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Treatment of patients with chronic headaches in a hospital for traditional Chinese medicine in Germany
A randomised, waiting list controlled trial☆

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KEYWORDS
Traditional Chinese medicine;
Migraine;
Tension-type headache;
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Summary
Objective: To investigate the effectiveness of a clinical treatment program with traditional Chinese medicine for migraine and tension-type headache.
Methods: Ninety-one patients with migraine, episodic or chronic tension-type headache according to the criteria of the International Headache Society were randomised into an experimental or a waiting list control group. Patients in the experimental group were treated 4 weeks in a hospital for traditional Chinese medicine after a baseline period of one month. Patients in the waiting list group continued their previous headache treatment. Main outcome measure was the difference in the number of days with headache of at least moderate intensity during baseline (month 1) and month 7.
Results: The difference in the number of days with headache of at least moderate intensity was 5.6 (S.D., 6.1) days in the experimental group and 1.2 (S.D., 4.5) days in the waiting list group ($P < 0.001$). A reduction of more than 50% in headache days was observed in 52% of the patients in the experimental group and 16% in the waiting list group. Patients with migraine and a combination of migraine and episodic tension-type headaches improved more than patients with other headaches.
Conclusion: The results of this study indicate that treatment in the hospital for traditional Chinese medicine in Kötzting is associated with lasting improvements in the majority of patients.

Abbreviations: IHS, International Headache Society; SF-36, Short Form 36 (quality of life questionnaire); SDS, Zung self-rating scale for depression; TTH, tension-type headache; NSAIDs, non-steroidal anti-inflammatory drugs

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INTRODUCTION

In 1991, a 76-bed hospital for traditional Chinese medicine was opened in Kötzting, Germany, in which a team of Chinese and German physicians treat about 1000, mostly chronically ill patients per year. Following the principles of traditional Chinese medicine patients are mainly treated with acupuncture, traditional herbs, Chinese manual therapy (tuina massage) and a specific relaxation technique (qi gong). Western therapies are continued or prescribed if necessary. German social health insurance companies have agreed to reimburse the clinical treatment in this hospital, if patient characteristics, treatments, outcomes, and side effects are continuously evaluated (see Refs. 1–5 for publications). The number of patients seeking treatment at the hospital is very high. Therefore, in the years 1996–2001 patients had to wait for about a year for admission.

About 20% of the patients seeking treatment at the hospital suffer from a variety of chronic, often insufficiently controlled headache disorders. In an observational study,[5] it could be shown that complaints decreased significantly after treatment at the hospital and for a period of at least 12 months in the majority of patients. As uncontrolled studies do not allow causal inferences, we performed the randomised trial described below. The objective of this pragmatic study was to investigate to what extent headache patients benefit from the stay in the hospital for traditional Chinese medicine.

Methods

Design

The study was performed as an open, randomised trial comparing an immediate intervention group (experimental group) with a waiting list control condition. A random list was generated with a computer program (random, idv, Gauting) providing blocks of six patients for each of three subgroups (migraine, tension-type headache, both). Consecutively numbered, opaque envelopes containing a sheet with the allocation were prepared and opened after patients had been included in the study. All patients gave both written and oral informed consent. The study protocol was approved by the local ethics committee (Bayerische Landesärztekammer).

Inclusion and exclusion criteria

Patients older than 18 years on the waiting list for admission to the hospital for traditional Chinese medicine in Kötzting were eligible when the following criteria were met: a predicted waiting period of more than 9 months; a diagnosis of migraine or tension-type headache according to a standardized instrument (Kieler Kopfschmerzbogen = Kiel Headache Questionnaire[6]) checking the criteria of the International Headache Society (IHS) and a telephone interview; a duration of the disease of more than 12 months; at least 5 headache days per months in each of the last 3 months; hospital stay feasible for the patient both in the next 5–10 weeks and in 8–9 months. Patients were excluded when they planned to start a new headache treatment before admission; if headaches were not the primary reason for admission; if they suffered from other headaches; if a waiting period of 9 months was not acceptable.

