

# Patient Characteristics and Variation in Treatment Outcomes

## *Which Patients Benefit Most From Acupuncture for Chronic Pain?*

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**Objectives:** The aim of this study was to identify patients' characteristics that increase or decrease their benefit from acupuncture treatment of chronic pain.

**Methods:** Patients with chronic low back pain, headache, neck pain, or pain due to osteoarthritis of the knee or hip, were included in 4 multicenter, randomized, controlled studies, all conducted in Germany. All patients received routine care; the patients randomized to the acupuncture group received additional acupuncture treatment. Data were pooled, and the main outcome was defined as the 3-month change from baseline of the SF-36 bodily pain subscale. To identify predictors for treatment effects and effect modifiers (ie, variables that interact with the form of treatment), patients' characteristics and their interaction with treatment were included in a mixed linear model to predict treatment outcome.

**Results:** A total of 9,990 patients who were treated by 2,781 physicians were analyzed. The outcome was markedly improved in the acupuncture group ( $P < 0.001$ ). Age, education, duration of illness, baseline pain, and some concomitant diseases predicted treatment outcome in both groups. Patients' characteristics that enlarged the acupuncture effect (ie, acted as effect modifiers) were being female ( $P = 0.028$ ), living in a multi-person household ( $P = 0.002$ ), failure of other therapies before the study ( $P = 0.049$ ), and former positive acupuncture experience ( $P = 0.005$ ).

**Discussion:** Future research to clarify the modifying effects with special focus on patients' expectations and other psychological variables is needed.

**Key Words:** acupuncture, effect modifiers, randomized controlled trial, patient characteristics

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There is no treatment that is equally effective for all patients. From the viewpoint of acupuncture practitioners it is worth exploring patient variables that predict a larger or smaller acupuncture effect to make better treatment decisions. In general, 3 approaches have been proposed to identify potential predictors of treatment outcome or factors that modify acupuncture effects: focusing on the therapeutic relationship between the practitioner and the patient; focusing on the practitioner; and focusing on the patient.<sup>1</sup> The first approach is best pursued in qualitative research as adequate measures of the therapeutic relationship in acupuncture treatment are still rare. The second approach is reflected in a recent study on acupuncture treatment of chronic pain, examining the influence of practitioner variables on treatment outcomes and interactions of practitioner variables with the kind of treatment applied. To some extent this study produced unexpected results as only the conventional specialization of the physician modified the effect of the applied treatment.<sup>2</sup> With regard to the patient variables as the third approach, a recent study on patients with chronic back pain found little evidence for subgroups of patients that especially profit from acupuncture. Only a greater dysfunction score at baseline led to greater changes on the Roland score when patients were treated with acupuncture compared with a routine care treatment.<sup>3</sup>

Besides sociodemographic and condition-related variables, a special focus in recent years when investigating patients' characteristics has been on patients' expectations at baseline with differing results: Positive influences of baseline expectations with regard to the received treatment<sup>4,5</sup> have been just as well reported as a negative influence<sup>6</sup> or no influence.<sup>7</sup> In a randomized controlled study comparing acupuncture with routine care that differentiated between the expectation that pain will become better during the treatment and the belief in the effectiveness of acupuncture, trends indicating a modification of the acupuncture effect emerged in opposite directions. Higher expectations about the improvement of pain led to a larger difference between acupuncture and control group in favor of acupuncture than low expectations, whereas concerning effectiveness beliefs, negative or uncertain beliefs enhanced the effect of acupuncture, which positive beliefs did not.<sup>8</sup> Thus, baseline characteristics of patients that might influence their responsiveness to acupuncture have been examined, albeit so far not with consistent results.

The aim of this study is to further follow this line of research using a large population sample for evaluating baseline variables that predict treatment outcome in general

or interact with the kind of treatment applied (ie, routine care and acupuncture or routine care only). The latter are of special interest as they make it possible to identify subgroups of patients that might profit from acupuncture treatment, and therefore might function as guidelines for practitioners.

