

Research article

Open Access

Measuring the effects of acupuncture and homoeopathy in general practice: An uncontrolled prospective documentation approach

Corina Güthlin*¹, Oliver Lange¹ and Harald Walach^{1,2}

Address: ¹Department of Evaluation Research in Complementary Medicine, Institute of Environmental Medicine and Hospital Epidemiology, Freiburg University Hospital Hugstetter Str. 55 D-79106 Freiburg Germany and ²Samueli Institute for Information Biology™ – European Office Freiburg University Hospital Institute of Environmental Medicine and Hospital Epidemiology Hugstetter Strasse 55 D-79106 Freiburg Germany

Email: Corina Güthlin* - guethlin@ukl.uni-freiburg.de; Oliver Lange - olange@ukl.uni-freiburg.de; Harald Walach - walach@ukl.uni-freiburg.de

* Corresponding author

Published: 04 March 2004

Received: 29 September 2003

BMC Public Health 2004, 4:6

Accepted: 04 March 2004

This article is available from: <http://www.biomedcentral.com/1471-2458/4/6>

© 2004 Güthlin et al; licensee BioMed Central Ltd. This is an Open Access article: verbatim copying and redistribution of this article are permitted in all media for any purpose, provided this notice is preserved along with the article's original URL.

Abstract

Background: Despite the increasing demand for acupuncture and homoeopathy in Germany, little is known about the effects of these treatments in routine care. We set up a pragmatic documentation study in general practice funded within the scope of project launched by a German health insurer. Patients were followed-up for up to four years.

Methods: The aim of the project was to study the effects and benefits of acupuncture and/or homoeopathy, and to assess patient satisfaction within a prospective documentation of over 5000 acupuncture and over 900 homoeopathy patients. As data sources, we used the documentation made available by therapists on every individual visit and a standardised quality-of-life questionnaire (MOS SF-36); these were complemented by questions concerning the patient's medical history and by questions on patient satisfaction. The health insurer provided us with data on work absenteeism.

Results: Descriptive analyses of the main outcomes showed benefit of treatment with middle to large-sized effects for the quality of life questionnaire SF-36 and about 1 point improvement on a rating scale of effects, given by doctors. Data on the treatment and the patients' and physicians' background suggests chronically ill patients treated by fairly regular schemes.

Conclusion: Since the results showed evidence of a subjective benefit for patients from acupuncture and homoeopathy, this may account for the increase in demand for these treatments especially when patients are chronically ill and unsatisfied with the conventional treatment given previously.

Background

In the light of increasing demand for alternative and complementary therapies (CAM) [1,2], discussions about the effectiveness and effects of these treatments have gained momentum. This has produced a growing amount of research, including randomised controlled trials (RCTs). Research on acupuncture and homoeopathy – two of the

main forms of CAM sought in Germany [3-5], has also been the subject of systematic reviews [6-8]. However, there is only scarce research on the effects of acupuncture and homoeopathy in general practice.

Moreover, most studies only investigate effectiveness in terms of clinical parameters, such as disease status and

well-being. Yet, the fact that this does not reflect the whole picture is evident from theoretical models of successful treatments and counselling [9] as well as from empirical findings: Acupuncture and massage, for instance, have proved to be beneficial if patients seek exactly this sort of therapy [10]. In addition, most studies use artificial settings, created through strict inclusion and exclusion criteria, or through the application of randomisation to create a control group. This procedure can lead to highly internally valid studies with low generalisability. A case can be made that although RCTs are studies that produce reliable results if efficacy is the research question, other designs need to be applied if, for instance, general effects are to be documented, or patients cannot be randomised, because they have strong preferences [11,12]. In this case, positive or negative health effects may be related to the patients' expectations and to the setting where treatment is applied. In general practice, therapeutic benefits are triggered by the purported specific effects of the treatment, by the patients' and doctors' expectations, and the non-specific effects of the therapeutic ritual, to name but a few factors.

In Germany, health insurance companies are permitted to pay for non-conventional therapies such as acupuncture and homoeopathy within so-called model projects. According to the law, the projects and hence the treatments given in general practice, have to be evaluated scientifically. Carrying out this type of evaluation in a prospective documentation gave us the opportunity (i) to investigate both treatments in real life conditions and (ii) to study a complex array of therapeutical effects. Our goal was to document the generic health effects of homoeopathy and acupuncture in general practice in an unselected patient population seeking the help of qualified doctors.

The study covered documentation of roughly 5000 patients and their treatments. The patients were followed up over the course of up to four years.

Objectives

The objective of this documentation study was to measure effects. These were specified in terms of three main outcome criteria pertaining to three different sources: Quality of life before and after treatment as reported by patients (MOS SF-36 German version [13,14]), change of main symptoms as rated by doctors, and data from the insurance company on work days lost (available for at least 3 years before and after treatment).

A further benefit of this type of documentation approach lies in the opportunity to gather data regarding the following questions:

- What kind of diseases do homoeopathic doctors and acupuncturists treat?

- Do patients see CAM practitioners on a regular basis or just once?

- What subjective benefit and satisfaction with treatment do patients experience?

- How does the general health status of the treated population change?

Methods

As a design a prospective documentation was used that followed the methodology outlined in a predefined and published protocol [15]. This means that all the patients insured with the insurance company "Innungskrankenkasse" (short IKK) who had visited one of the participating doctors between 1995 and 1998 were eligible for treatment and hence for inclusion in this study. The IKK offered these treatments in the three German *Länder* of Baden-Württemberg, Saxony, and Saxony-Anhalt and funded this study.