Recruitment

Patients from all over Germany seek admission for treatment in the hospital. To be admitted all patients routinely have to provide detailed information on their case history, together with a referral from their home physician. Based on this information physicians try to assess whether a treatment in the hospital is indicative or not. For the study, patients referred for the treatment of migraine and tension-type headache were identified from the waiting list and sent a letter informing them about the study and offering participation. If patients were interested they were asked to fill in the Kiel Headache Questionnaire[6] and to answer a number of additional questions. The physicians in the hospital then evaluated the questionnaire and telephoned the patients to check inclusion criteria and discuss open questions. If the patient was eligible and confirmed orally his written informed consent, the respective sealed envelope containing the information about allocation was opened. In a screening list all contacts with patients were documented.

Patients randomised to immediate intervention were admitted to hospital treatment 5–8 weeks after randomisation. Patients randomised to waiting list were admitted 8–9 months after randomisation. In the hospital a final headache diagnosis was made and details on the patient history documented.

Outcome measurement

After randomisation all patients were asked to fill in a headache diary for one month in which the following aspects were documented: whether headache occurred on a given day; intensity of pain on a rating scale ranging from 1 (minimal pain) to

Box 1. Example of clinical features relevant for the diagnosis according to traditional Chinese medicine and treatment

Forty-two-year-old, male patient suffering from migraine without aura since 20 years; currently 1–2 attacks per week, attack treatment with rizatriptan 10 mg p.o., no prophylaxis

Symptoms: Stabbing pain from neck to temporal and orbital region, sometimes bilateral. Triggered by alcohol or change of weather. Improved by cold wash-rag on the forehead, quiet and dark environment. Accompanying symptoms: vision problems, tinnitus, sometimes nausea

Findings: Purple tongue with a red tip and thin, white coating. Pulse tight, tender and fast

Differential diagnosis of syndromes according to traditional Chinese medicine: Up-stirring of wind-heat with phlegm-dampness and blood stasis

Principle of treatment: Expelling wind and heat, removing phlegm-dampness, promoting blood circulation to remove blood stasis

Treatment: Decoction from 12 traditional Chinese herbs for daily intake. The ingredients of the recipe were modified according to the changes of the clinical manifestations. Twelve acupuncture treatments (most frequently treated points GB20, GB14, Ex HN5, LI4, LI20, CV20, LR3). Single Qi-Gong treatment and group exercises of Qi-Gong

10 (extreme pain); occurrence of accompanying symptoms; analgetic medication; other measures against headache. In addition, on the last day patients were asked to rate their complaints in the preceeding month on a 100 mm visual analogue scale; to report on how many days headache inhibited usual activities or work; to fill in a questionnaire to measure health-related quality of life (the SF-36[7]) and the Zung self-rating scale for depression (SDS[8]); and to report on any other prophylactic headache treatments used. Patients in the experimental group during the hospital stay also kept a headache diary. All patients filled in the diary in months 4 and 7 after randomisation. At the end of month 7 health-related quality of life and depressive symptoms were assessed again.

Treatment at the hospital

For every patient a Chinese diagnosis was made by collecting the patients' individual symptoms (by history) and signs (including feeling the pulse and inspection of the tongue), and classifying these according to the theoretical framework of traditional Chinese medicine (see Ref. 9 for a short summary of the principles of traditional Chinese medicine). Patients then received individualized treatment with traditional Chinese medicine at the hospital for 4 weeks. All therapies were documented. Box 1 presents an example describing the approach to diagnosis, treatment and the interventions applied in one of the study patients. After discharge the majority of patients continued the intake of traditional Chinese drugs for at least 4 weeks. Patients in the waiting list group were asked to continue their previous treatment.

Statistics

The main analysis was performed for the per protocol population (all patients meeting the inclusion criteria and with headache data for months 1 and 7). An additional 'intent to treat' analysis was performed for the main outcome measure (setting the difference for all missing patients as 0). Main outcome measure was the difference in the number of days with at least moderately severe headache (an intensity >3 on the rating scale) between months 1 and 7. Confirmatory testing was performed using a one-sided Wilcoxon–Mann–Whitney test. All additional analyses should be considered exploratory. According to a sample size calculation (performed with N, idv, Gauting, Germany) 51 patients per group were necessary to detect an effect (difference between experimental and control group) of 0.5 standard deviations with a power of 80%.