In Germany, acupuncture is predominantly provided by physicians. Women use acupuncture, as complementary and alternative medicine (CAM) in general, more frequently than men, as do patients with higher level of education compared with patients with lower educational level, and patients who are married compared with single.<sup>9</sup> Such sociodemographic variables were included in this study, as they can be assumed to influence the outcome of acupuncture treatment. In addition, we regarded concomitant diseases, experience with CAM, and reasons for seeking acupuncture treatment as potentially relevant baseline variables.

## MATERIALS AND METHODS

### Patients and Measurement Instruments

This study reanalyses data from 4 large pragmatic, randomized, controlled trials, each evaluating the effectiveness of acupuncture treatment in patients with 1 of the following pain conditions: osteoarthritis of the knee or hip,<sup>10</sup> low back pain,<sup>11</sup> neck pain,<sup>12</sup> or headache.<sup>13</sup> For all 4 trials, informed consent was obtained from each patient and the trials were approved by the Institutional Review Board of the Charité University Medical Center and the regional Institutional Review Boards.

The data from these 4 pragmatic, randomized, controlled trials on the effectiveness of acupuncture in addition to usual care, compared with usual care alone, were pooled. Within each trial, the patients fulfilled predefined diagnosis-specific criteria and completed standardized questionnaires (diagnosis-specific and general, health-related quality of life according to the SF-36 Health Survey<sup>14</sup>) at baseline and after 3 and 6 months. Sociodemographic information and concomitant diseases were collected at baseline. In each of the 4 trials, the patients were randomized using central telephone randomization (stratification for centers and block design) into the acupuncture or the control group. All patients received usual medical care, but the patients in the acupuncture group were also given an average of 10 acupuncture sessions after randomization. The patients in the control group were instructed not to receive acupuncture for the first 3 months of the trial (further details on the trial methodology are given in the cited references<sup>10-13</sup>).

### Statistical Analysis

The main outcome parameter was defined as the difference in the pain subscale from the SF-36 questionnaire between baseline and after 3 months. This scale was dichotomized at a threshold of 5 points, that is an improvement of 5 points or more was regarded as a treatment success, smaller improvements or point reductions (pain worse after 3 months than at baseline) were regarded as treatment failure. Differences of 5 points on the subscales of the SF-36 are considered clinically and socially relevant according to the German manual.<sup>14</sup>

A mixed linear model was fitted to the data using the logit function as the link function, considering the following patient variables as independent factors: baseline bodily pain, measured with the SF-36 bodily pain subscale, divided

into 5-point integrals; interaction between treatment group and indication; sex; age as a dichotomous variable ( $\leq 50$  y vs.  $> 50$  y); education (duration of schooling  $> 10$  y vs.  $< 10$  y), university degree (yes vs. no); family status (single household vs. multi-person household); duration of pain ( $\leq 4$  y vs.  $> 4$  y); concomitant diseases (hypertension, circulatory disorders, heart attack, cardiac failure, stroke, asthma, diabetes, cancer, coronary heart disease, inflammatory joint diseases, and other); earlier treatment with CAM (yes vs. no within 12 mo before the study; if yes: acupuncture, homeopathy, or other treatment); reasons for choosing acupuncture (earlier successful acupuncture therapy, recommended by physician, failure of other therapies, recommended by friends/relatives, preference of holistic treatment, wish to reduce pain medication, other reasons). The thresholds for the dichotomized variables age and duration of pain were set at even values near the median of the respective variable; the threshold of more than 10 years of schooling for the education variable is consistent with the differentiation of German schools into non-college-qualifying schools (9 y or 10 y) and college-qualifying schools (12 y or 13 y). We considered a dichotomization of these variables rather than using continuous variables as reasonable, as this facilitates the interpretation of the odds-ratios (OR), for example, by comparing older to younger patients instead of referring to 1-year differences. In addition, we adjusted for the attending physician by including the physician as a random effect. Each of these variables was modeled as a potential predictor (main effect on outcome) and, additionally, as a potential effect modifier (interaction with treatment, ie, acupuncture and routine care vs. routine care alone).