As the study was designed as a real routine-care-assessment the only inclusion criteria were: written informed consent, ability to read and write German and being insured with the funding insurance company.

The eligibility criteria of the doctors ensured the quality of treatment. All of them had to be medical doctors. For inclusion in the trial phase, they had to send proof of their qualification to a quality control committee set up by representatives of the insurance company and the doctors' associations. Homoeopaths had to possess the comprehensive additional qualification "homoeopathic doctor" according to standards of the German Homoeopathic Doctors' Association (*Zentralverein homöopathischer Ärzte*); acupuncturists had to have at least 140 hours of training and hold a so-called A -diploma (certified by an acknowledged acupuncture association).

At the beginning of the study, patients were asked to give written consent to allow documentation. Consenting patients were given baseline questionnaires while awaiting treatment. Post-treatment, acupuncture patients were asked to fill in a set of questionnaires after the final session of a treatment cycle as well as follow-up questionnaires once a year. For homoeopathy – where treatment is more likely to last several months or years – patients were asked to fill in questionnaires prior to the treatment and every 6 months thereafter. The questionnaires after the treatment had to be answered at home and mailed to the study centre. This ensured that doctors remained unaware of the answers given by the patients.

Doctors were asked to document the diagnosis, the application of treatment and improvement or deterioration of the main symptom every time they saw the patient.

At the end of the trial phase, the insurance company supplied information on absence from work.

The following data were recorded:

Patients

Pre-treatment questionnaire on

- socio-demographic variables
- complaints (free text)
- number and type of therapeutic approaches used
- current treatment
- current medication

- reasons for seeking alternative therapy

- health-related quality of life (MOS SF-36)

The post-treatment questionnaire contained the following items:

- subjective perception of effectiveness
- satisfaction with treatment
- in case of failure or disruption of therapy: reasons
- side effects
- concurrent illnesses during treatment
- health-related quality of life (MOS SF-36)

Follow-up questionnaires repeated the main questions post-treatment.

Doctors

Initially, a practice profile questionnaire documented details about training, experience, and techniques normally applied.

After each session, doctors filled in one sheet concerning

- the type of consultation (first, follow-up, telephone)
- time spent with patient

- up to 3 diagnoses, indicating the main diagnosis

- with each diagnosis: duration and severity of disease, acute or chronic

- prescriptions (allopathic, homoeopathic, other)

- referrals (specialist, clinic, cure, physio- or psychotherapy)

- side effects, aggravation, indication of antidotation (only homoeopathy)

- in the case of acupuncture: acupuncture points and meridians

- in the case of homoeopathy: key symptoms

Health insurance data

The insurance company provided information for each patient on:

- work days lost, reasons (diagnoses) for absenteeism

- time insured over the past 8 years

- days in hospital, reasons (diagnoses) for hospital stay

Main outcome criteria

As target criteria we measured

- health related quality of life (SF 36)

- doctors' rating of improvement of main complaint as 7 point symmetrical improvement-deterioration-scale with anchors "-3 (very much worse)" to "+3 (very much improved, healed)"

- work absenteeism.

Procedures, data handling and statistics

At the beginning of the study, doctors were informed by the insurance company and their respective associations. Interlocutions between the study group and/or the insurance company and the doctors' associations insured cooperation. Conferences were held to inform doctors about the procedures and aims of the study and to ensure their compliance.

Treatment of data followed the prerequisites for anonymity of patients, and patients' data were neither shown to their GPs nor to the insurance company. All the data were sent directly to the study centre and were checked for completeness. Follow-up questionnaires were sent out to patients with pre-stamped envelopes by automatised

Table 1: Baseline characteristics

	<i>Acupuncture</i>	<i>Homeopathy</i>
Sample size	N _{max*} = 5116	N _{max*} = 515
Gender	53 % women	55 % women
Mean age	42 (SD 14)	30 (SD 18)
Married	71%	48%
Employed	62%	49%
Most frequent self-reported symptoms:		
Back pain	31%	14%
Headache	24%	12%
Problems with respiration	14%	9%
Saw doctors for same complaints beforehand:	75%	67%
Of these: seen > 4 other doctors for same complaints:	21%	35%
Received acupuncture / homeopathy before+	20%	20%
Subjective reasons for seeking out this treatment+:		
"Paid for by insurance company"	69%	73%
"Other treatments unsuccessful"	73%	70%
"Wanted to try"	40%	56%
"Side effects of other treatments"	37%	60%

* depends on the question, some items showed missing data +analysed according to the baseline questionnaire (N = 4487 for acupuncture and N = 465 for homeopathy)

routines and up to two reminders were sent out in case of no return.

The data were checked for completeness immediately upon arrival, and reminders or individual letters were sent, if any material was missing. The data were entered by hand or using scanning software (Cardiff Teleform), and plausibility checks were run. If data were missing the following procedures were employed:

Imputation of missing data was only carried out for the SF-36. We followed the published routines [14] of imputing the personal mean if less than half of the items were missing. If whole questionnaires were missing, but subsequent questionnaires were available, we imputed the values of the next questionnaire in order to prevent overestimation over time. This guaranteed a conservative handling of missing data, but also allowed us to impute at least half of the missing questionnaires, as the missing data pattern was rather random than increasing over time.