RESULTS

Two hundred and two patients on the waiting list were contacted and 196 responded. A total of 102 were eligible and gave consent. Fifty-two were randomised into the experimental group and 50 into the waiting list group. Six patients in the experimental and five in the control group dropped out or were excluded leaving 91 patients (46 in experimental and 45 in control group) for the main

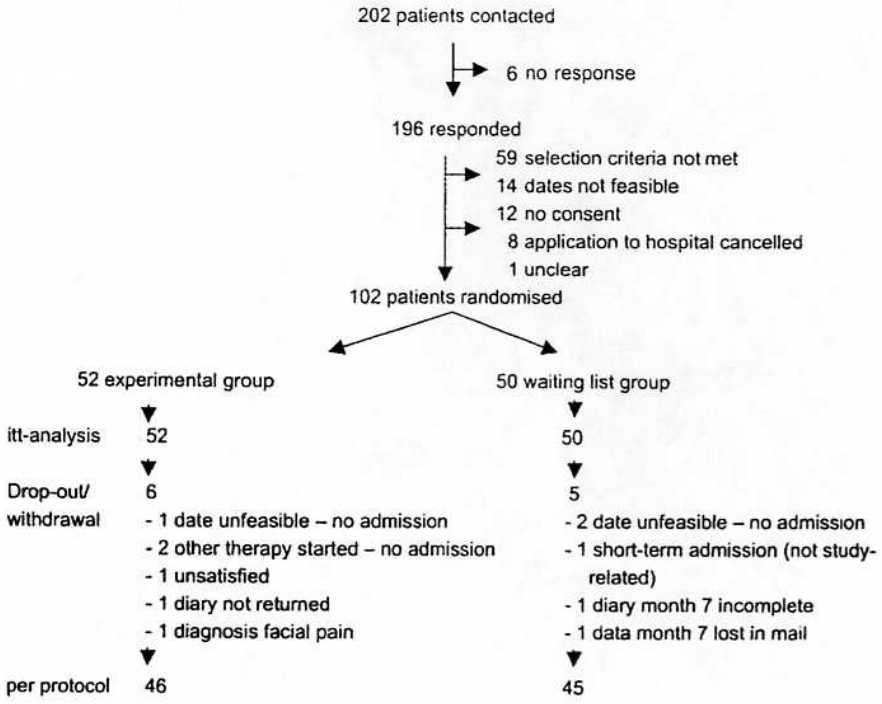

Figure 1 Trial profile (itt = intention to treat).

analyses (see Fig. 1 for details). Due to the strong heterogeneity of patients, additional post hoc subgroup analyses were performed. The subgroup I includes all 56 patients with migraine alone, as well as patients with migraine and episodic tension-type headache for whom an abuse of analgetic drugs could be ruled out (clinically, and less than 15 days analgetic use in month 1). The subgroup II comprises all remaining patients (see Table 1).

Eighty-three of the 91 patients were women, the mean age was 49 years. Forty-six suffered from migraine only, 17 from migraine and episodic tension-type headache, 20 from migraine and chronic tension-type headache and 8 from chronic tension-type headache. In a total of 15 patients, a drug-induced headache could not be ruled out. On average patients suffered for 25 years from their migraine headaches and for 19 years from

Table 1 Patient characteristics and baseline data.

	All patients		Subgroup I		Subgroup II	
	Experimental ($n = 46$)	Control ($n = 45$)	Experimental ($n = 28$)	Control ($n = 28$)	Experimental ($n = 18$)	Control ($n = 17$)
Female/male	43/3	40/5	26/2	25/3	17/1	15/2
Age	48 ± 11	49 ± 11	46 ± 10	46 ± 10	52 ± 11	52 ± 10
Headache diagnosis						
Migraine without aura	15	15	13	13	2	2
Migraine with aura	10	6	9	6	1	–
Migraine + episodic TTH	7	10	6	9	1	1
Migraine + chronic TTH	11	9	–	–	11	9
Chronic TTH	3	5	–	–	3	5
Analgesic abuse cannot be excluded	8	7	–	–	8	7
Intake of prophylactic medication	10	11	4	10	6	1

Subgroup I includes all patients with migraine or migraine + episodic tension-type headache exclusive patients in whom a drug abuse is suspected. Subgroup II includes all remaining patients.

