupuncture *v* waiting list).

Compared with the waiting list control group, patients receiving acupuncture or minimal acupuncture fared significantly better for most secondary outcome measures; however, we found no significant differences between the acupuncture and the minimal acupuncture group (table). Differences compared with waiting list became apparent in the headache diary after the first four weeks of treatment and increased until week 12 (fig). The improvements seen in the acupuncture and minimal acupuncture group persisted during the follow-up period.

Discussion

Principal finding

The acupuncture intervention tested in this study was significantly more effective than no preventive treatment but not significantly more effective than the minimal acupuncture intervention in patients with tension-type headache.

Secondary outcome measures after treatment

Outcome	Acupuncture		Minimal acupuncture		Waiting list		Acupuncture <i>v</i> minimal acupuncture		Acupuncture <i>v</i> waiting list	
	No	Mean (SD)	No	Mean (SD)	No	Mean (SD)	Difference* (95% CI)	P value†	Difference* (95% CI)	P value†
Headache diary weeks 9-12										
Days with headache	118	9.9 (8.7)	57	10.8 (8.3)	63	16.3 (7.4)	-0.6 (-2.4 to 1.2)	0.51	-5.8 (-7.6 to -4.0)	<0.001
Hours with headache	118	88 (128)	57	111 (162)	63	164 (145)	-8 (-33 to 17)	0.51	-48 (-72 to -23)	<0.001
Headache score‡	118	15.8 (15.3)	57	17.2 (14.4)	63	26.4 (14.3)	-0.8 (-4.4 to 2.7)	0.64	-10.9 (-14.3 to -7.4)	<0.001
Pain questionnaire week 12										
Disability (PDI)	119	12.2 (10.8)	57	13.5 (11.5)	63	22.8 (9.7)	-1.4 (-4.3 to 1.5)	0.35	-8.8 (-11.7 to -5.9)	<0.001
SF-36 physical health§	119	48.2 (7.5)	57	49.0 (6.1)	63	42.5 (7.2)	-0.2 (-2.0 to 1.6)	0.83	5.4 (3.7 to 7.2)	<0.001
SF-36 mental health§	119	47.4 (9.8)	57	46.1 (11.8)	63	41.9 (10.9)	0.0 (-2.4 to 2.5)	0.97	2.5 (0.2 to 4.9)	0.04
Average pain (scale 1-10)	119	2.9 (1.6)	58	3.1 (1.7)	63	4.6 (1.5)	-0.1 (-0.6 to 0.4)	0.77	-1.6 (-2.1 to -1.1)	<0.001

PDI=pain disability index.

*Mean difference between groups.

†Analysis of covariance with adjustment for baseline values.

‡Headache score=sum of intensity ratings (1=mild, 2=moderate, 3=severe) of days with headache.

§Higher values indicate better status.

Division of Complementary Medicine, Department of Internal Medicine, University Hospital Zurich, Switzerland
Dieter Melchart
researcher

Correspondence to: K Linde
Klaus.Linde@lrz.tu-muenchen.de

What is already known on the topic

Acupuncture is widely used in patients with tension-type headache

Available trials had small sample sizes and controversial results

What this study adds

In this randomised trial, acupuncture had a significant and clinically relevant effect compared with no treatment

Minimal acupuncture (superficial needling distant from traditional acupuncture points) had a similar effect

Strengths and weaknesses

Compared with available studies of acupuncture for tension-type headache,⁷⁻¹² which included up to a maximum of 69 patients, our study has a much larger sample size. Other advantages include adherence to current guidelines for headache trials,¹³ strictly concealed central randomisation, an assessment of the credibility of interventions, blinded evaluation of diaries, interventions based on expert consensus provided by qualified and experienced medical acupuncturists, high follow-up rates, and an external audit of the quality of data.

Although the groups were comparable for socio-demographic characteristics and headache outcomes at baseline, differences existed for some scores on the pain questionnaire in spite of randomisation. The credibility of acupuncture and minimal acupuncture was rated very similarly by patients, but guesses at the end of the trial about treatment allocation differed slightly between the acupuncture and minimal acupuncture groups, possibly indicating some degree of unblinding. Trial physicians could not be blinded. Therefore, the small non-significant differences between acupuncture and minimal acupuncture could be due to bias. It was not possible to blind waiting list patients, so we cannot rule out that the difference from acupuncture and minimal acupuncture is overestimated. However, several arguments exist as to why the influence of bias should be limited. A slight improvement over time occurred in the waiting list group in the first 12 weeks, probably due to the natural course of the disease, making it unlikely that patients in the waiting list group reported negatively biased data in their diaries. Use of analgesics was lower in both the acupuncture and minimal acupuncture groups than in the waiting list group, making an influence of effective co-interventions unlikely. Follow-up data confirmed the improvements observed after treatment. After completion of the treatment, patients had no further contact with acupuncturists, decreasing the likelihood of positively biased diary data.