In a separate study, we checked for the effects of different missing data interpolation routines and found no difference between sophisticated regression analytical methods and interpolation using propensity score and no interpolation [16], which is likely to be an indicator that data are missing at random. In a telephone interview study, which is still ongoing, we checked whether non-responders differed systematically from responders. So far, our experi-

ence favours the hypothesis that non-responders do not systematically differ from responders in terms of outcome (data to be published elsewhere).

A comparison of the data given in questionnaires that were returned too late revealed that there was no significant difference in answer patterns. The given descriptive analysis was therefore carried out for all available data. Neither work days lost nor the doctor's rating was imputed when missing, as there was no hint for biased results. By nature, work days lost are not subject to overestimation bias, and by cross-checking the billing forms it was ensured that the doctor's rating was given for nearly every patient included in the study.

Data were analysed by Access and SPSS. Due to the descriptive nature of the study, we relied mainly on descriptive statistics. In order to quantify effects, we calculated effect sizes as standardised mean differences according to Cohen [17], with the standard deviation at pre-time-point as standardisation factor.

Because this was an evaluation taking place in general practice together with some political necessities, the study had to begin before all data collection and monitoring routines were in place. This resulted in a somewhat loose monitoring of data in the first six months of the study, with many questionnaires being filled in too late, etc. In all cases of doubt we ran analyses to estimate if there

Table 2: Descriptors doctors' sample

	Acupuncture	Homoeopathy
Patients seen quarterly*	min = 4/ max = 3000 mean = 1060/ SD = 556	min = 60/ max = 1500 mean = 834/ SD = 428
Time since start of practicing (in years)	min = 1/ max = 39 mean = 8/ SD = 5	min = 3/ max = 35 mean = 13/ SD = 10
Other treatments used		
Allopathy	95% yes	88% Yes
Acupuncture/homoeopathy	36% yes	69% yes
Phytomedicine	56% yes	63% yes
Anthroposophical medicine	6% yes	6% yes
Neural therapy	63% yes	50% yes

* doctors may have understood this question as referring to the trial phase, or to their practice size in general

would be a distortion of results when using the data. We discarded data suspected of being invalid, always following the conservative rule of trying to avoid overestimation of effects.

In particular, the doctor's rating of success was treated very conservatively and corrected accordingly to avoid overestimation of success. Since this scale was to be gauged to the last session (change of patient compared to last time seen), all points were added and standardised on the number of sessions, which yields a theoretical range from -3 to +3 with 0 marking the unchanged status. If a doctor scored "3" more than once a sequence, the following ratings were automatically recoded as unchanged.

Results

Overall, 5292 patients were treated with acupuncture and 933 patients with homoeopathy. Fifty-three patients received both acupuncture and homoeopathic treatment. This difference reflects the specialty of participating doctors: Acupuncture was offered by 622 GPs, yet homoeopathy by only 52. In addition, for technical and legal reasons, the evaluation of homoeopathy had only been incorporated in two of the three German Länder where the trial phase was launched. These regions of East Germany do not have a long-standing tradition of homoeopathy and therefore do not have many practising homoeopaths.

Within the trial phase, 12% of the acupuncture patients attended booster sessions or reappeared for follow-up sessions with the same treatment, compared with 10% of the homoeopathy patients. Return rates corresponded to 90% of all pre-questionnaires. Post treatment, 60% of the patients returned the questionnaire within an appropriate time frame. This figure dropped slightly to 50% in the follow-up period. This is still an acceptable return rate, given the fact that this was 24 months after therapy and that the questionnaires were sent by mail.

Results are presented separately for acupuncture and homoeopathy in table 1.

Doctors

Some data describing the practice size is given in Table 2. It is evident that doctors not only applied the treatment options they were accredited for in the trial phase, but to a great extent also other allopathic and CAM treatments.

Acupuncture

More than 5000 patients were treated with acupuncture. Around 4400 patients participated in the study and filled in the baseline questionnaire. Sample size is smaller than the overall number of patients due to missing consent or failure to reply in time. The mean age was 42 years, 71% were married and 62% employed (Table 1). The low employment rate is due to the fact that also family members, who often are housewives or students were entitled to the treatment.

In response to a free text question about complaints at baseline, acupuncture patients most frequently reported the following symptoms: Back pain (31%), headache (24%), and problems with the respiratory system (14%). Moreover, 75% of the patients reported having had conventional treatment for these symptoms and 20% had had acupuncture before. The main reasons why patients sought acupuncture were (i) the low perceived effectiveness of other treatments (73%) and (ii) payment by the insurance company (69%).

The main diagnoses documented by the GPs according to the ICD-system were *diseases of the musculoskeletal system and connective tissue* (52%, mainly dorsopathies), *diseases of the nervous system and sensory organs* (19%, predominantly migraine) and *diseases of the respiratory system* (18%, see Figure 1).

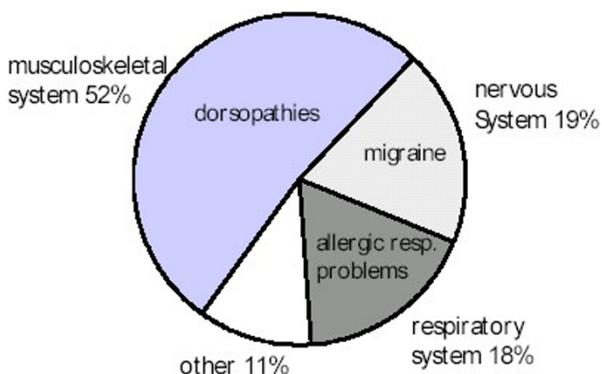


Figure 1
Diagnoses according to the documentation of GPs (acupuncture)

Table 3: Subjective change after treatment

Acupuncture	
Change of complaints	
„Better“	36%
„somewhat better“	49%
„Unchanged“	13%
„Worse“	1%
Homoeopathy	
Change of complaints	
„Better“	39%
„somewhat better“	38%
„Unchanged“	17%
„Worse“	2%

It is noteworthy that 82% of the conditions appeared to be chronic (lasting longer than 6 months) and 36% were labelled by the doctors as being severe.