tension-type headaches. All patients had been treated before, approximately half had received an adequate headache prophylaxis according to current German guidelines[10,11] in the last 3 years and 80% had already tried some form of unconventional treatment. Only 6 patients considered the interventions they had received in the past as satisfying, while 26 patients felt that they had some influence on the complaints themselves. In the baseline period 21 patients used triptans only for headache treatment, 27 used triptans and peripheral analgetics/NSAIDs, 27 used exclusively analgetics/NSAIDs, 2 used ergotamines only, 8 used occasionally ergotamines in addition to analgetics or triptans and 6 did not treat headache with any type of medication. In the hospital all patients received acupuncture, and traditional Chinese drug treatment. Only a minority of patients received Qi-Gong (23%) and Tuina massage (33%).

Experimental and control group were well comparable for all pre-randomisation variables (see Table 1). In the post-randomisation baseline phase (month 1) the number of days with analgetic use was significantly higher in the control group and there was a statistical trend for reduced mental wellbeing and higher depression scores in the control group (see Table 2). Use of conventional drug prophylaxis and other methods to prevent headaches (mainly relaxation techniques) was similar in both groups at baseline (10 patients versus 11 patients for conventional drug and 24 patients versus 24 patients, respectively), in month 4 (9 patients versus 8 patients and 34 patients versus 27 patients) and in month 7 (10 patients versus 8 patients and 29 patients versus 24 patients).

Independently from the allocation of experimental or control group, the patients in subgroup II had significantly more complaints than the patients in the subgroup I.

In the experimental group the number of days with at least moderately severe headache decreased between months 1 and 7 by 5.5 (S.D., 6.1) days compared to 1.2 (S.D., 4.5) days in the waiting list group ($P < 0.001$; mean difference between groups 4.2 days, 95% confidence interval 2.0–6.5 days; see Fig. 2). In the "intent to treat" analysis, the mean difference between groups was 4.4 days (2.2–6.6 days). In subgroup I the difference between groups was 3.4 days (1.6–5.2 days), in subgroup II a difference of 5.6 days (0.4–10.7 days; see Fig. 3) was observed. Seventeen (61%) subgroup I patients in the experimental group experienced a reduction of more than 50% in their headache days compared to only 4 (14%) patients in the control group. The respective numbers for the subgroup II patients were 7 (39%) and 3 (18%).

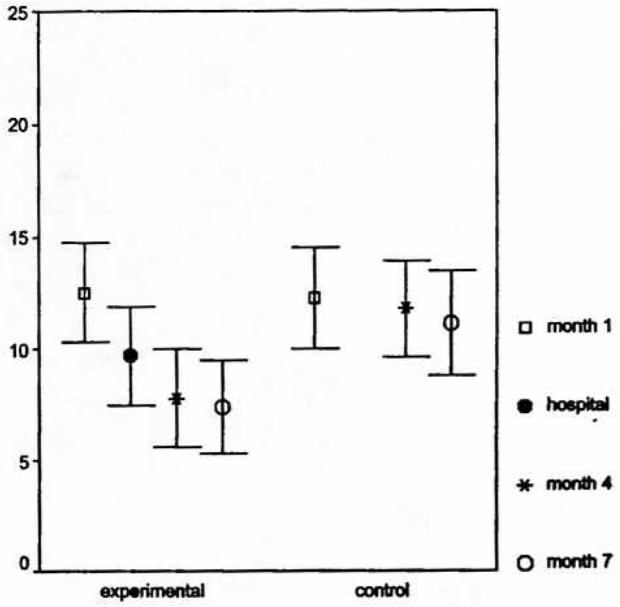

Figure 2 Mean (95% confidence intervals) number of days with headache with an intensity >3 (on a scale ranging from 1 = minimal pain to 10 = unsupportable pain) per group in all patients.

Patients in the experimental group faired significantly better than the control group patients for all secondary outcomes in months 4 and 7 with the exception of physical wellbeing scale of the SF-36 (see Table 2). When baseline differences were taken into account the decrease in analgetic use was no longer significant in month 7. With regard to the reduction of headache frequency, the subgroup analyses suggest that the patients in subgroup I benefited more from the treatment in the hospital than patients from subgroup II.