Interpretation of findings

The lack of significant difference between acupuncture and minimal acupuncture in our study indicates that point location and other aspects considered relevant for traditional Chinese acupuncture did not make a

major difference. Our findings are similar to those of three of the available trials,^{7, 8, 11} whereas two others found significant effects of acupuncture over sham acupuncture.^{10, 12}

An intriguing finding of our trial is the strong and lasting response to minimal acupuncture. The minimal acupuncture intervention was designed to minimise potential physiological effects by needling superficially at points distant from classical sites and by using fewer needles than in the acupuncture group. The observed physiological effects may include local alteration in circulation as well as neurophysiological and neurochemical responses.

Another explanation for the improvements we observed could be that acupuncture and minimal acupuncture are associated with particularly potent placebo effects. Acupuncture treatment has characteristics that are considered relevant in the context of placebo effects,¹⁴ such as emphasis on the “individual as a whole” and frequent patient-practitioner contacts. Finally, the high expectations of participants and our way of informing patients might have been a relevant factor.

Conclusions

A significant proportion of patients with tension-type headache benefited from acupuncture. The size of the effect seems comparable to those of accepted treatments for tension-type headache and is larger than that found in most trials comparing placebo interventions with no treatment.^{15, 16} Acupuncture was well tolerated, and improvements lasted several months after completion of treatment. However, minimal acupuncture—the superficial needling of non-acupuncture points—had a similar effect.

We thank the acupuncture experts who participated in the consensus process to establish the trial interventions. Trial centres contributing to the main analysis are listed on bmj.com. The trial was initiated after a request from German health authorities (Federal Committee of Physicians and Social Health Insurance Companies, German Federal Social Insurance Authority) and sponsored by German Social Health Insurance Companies. The health authorities had requested a randomised trial including a sham control condition with an observation period of at least six months to decide whether acupuncture should be included in routine reimbursement. All other decisions on design, data collection, analysis, and interpretation, as well as publication, were the responsibility of the researchers.

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Variability in interpretation of chest radiographs among Russian clinicians and implications for screening programmes: observational study

Y Balabanova, R Coker, I Fedorin, S Zakharova, S Plavinskij, N Krukov, R Atun, F Drobniowski

Abstract

Objective To determine variability in interpretation of chest radiographs among tuberculosis specialists, radiologists, and respiratory specialists.

Design Observational study.

Setting Tuberculosis and respiratory disease services, Samara region, Russian Federation.

Participants 101 clinicians involved in the diagnosis and management of pulmonary tuberculosis and respiratory diseases.

Main outcome measures Interobserver and intraobserver agreement on the interpretation of 50 digital chest radiographs, using a scale of poor to very good agreement (κ coefficient: ≤ 0.20 poor, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 good, and 0.81-1.00 very good).

Results Agreement on the presence or absence of an abnormality was fair only ($\kappa = 0.380$, 95% confidence interval 0.376 to 0.384), moderate for localisation of the abnormality (0.448, 0.444 to 0.452), and fair for a diagnosis of tuberculosis (0.387, 0.382 to 0.391). The highest levels of agreement were among radiologists. Level of experience (years of work in the specialty) influenced agreement on presence of abnormalities and cavities. Levels of intraobserver agreement were fair.

Conclusions Population screening for tuberculosis in Russia may be less than optimal owing to limited agreement on interpretation of chest radiographs, and may have implications for radiological screening programmes in other countries.

Introduction

Radiological examination plays an important part in the diagnosis and monitoring of tuberculosis, particularly in the Russian Federation, yet the control of tuberculosis in Russia remains a challenge and an economic burden.¹ Case finding is based on fluorographic screening of the population, and diagnosis may be made on the basis of radiological abnormalities without bacteriological confirmation.^{2 3}

We determined interobserver and intraobserver variability in interpretation of chest radiographs among a group of Russian clinicians from the disciplines of radiology, respiratory medicine, and tuberculosis.

Methods

Our study was carried out in Samara, a Russian city about 1000 km south east of Moscow (population 1.2 million). We invited to take part in our study all specialists in tuberculosis, respiratory physicians from the two main local general hospitals, radiologists specialising in tuberculosis, and general radiologists.

The study material consisted of 50 high resolution digital posterior-anterior chest radiographs selected from the archives at King's College

Health Protection Agency National Mycobacterium Reference Unit, Department of Microbiology and Infection, Guy's, King's, and St Thomas' Medical School, London
Y Balabanova
research associate
F Drobniowski
professor

Samara Regional Tuberculosis Service, Samara Oblast Dispensary, Samara, Russia
I Fedorin
chief physician

Samara City Tuberculosis Service, Samara, Russia
S Zakharova
chief physician

College for Public Health, St Petersburg Academy for Postgraduate Sciences, Russia
S Plavinskij
professor

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Table showing levels of experience is on bmj.com



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