When asked after treatment whether and how their complaints had changed, the following picture emerged: 36% of all acupuncture patients felt very much better and 49% felt somewhat better, 13% thought their symptoms were unchanged, and only 1% reported a deterioration of symptoms (see upper half of table 3).

Therapeutic effects as rated by the GPs showed a 0.9 (SD = 0.5) improvement of on a 7-point scale (accumulated and standardised ratings in the range between "-3 = much

worse" and "+3 = much better" for change from session to session).

As mentioned above, one main outcome criterion was quality of life as assessed by the SF-36.

Table 4 and figure 2 show that all scales revealed substantial improvement over the first 6 months after treatment and that this effect remained more or less stable over the following years. It should be noted that pre-measurement and post-measurement reflects the status before and after the first treatment, as this is the state patients were in at the beginning of the trial phase. The follow-up measurements were sent out to patients at the time points 12 months after treatment and then every 12 months. It is noteworthy that the ratings refer to the last four weeks, irrespectively of additional treatments within the preceding weeks and months. As indicated above, about 16% of the patients reappeared for the same treatment within the trial phase.

The effect sizes show middle-sized effects, with best effects for the bodily pain scale and the physical role scale.

Regarding work absenteeism, the insurance company provided us with data on work days lost over 16 years, including up to 9 years before treatment and up to 7 years since treatment. Figure 3 gives the results of work days lost from 6 years before treatment up to 5 years after treatment. As can be seen, there is a steady incline in days until the year the first treatment took place followed by a continuous decline. The Friedman test of median ranks also showed the significant incline and decline. Records of absenteeism rather than days lost show an equivalent increase and decrease (data not shown). Figure 3 also gives the results for all patients treated. The lower three lines of figure 3 give the results for patients treated in 1997 (see 'S-1997' for the sample size and 'Smean' for mean values of the subsample). These results can be compared with a reference population consisting of all patients insured with the same health insurer in the same part of Germany (see lowest line in figure 3).

While the reference population remained more or less the same, the mean values of the subsample rise to twice the work days lost in the 2 years prior to treatment, but return to normal within 2 to 3 years.

Homoeopathy

Some 1000 patients received homoeopathic treatment. The patients participating in the study had a mean age of 30 years, 55% were female, 47% were married and 49% were employed (Table 1).

Table 4: Quality of life pre and post treatment (SF-36 scales)

	Acupuncture			Homoeopathy		
	Baseline	Post Measurement	Effect sizes (d)\$	Baseline	6 months post	Effect sizes (d\$)
Physical Functioning (PF)	N = 4029 mean = 70 SD = 26	N = 3070 mean = 77 SD = 24	d = .28	N = 359 mean = 84 SD = 21	N = 301 mean = 89 SD = 18	d = .24
Role Physical (RP)	N = 3950 mean = 44 SD = 41	N = 3019 mean = 64# SD = 41	d = .49	N = 359 mean = 62 SD = 41	N = 301 mean = 83# SD = 32	d = .51
Bodily Pain (BP)	N = 4220 mean = 36 SD = 26	N = 3147 mean = 49# SD = 27	d = .45	N = 373 mean = 57 SD = 31	N = 312 mean = 73# SD = 30	d = .52
Gen. Health Perception (GH)	N = 4094 mean = 54 SD = 20	N = 3075 mean = 59 SD = 19	d = .26	N = 368 mean = 53 SD = 19	N = 305 mean = 68# SD = 20	d = .79
Vitality (VT)	N = 4214 mean = 46 SD = 19	N = 3140 mean = 54 SD = 19	d = .36	N = 376 mean = 48 SD = 18	N = 309 mean = 61# SD = 19	d = .72
Social Functioning (SF)	N = 4293 mean = 70 SD = 25	N = 3194 mean = 79# SD = 22	d = .37	N = 378 mean = 72 SD = 25	N = 314 mean = 84# SD = 20	d = .48
Role Emotional (RE)	N = 3875 mean = 68 SD = 41	N = 2977 mean = 78# SD = 37	d = .23	N = 356 mean = 73 SD = 39	N = 298 mean = 87# SD = 30	d = .36
Mental Health (MH)	N = 4170 mean = 60 SD = 19	N = 3117 mean = 67 SD = 18	d = .31	N = 376 mean = 59 SD = 18	N = 312 mean = 69# SD = 16	d = .56

clinically relevant (>=10 % improvement) \$ d means effect size according to Cohen, with $(MEAN_{post} - MEAN_{baseline})/SD_{baseline}$, d < 0.3 defined as small, d < 0.8 is assumed as being middle-sized, d > 0.8 is regarded as high [17]

The most frequently self-reported symptoms and complaints concerned the respiratory system (16%) and skin problems (19%). Less frequently, back pain (7%) and headaches (10%) were reported. Of the homoeopathy patients, 65% stated that they had received conventional treatment and 29% had visited more than 4 doctors in advance. 19% of the patients had had homoeopathic treatment for the reported symptoms before.