No serious adverse effects occurred during the study. However, patients reported minor adverse effects of acupuncture in eight cases (e.g., needling pain), and of traditional Chinese herbs in 23 cases (e.g., bad taste and gastrointestinal complaints).

DISCUSSION

The results of this study indicate that the clinical treatment in the hospital for traditional Chinese medicine in Kötzting is associated with lasting improvements in the majority of patients. It is not possible to draw any causal inferences on which components of the treatment have made a significant impact, or to quantify the influence of unspecific effects.

Our study should not be compared directly with trials evaluating the efficacy of drugs for migraine or tension-type headache prophylaxis. The aim

Table 2 Outcome measures in all patients and in the two subgroups.

	All patients			Subgroup I			Subgroup II		
	Experimental ($n = 46$)	Control ($n = 45$)	Mean difference (95%CI)	Experimental ($n = 28$)	Control ($n = 28$)	Mean difference (95%CI)	Experimental ($n = 18$)	Control ($n = 17$)	Mean difference (95%CI)
Headache days with intensity >3									
Month 1	12.5 ± 7.8	12.4 ± 7.9	0.0 (−3.2; 3.3)	12.6 ± 5.3	14.0 ± 5.1	−1.4 (−4.2; 1.4)	25.9 ± 5.4	24.5 ± 5.9	1.4 (−2.5; 5.2)
Month 4	7.6 ± 7.5	11.6 ± 7.4	−4.0 (−7.2; −0.9)	7.1 ± 4.4	13.2 ± 4.4	−6.1 (−8.4; 3.7)	21.4 ± 9.4	23.0 ± 8.6	−1.6 (−7.7; 4.6)
Month 7	7.0 ± 6.7	11.2 ± 7.8	−4.2 (−7.2; −1.1)	6.7 ± 3.9	12.1 ± 5.4	−5.4 (−7.9; −2.8)	21.7 ± 9.3	22.7 ± 8.2	−1.0 (−7.1; 5.0)
Total headache days									
Month 1	17.8 ± 8.4	18.0 ± 7.4	−0.2 (−3.5; 3.1)	8.0 ± 4.4	8.8 ± 4.6	−0.8 (−3.2; 1.6)	19.5 ± 6.7	18.4 ± 8.7	1.1 (−4.3; 6.4)
Month 4	12.7 ± 9.7	16.9 ± 7.8	−4.2 (−7.9; −0.5)	4.3 ± 3.5	9.2 ± 4.4	−4.9 (−7.0; −2.8)	12.8 ± 9.1	15.7 ± 9.6	−2.9 (−9.3; 3.6)
Month 7	12.6 ± 9.8	16.1 ± 8.3	−3.5 (−7.3; 0.3)	3.8 ± 3.2	7.9 ± 4.5	−4.1 (−6.2; −2.0)	12.1 ± 7.6	16.6 ± 9.0	−4.5 (−10; 1.2)
Sum daily intensities									
Month 1	94 ± 55	93 ± 51	1 (−21; 23)	63 ± 34	69 ± 31	−6 (−24; 11)	144 ± 44	133 ± 54	11 (−23; 45)
Month 4	56 ± 49	89 ± 50	−33 (−54; −12)	30 ± 22	71 ± 29	−41 (−54; −27)	98 ± 52	120 ± 63	−23 (−62; 17)