As an initial step, all possible predictors were included in the model. In the subsequent steps all nonsignificant parameters were consecutively excluded from the model using a *P* value of 0.10 as a threshold for significance; the parameter with the highest *P* value was always excluded. The main effects (ie, the patient characteristics) could only be excluded when the associated interaction term had been excluded earlier.

The analysis population consisted of the pooled intention-to-treat populations of the individual trials. Missing values were not replaced or imputed, neither in outcome nor in covariates, and each part of the analysis was carried out on the maximum available data set. We used the GLIMMIX procedure of the SAS 9.1 statistical software (SAS Inc, Cary, NC). All the results were displayed as OR, supplemented by 95% confidence intervals (CIs) and the respective *P* values. The statistical analysis plan was predefined before starting data analysis.

## RESULTS

A total of 9,900 patients were included in the study. Patients' characteristics at baseline are presented in Table 1. The patients were treated by 2,781 physicians from all over Germany [mean age (SD), 46.3 y (7.0); 37% women, mean duration of experience in acupuncture 7.3 y (5.2)].

Preliminary analyses (including only the baseline characteristics as fixed and the physician numbers as random effects) showed that pooling the data from the 4 different trials was valid: When analyzed separately for each diagnosis, treatment effects were estimated at an OR = 3.8 (CI, 3.2-4.5) for low back pain; OR = 4.4 (CI, 3.8-5.2) for neck pain; OR = 3.7 (CI, 3.1-4.4) for headache; OR = 4.6

TABLE 1. Patients' Characteristics at Baseline

	Acupuncture	Control	P
Age [mean (SD)]	49.4 (13.6)	49.8 (13.7)	0.08
Sex [n (%)]			
Women	3,452 (67.9%)	3,314 (67.5%)	0.69
Men	1,631 (32.1%)	1,593 (32.5%)	
Education [n (%)]			
> 10 y at school	1,543 (30.4%)	1,593 (32.5%)	0.21
Academic degree	590 (11.6%)	565 (11.5%)	
Single person household	781 (15.4%)	793 (16.2%)	0.20
Diagnoses [n (%)]			0.99
Chronic headache	1,592 (31.3%)	1,546 (31.5%)	
Low back pain	1,449 (28.5%)	1,389 (28.3%)	
Neck pain	1,753 (34.5%)	1,698 (34.6%)	
Osteoarthritis of hip or knee	289 (5.7%)	274 (5.6%)	
Duration of disease [mean (SD)]	7.7 (8.5)	8.0 (9.0)	0.41
Concomitant diseases [n (%)]			
Asthma	644 (12.7%)	635 (12.9%)	0.53
Hypertension	1,136 (22.3%)	1,173 (23.9%)	0.04
Diabetes mellitus	178 (3.5%)	190 (3.9%)	0.28
Coronary heart disease	276 (5.4%)	261 (5.3%)	0.90
Circulatory problems in legs	481 (9.5%)	456 (9.3%)	0.93
Cardiac failure	200 (4.3%)	202 (4.6%)	0.53
Heart attack	96 (1.9%)	83 (1.7%)	0.52
Cancer	219 (4.3%)	194 (4.0%)	0.42
Stroke	90 (1.8%)	103 (2.1%)	0.20
Inflammatory joint diseases	1,031 (20.3%)	977 (19.9%)	0.87
Other	2,167 (44.2%)	2,166 (46.1%)	0.06
Complementary treatments in the previous year			
Acupuncture	547 (10.8%)	553 (11.3%)	0.33
Homeopathy	324 (6.4%)	294 (6.0%)	0.50
Reasons for choosing acupuncture treatment			
Other therapies not successful	2,346 (51.4%)	2,298 (52.4%)	0.37
Recommended by friends	1,352 (29.1%)	1,335 (29.9%)	0.42
Requesting a "holistic" treatment	2,641 (57.8%)	2,539 (58.4%)	0.57
Hope to reduce painkillers	4,091 (84.4%)	3,880 (83.9%)	0.44
Previous acupuncture treatment successful	1,503 (30.7%)	1,444 (31.0%)	0.81
Recommended by General Practitioner	3,548 (72.6%)	3,420 (73.4%)	0.38
Other reasons	619 (12.2%)	565 (11.5%)	0.37
SF-36 subscale pain at baseline [mean (SD)]	40.2 (21.4)	41.8 (21.7)	0.001