Treatment motivation was given as being, (i) the low perceived effectiveness of other treatments (70%) and (ii) payment by the insurance company (73%). Less prominent reasons were (iii) the side effects of other treatments (60%) and (iv) the desire to be treated with homoeopathy (56%) (also Table 1).

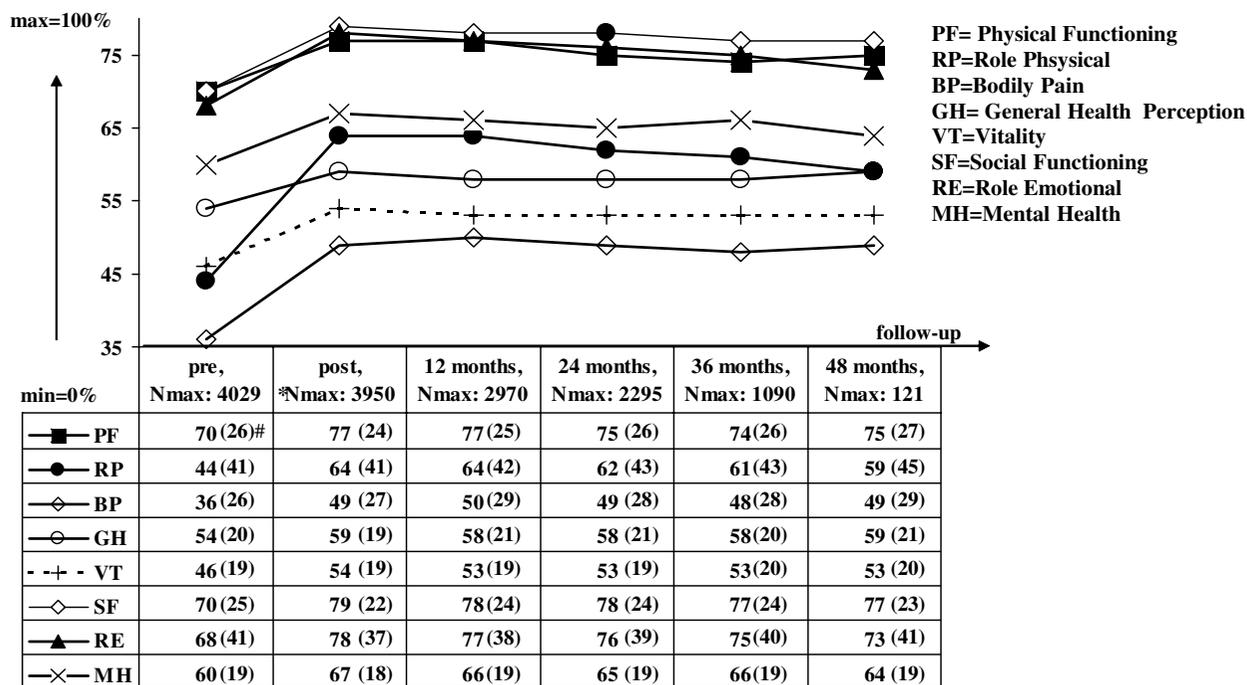
The main ICD diagnoses given by the GPs were *diseases of the skin and subcutaneous tissue* (21%, mainly *dermatitis*) and *diseases of the respiratory system* (19%, see Figure 4). Other diagnoses did not exceed 15%. Similarly to the case of acupuncture patients, doctors diagnosed 76% of the conditions as being chronic (lasting longer than 6 months) and 30% as being severe.

After treatment, the patients were asked to rate whether and how complaints had changed. Over follow-up time, 39% of homoeopathy patients felt very much better and 38% felt somewhat better, 17% thought the symptoms were unchanged, and only 2% reported a deterioration of symptoms (see bottom half of table 3).

Therapeutic effects as rated by the GPs showed a 0.95 improvement (SD = 0.7) on a 7-point rating scale (accumulated over all the homoeopathic sessions).

Results regarding quality of life as assessed by the SF-36 are presented in Table 4 and Figure 5. All scales revealed substantial improvement over the first 6 months after treatment and this effect remained more or less stable over the following years.

Work days lost show an incline of mean values before treatment, followed by a decline after treatment. This is not reflected by the median values, but the Friedman test of mean ranks of medians also revealed a significant increase and decrease of days of absenteeism (see Figure 6). This is also true for the records of absenteeism (data not shown).



represents percent on the 0 to 100-scale; mean scores (SD) given

Figure 2
Quality of life during follow-up (acupuncture)

Compared to the reference population, the patients included in the trial phase showed less work absenteeism prior to treatment. This could have been assumed as work absenteeism is mostly due to back pain and accidents (for long periods), but not migraine and allergic rhinitis. Nevertheless, around the year of treatment work absenteeism exceeds the mean values of the reference population, but drops to a lower level compared to reference means.