Month 7	54 ± 46	84 ± 52	−30 (−50; −9)	29 ± 22	62 ± 34	−33 (−48; −18)	93 ± 47	119 ± 58	−26 (−62; 10)
Average intensities									
Month 1	5.2 ± 1.6	5.2 ± 1.6	0.0 (−0.6; 0.7)	4.9 ± 1.7	5.0 ± 1.5	−0.1 (−0.9; 0.8)	5.6 ± 1.5	5.4 ± 1.8	0.2 (−0.9; 1.3)
Month 4	4.4 ± 1.6	5.3 ± 1.6	−1.0 (−1.6; −0.3)	4.3 ± 5.3	5.3 ± 1.3	−1.0 (−1.8; −0.2)	4.5 ± 1.6	5.4 ± 2.0	−0.9 (−2.1; 0.3)
Month 7	4.2 ± 1.8	5.2 ± 1.6	−0.9 (−1.6; −0.2)	4.3 ± 1.8	5.1 ± 1.6	−0.9 (−1.8; 0.0)	4.3 ± 1.7	5.3 ± 1.7	−1.0 (−2.2; 0.2)
Days with analgestic medication									
Month 1	8.4 ± 6.2	11.0 ± 6.2	−2.6 (−5.2; 0.0)	7.0 ± 4.3	10.0 ± 3.8	−3.0 (−5.2; −0.8)	10.6 ± 7.9	12.8 ± 8.8	−2.2 (−7.9; 3.6)
Month 4	4.4 ± 4.1	10.0 ± 5.6	−5.7 (−7.7; −3.6)	3.8 ± 3.0	9.0 ± 3.5	−5.2 (−7.0; −3.5)	5.2 ± 5.4	11.7 ± 7.8	−6.5 (−11; −1.8)
Month 7	4.7 ± 4.4	9.6 ± 6.2	−4.9 (−7.1; −2.6)	3.9 ± 2.9	8.5 ± 4.2	−4.6 (−6.6; −2.7)	5.9 ± 6.0	11.2 ± 8.4	3–5.3 (−10; −0.3)
Days activities constrained									
Month 1	7.7 ± 5.6	7.5 ± 5.9	0.1 (−2.3; 2.6)	5.9 ± 2.9	5.5 ± 2.8	0.4 (−1.2 ± 1.9)	10.9 ± 7.6	10.6 ± 7.9	0.3 (−5.2; 5.8)
Month 4	4.2 ± 3.9	8.3 ± 7.2	−4.1 (−6.6; −1.6)	3.3 ± 2.7	6.5 ± 4.6	−3.2 (−5.3; −1.2)	5.8 ± 5.1	11.4 ± 9.8	−5.6 (−11; 0.0)
Month 7	4.2 ± 4.2	8.7 ± 7.1	−4.5 (−6.9; −2.0)	3.4 ± 2.8	7.7 ± 5.9	−4.3 (−6.8; −1.8)	5.6 ± 5.5	10.3 ± 8.6	−4.7 (−10; 0.2)
Depressive symptoms (SDS)									
Month 1	49.9 ± 10.6	54.1 ± 11.2	−4.2 (−9.2; 0.7)	49 ± 10	52 ± 12	−2.9 (−8.9; 3.2)	52 ± 12	59 ± 9	−6.5 (−15; 2.1)
Month 7	46.4 ± 10.3	55.5 ± 11.1	−9.0 (−14.0; −4.0)	44 ± 9	53 ± 11	−8.8 (−15; 2.3)	50 ± 11	60 ± 9	−10.6 (−18; −3.1)
SF-36-physical wellbeing									
Month 1	36.3 ± 6.6	35.9 ± 7.0	0.4 (−2.6; 3.5)	38 ± 6	38 ± 7	0.0 (−3.8; 3.8)	34 ± 7	33 ± 6	1.4 (−3.4; 6.3)
Month 7	40.3 ± 9.4	38.0 ± 7.6	2.3 (−1.5; 6.0)	42 ± 10	41 ± 8	1.1 (−3.9; 6.0)	39 ± 9	34 ± 5	4.9 (−0.8; 11)
SF-36-mental wellbeing									
Month 1	40.7 ± 11.1	36.7 ± 9.6	4.0 (−0.7; 8.7)	42 ± 11	37 ± 10	5.3 (−0.7; 11)	38 ± 12	36 ± 9	1.9 (−6.1; 9.8)
Month 7	47.1 ± 8.5	37.5 ± 10.1	9.6 (5.5; 13.6)	49 ± 9	40 ± 9	8.5 (3.4; 14)	45 ± 8	34 ± 10	10.7 (4.0; 17)

Values for experimental and control groups are means and standard deviations.