(CI, 3.2-6.7) for osteoarthritis. These figures were minimally affected by pooling the data and modelling the diagnosis as a covariate in a mixed linear model: low back pain, OR = 4.0 (CI, 3.3-4.7); neck pain, OR = 4.5 (CI, 3.8-5.3); headache, OR = 3.3 (CI, 2.8-3.9); and osteoarthritis, OR = 4.9 (CI, 3.3-7.2). Similarly, in the chosen final model, the overall treatment effect (averaged for all diagnoses) was large and statistically significant (OR = 3.5; CI, 3.0-4.1;  $P < 0.0001$ ).

We identified 9 patient characteristics that directly predicted better prognosis, independent of treatment (Table 2). Worse prognosis was found among persons with less baseline pain, previous acupuncture treatment (without considering whether the treatment was successful), and the presence of certain concomitant diseases. In contrast, better prognosis was found among patients under the age of 50 years compared with older patients, patients with higher school education, and for patients whose pain condition began less than 4 years ago.

Four variables were identified as effect modifiers (interaction of patient characteristic and treatment): sex, living situation, positive acupuncture experience before the study, and failing of other therapies. Table 3 shows the ORs for the effect modifiers in the acupuncture group and the control group respectively.

However, as the primary interest of the analysis was to identify characteristics that predict a better response to acupuncture treatment, we analyzed the interactions the other way round and calculated the ORs of an additional acupuncture treatment compared with routine care only. The overall OR for acupuncture compared with routine care only was 3.51 (CI, 3.01-4.09;  $P < 0.0001$ ; Table 2). Compared with this OR, the difference between both treatments in favor of acupuncture was larger for women (OR = 3.91; CI, 3.34-4.58;  $P < 0.0001$ ), whereas men had a smaller effect (OR = 3.14; CI, 2.53-3.90;  $P < 0.0001$ ). The superiority of acupuncture was more prominent in patients who had an earlier positive experience with acupuncture (OR = 4.09; CI, 3.30-5.06;  $P < 0.0001$ ) as in patients without such experience (OR = 3.01; CI, 2.56-3.53;  $P < 0.0001$ ). For patients who reported a earlier failure of other therapies, a larger difference between acupuncture and control group was observed (OR = 3.88; CI, 3.22-4.66;  $P < 0.0001$ ), whereas it was lower in those who reported no earlier therapy failure (OR = 3.17; CI, 2.64-3.81;  $P < 0.0001$ ). Finally, also for patients living in a multi-person household, a higher OR was found (OR = 4.35; CI, 3.83-4.94;  $P < 0.0001$ ), whereas it was smaller for those living in a single household (OR = 2.83; CI, 2.17-3.67;  $P < 0.0001$ ).

**TABLE 2.** ORs, CIs, and P Values for Significant Predictors

	OR	95% CI	P
Acupuncture (vs. Control)			
All diagnoses	3.51	3.01-4.09	< 0.0001
Osteoarthritis of hip or knee	4.90	3.04-7.91	< 0.0001
Neck pain	3.60	2.74-4.72	< 0.0001
Headache	2.60	1.94-3.46	< 0.0001
Low back pain	3.28	2.52-4.29	< 0.0001
Less baseline pain (SF-36 bodily pain, steps of 5 points)	0.80	0.79-0.81	< 0.0001
Age < 50 y	1.25	1.11-1.41	0.0002
Duration of illness < 4 y	1.13	1.02-1.26	0.0215
> 10 y of schooling	1.26	1.12-1.42	0.0002
Previous acupuncture treatment last 12 mo	0.81	0.68-0.96	0.0146
Concomitant diseases			
Hypertension	0.84	0.74-0.95	0.0074
Asthma	0.74	0.64-0.87	0.0002
Diabetes	0.73	0.56-0.96	0.0266
Other concomitant diseases	0.77	0.69-0.85	< 0.0001

CI indicates confidence interval; OR, odds ratios.