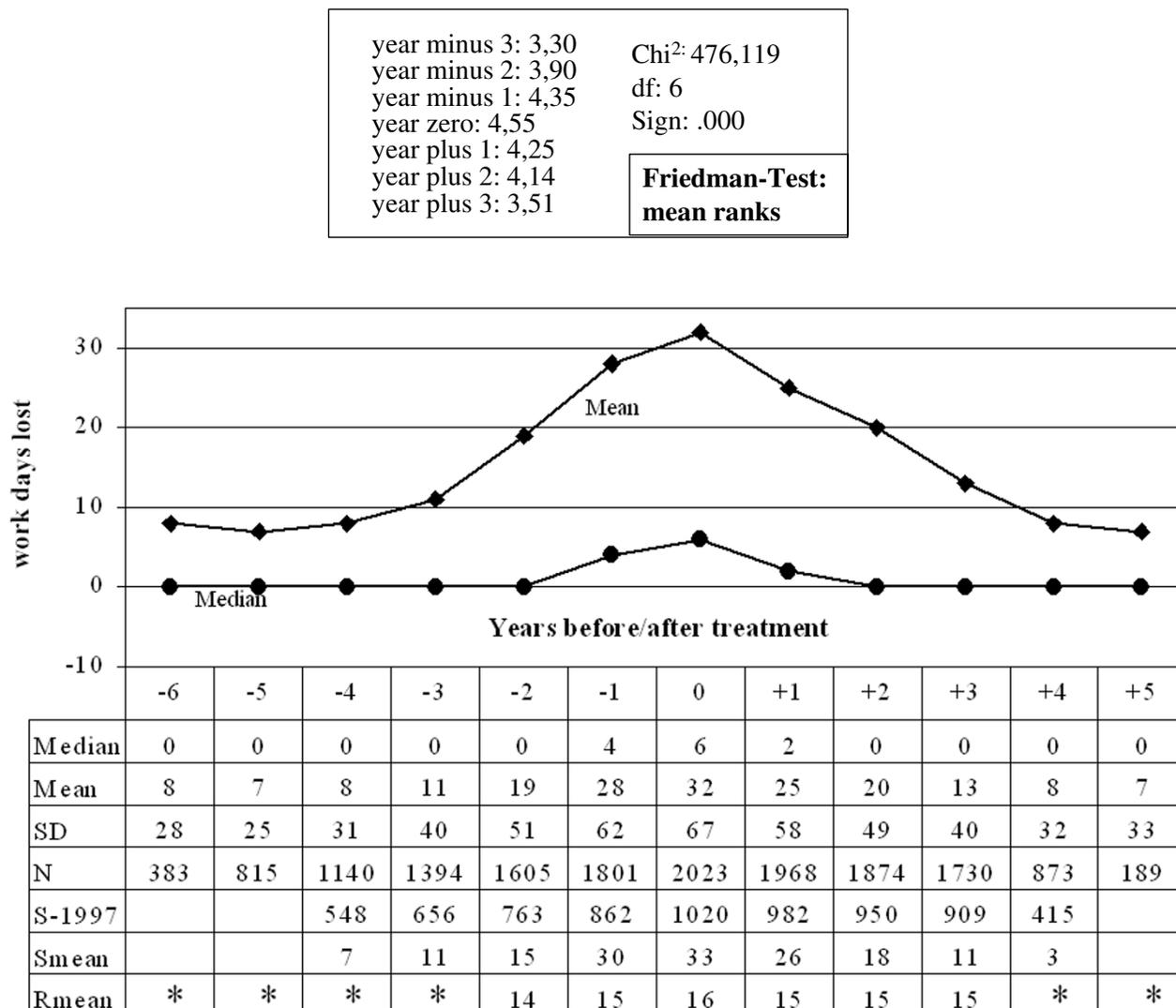
Adverse events

Both patients and doctors were asked to report adverse reactions to the treatment (see Table 5). The highest rate was given by homeopathy patients (7%). One has to bear in mind that homeopathy sometimes produces symptoms of initial aggravation, when therapy is going to work well. 5% of the acupuncture patients felt some adverse reactions to the treatment. Further investigation revealed that these were minor reactions like needle sensation.

Discussion

This prospective observational documentation study was designed to bridge the gap between clinical studies in the tradition of pharmaceutical research in CAM and everyday, real life practice. It also gives an insight into the everyday practice of acupuncture and homoeopathy delivered by general practitioners or CAM specialists within the insurance system.

The results show evidence of subjective benefits in all three main outcome criteria. The doctors' ratings of the change of complaints showed significant improvement of complaints over the course of treatment. Taking standard deviations into account, it is apparent that this is not due to overestimation. The improvement under acupuncture treatment was about 2 SDs and the improvement under homoeopathy (which is an even more comprehensive treatment) was a little lower. This overall improvement was vindicated by quality-of-life data. Effect sizes from pre to post-treatment showed middle to large effects. The effect sizes of homoeopathy are even greater. This might



* No data available

Figure 3
Work days lost before/after treatment (acupuncture patients)

be because a longer period was observed and the therapy seems to result in a significant improvement of the perception of well-being (general health, vitality) and role scales.

Despite being very satisfied with the treatment and experiencing a clear subjective benefit, only about 16% of the patients sought booster treatments. Follow-up

questionnaires from a subsidiary study part, which have not as yet been fully analysed show that about half the patients did not go to booster sessions simply because they felt they had been cured. This is even more astonishing because their physicians labelled their diagnoses as chronic and severe. Nevertheless, it seems to fit the general notion of improved subjective health and well-being of the patients seen in the stable course of the SF-36-scales.