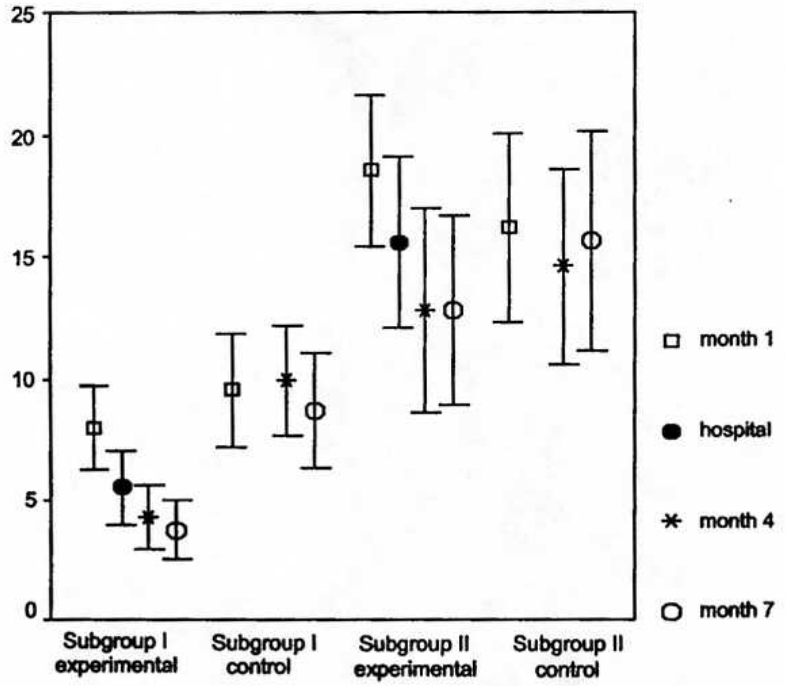

Figure 3 Mean (95% confidence intervals) number of days with headache with an intensity >3 (on a scale ranging from 1 = minimal pain to 10 = unsupportable pain) per group in the subgroups I and II.

was to evaluate an existing treatment option for German headache patients in a pragmatic manner. Therefore, inclusion criteria were wide to warrant that the results are valid for the majority of headache patients treated in Kötzting. Many of the patients in our study suffered from severe headache and would have been excluded in drug trials performed according to the recommendations of the International Headache Society[12,13] due to the complexity of their symptoms, previous prophylactic treatment, etc. Most patients had already tried a number of therapies including complementary treatments. We consider that such pragmatic trials in "natural" populations are justified and necessary. The responder rates observed in these are, however, difficult to compare with those of conventional drug trials (where responder rates are typically around 50%).

The most important shortcoming of our study is the fact that randomisation had to be performed at an early stage before headache diary and full questionnaire data were available. This was necessary as patients had to have enough time (at least one month) to plan and prepare for the hospital stay. Therefore, patients were aware whether they were going to the hospital soon or whether they had to wait for a longer period. It is likely that the group differences in the scores for mental wellbeing, depressive mood and analgetic drug use in month 1 are a consequence of this knowledge. It could be that due to the positive expectations associated with admission in near future patients in the experimental group felt better, or that patients in the waiting list were disappointed and therefore felt worse. Also, at the end of the waiting period control patients were close to admission and might have reported more positive information. All these potential biases would decrease group differences at months 4 and 7.

Traditional Chinese treatment was provided on an individualized basis using combinations of herbs and acupuncture. A number of randomised trials of acupuncture for chronic headache have been previously performed (see Ref. 14 for review). While acupuncture is a major component, this therapy alone cannot be considered as full traditional Chinese medicine. To the best of our knowledge our study is the first randomised trial in the 'West' investigating a classical combination therapy in headache patients.

Despite its limitations we believe that our study reports interesting data on the potentials of traditional Chinese medicine treatment of migraine and tension-type headache. The results suggest that the treatment has a lasting beneficial effect in many patients. However, it also makes very clear that traditional Chinese medicine is not a 'magic bullet'. A relevant proportion of the patients report no or only minor improvements. The results further suggest that patients with migraine alone or combined with episodic tension-type headache benefit more than patients with

chronic tension-type headache or other headache disorders.

A growing number of western physicians and other health care professionals are using traditional Chinese medicine in outpatient care. It is unclear whether the results of the treatment in such settings are similar as in our study where specifically trained and highly experienced Chinese physicians (who, however, needed translators to communicate with the patients) treated patients for 4 weeks in a hospital.

In conclusion, our results provide some preliminary evidence that a complex individualized treatment with traditional Chinese medicine might be beneficial in patients suffering from migraine and tension-type headache. Further research is clearly warranted.

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