**DISCUSSION**

After pooling the data from 4 large-scale randomized controlled trials, we were able to confirm that additional acupuncture treatment had a positive influence on pain reduction in patients suffering from chronic pain. In addition to several predictors that influenced the treatment outcome independent of the treatment groups, 4 characteristics were found that interacted with the treatment group: sex, living situation of the patients, earlier positive acupuncture experience, and a failure of other therapies.

The advantages of our analysis include the randomized study design, the large sample size (approximately 10,000 randomized patients all with chronic pain), and the large variety of participating physicians (approximately 10% of all physicians practicing acupuncture in Germany). The 4 studies included all had a similar study design and took a pragmatic approach, with the common aim of evaluating acupuncture with a high external validity, whereby the study conditions reflect as closely as possible routine medical care. We were not able to use the primary outcome measures from the 4 trials in this analysis because the parameters were disease specific, and thus, not directly comparable. Instead, we used the pain subscale from the SF-36 questionnaire, which was

evaluated in all 4 trials at identical time points. Nevertheless, the problem of using secondary outcome parameters for post hoc data pooling is also common in meta-analyses. Further limitations of our analysis include the lack of some supposedly important control variables, especially patients' expectations and other psychological parameters, such as social support, locus of control, or strategies in coping with pain.

Some patient characteristics facilitated treatment irrespective of whether acupuncture was administered. Younger age of patients, shorter duration of illness, and a more education were independently associated with less bodily pain. These findings correspond to results from nonacupuncture studies. In a study on manipulation techniques and exercise for chronic pain patients, higher education level, younger age, shorter duration of the current pain episode, and being at work were found to positively correlate with outcome, independent of the intervention.<sup>15</sup> In a study on total knee replacement in patients with chronic knee pain, low socioeconomic status (often correlated with less education) and older age were found, besides other variables, to influence the outcome negatively.<sup>16</sup> It seems medically plausible that in our study younger age and a shorter history of pain have a positive impact on improvement. With regard to the association of positive outcome with a higher education, this might be because of a difference in professions with patients of lower education more often working in jobs that include heavy lifting or working in an unhealthy posture as at a cash register in a supermarket or other. However, this would have to be confirmed as other explanations, such as expectations or treatment adherence, might also be of explanatory value. Another variable that led to increased treatment was higher baseline pain. This might be because of regression to the mean, or to floor effects making it improbable to lessen pain much more during the course of treatment, if it has already reached a certain (low) threshold. Higher baseline pain or dysfunction has been found to heighten treatment effects in other acupuncture studies as well.<sup>3,17</sup>

The result that patients who received acupuncture treatment within 12 months before the study had a worse outcome than patients without former acupuncture treatment, independently of the treatment group, is certainly an issue for further investigation, as we are currently unable to explain this. It is of note, that in a United States no effect of acupuncture experience on outcome was found.<sup>6</sup>

Not surprisingly, some concomitant diseases lessened treatment effects, in particular, hypertension, asthma, diabetes, and other, not further specified diseases. Patients

**TABLE 3.** ORs and CIs of Effect Modifiers for Treatment Groups

	Acupuncture		Control		P Value for Interaction
	OR	CI	OR	CI	
Female (vs. male)	1.10	0.93-1.29	0.88	0.76-1.03	0.028
Single household (vs. multi-person household)	0.75	0.61-0.92	1.16	0.96-1.40	0.002
Earlier positive acupuncture experience (vs. no or negative acupuncture experience)	1.25	1.04-1.47	0.92	0.78-1.07	0.005
Earlier failure of other therapies (vs. no failure or success)	0.90	0.77-1.05	0.74	0.64-0.85	0.049

CI indicates confidence interval; OR, odds ratios.

under such multiple strain because of chronic pain, in addition to another disease, might take longer to benefit from any treatment. This also is in line with findings from studies on conventional treatments.<sup>16</sup>

Of special interest for acupuncture practice were patient characteristics that modified the effect in the acupuncture group. This might help to identify groups of patients that especially benefit from acupuncture or experience less effect. We found sex, living situation, and aspects of former treatment experiences as acupuncture effect modifiers.