However, some problems were encountered in this long-term documentation study. At the beginning of the study, persistent efforts were made to set up a control group of conventional treatment. We also tried to obtain data on the insurance company's cost records. Unfortunately, both efforts failed. This was partly due to German data protection laws and partly to the lack of interest among conventional practitioners, who would only have cooperated on reimbursement, which is not a legally viable option for publicly funded insurance companies. This is particularly unfortunate because being dissatisfied with other therapies a great number of patients had come to see the CAM therapists. Without a concurrent control group it is difficult to put the data into context, and conclusions therefore have to be made using indirect methods. What we can derive from our data is that in general patients are very satisfied, not only with the treatment, but also with the effects of the treatment. This satisfaction is not only seen in self-report items, but is also reflected in the standardised and well-validated scale SF-36, which is known to be very robust and does not easily overestimate change.

Effect sizes and numerical differences show that the experienced effects were sizeable, clinically meaningful [18], and stable over time.

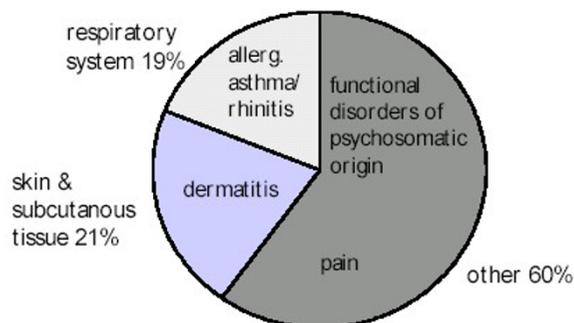
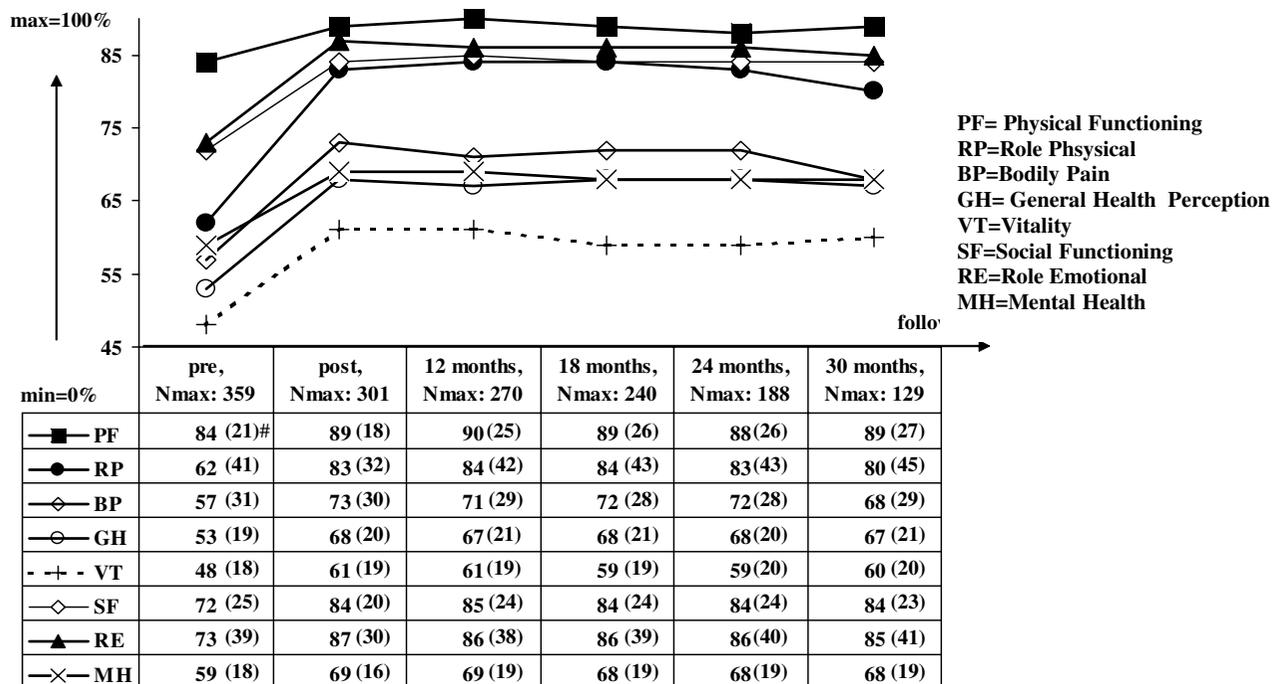


Figure 4
Diagnoses according to GP's documentation of (homoeopathy)



mean scores and SD's (0-100 percent scale)

Figure 5
Quality of life during follow-up (homoeopathy)