Women profited more from acupuncture than men, a difference that might be explained by expectations and attitudes toward the treatment as well as adherence. As women seem to be more in favor of CAM therapies,<sup>9,18</sup> they might be less satisfied when allocated to the control group and have higher expectations when allocated to the acupuncture group, which results in less or more pain reduction. However, these sex issues are certainly a matter of further investigation.

The favorable effect of acupuncture for patients living in a multi-person household compared with those living in a single household remains difficult to explain, as it was not assessed what kind of multi-person household the patients were referring to. A multi-person household can be anything from living as a couple, sharing an apartment with friends or strangers, living alone with a child, or living as a family unit. Such circumstances might allow conclusions about patients' social support, which can play a role in coping with pain.<sup>19,20</sup>

Experiences with earlier treatments also influenced the effect of acupuncture treatment. Patients with earlier positive acupuncture experience had a more positive outcome. This might be because of higher expectations. Another explanation might be conditioning, whereby acupuncture experience is tied to the experience of reduced pain. To understand the effects of former acupuncture experience fully, it is necessary to control especially for expectations in future studies. The same is true for the moderating effect of the failure of other therapies before the study. Although in both groups patients with an experience of treatment failure had a worse outcome than those without treatment failure, nevertheless, additional acupuncture would be the more preferable treatment, as it led to a better outcome than no additional acupuncture in those patients. The effect of acupuncture in this subgroup was even larger than the average acupuncture effect including all patients. As noted above, expectations might explain this. Patients who have experienced the failure of other treatments might be especially disappointed when assigned to the routine care only group, and have especially high expectations when assigned to the acupuncture group, notwithstanding their overall prognosis being worse than if no treatment failure was experienced beforehand. A second explanation might be that acupuncture differs from other therapies in many regards, one of them the experience to receive a treatment while remaining passive and just relaxing. It is possible that certain types of patients especially benefit from this treatment. Internal or external health locus of control<sup>21</sup> or active and passive coping with pain<sup>22</sup> might determine the profit that patients receive from such passive sort of treatment. In this way, patients who reported failure of other, supposedly more active therapies such as physiotherapy, might be those who profit more from a passive therapy, such as acupuncture.

Finally, it must be considered that in patients with a history of treatment failure pain was not lessened, but they nevertheless reported less pain, because of a process of self-convincing; namely if other treatments have failed and this treatment does not work either, then little hope remains. Therefore, patients may rate the acupuncture treatment as better than it actually is, in a process of trying to maintain hope.

As the above-mentioned reasons for moderating effects are predominantly assumptions, it is necessary to investigate them further to come to a conclusion on the question which patients benefit most from acupuncture treatment of chronic pain. Treatment expectations, but also other psychological variables such as social support, locus of control, or strategies in coping with pain might mediate the influence of the patient characteristics that were found as effect modifiers in this study.

In addition, taking care of possible reporting biases because of hope, might be promising. This could be tried by comparing patients' reports with estimations of the physicians or significant others as the partner or friends. Using a broader set of measures than simply the SF-36 subscale for pain might also add to clarification of the effects.

In summary, we were able to detect some variables that predicted treatment outcome in chronic pain patients in general and some that acted as effect modifiers with regard to acupuncture. The modifying effects lack adequate explanations, thus further research is necessary to clarify sex effects and the effects of the living situation of the patients as well as the impacts of earlier treatments. Controlling for expectations and incorporating psychological variables seems especially worthwhile.

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