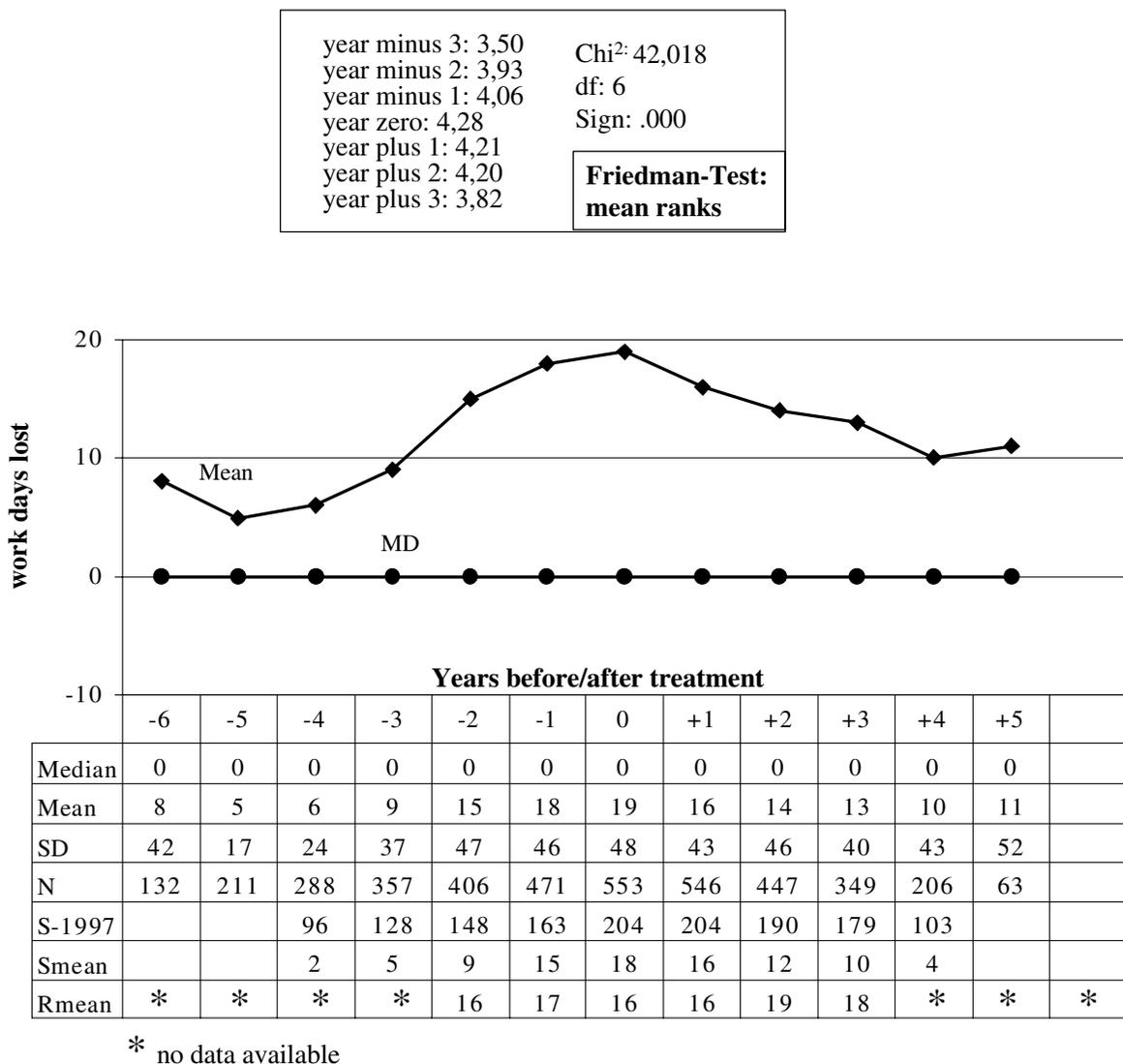


Figure 6
Work days lost before/after treatment (homoeopathy patients)

One might argue that in a study like ours there are always a large number of non-responders due to the long observation time, and because patients do not understand why they should fill in questionnaires regarding treatment they had years ago. While our return rate was not bad, it was far from perfect. We achieved acceptable return rates of roughly 90% for the pre-treatment questionnaires and 50% for the follow-up questionnaires. Interpolating the missing data points with intricate routines derived from regression analytical methods did not change the picture, indicating that data were missing at random. We are in the

process of conducting a subsidiary study with telephone interviews to find out if and how non-responders differ from responders. A first study to that effect employing telephone interviews with randomly selected non-responders showed that they did not differ in follow-up parameters from responders in that sample. Thus, we are confident that our data do not reflect a response bias of particularly healthy or diseased patients, but document a fair average of the whole population.

Table 5: Adverse events

	<i>Acupuncture</i>	<i>Homoeopathy</i>
<i>Patients rating</i>	N = 3052	N = 852
Yes	4,8%	7,4%
No	94,0%	89,2%
<i>Doctors' rating</i>	N = 5435 treatment cycles	N = 553 treatment sessions
Yes	0,8%	2,2%
No	56,9%	16,3
Missing Data*	42,2%	81,6%

* highly likely that item was not completed when no adverse event occurred

Is it possible that the patients would have experienced the same pattern of improvement if no therapy or conventional therapy had been applied? This seems rather unlikely, since the majority of patients sought help for long standing problems, which were resistant to conventional treatments, and thus by default unlikely to regress back to normal. The documented improvement is also unlikely to be due to concurrent conventional or other treatments. The documented usage of other medical treatments pertained rather to routine visits and decreased slightly. This is also true for the intake of painkillers and other pills.

The data on work days lost show that the patients go back to normal after treatment. Mean values peak around the year when treatment was applied. Since these data are skewed toward zero, the Friedman-Test of significance of mean ranks was applied and resulted in highly significant orders of median ranks before and after treatment. Compared to a reference population, acupuncture patients have much higher rates of absenteeism, whereas homoeopathy patients show only higher rates for the time close to the treatment. This underlines the validity of the data on work days lost as patients with back pain are known to produce constant and high rates of absenteeism. Since the data is highly skewed and the regression may be due to outliers, we also analysed the proportion of patients with 0 days and the proportion of outliers (mean values plus 1 SD). For acupuncture the number of patients with 0 days was 71% for a period of 2 years before treatment, and 58% for the year of treatment. The rate returned to 64% 2 years post treatment. 6% were outliers 2 years prior to treatment, 7% when treatment was applied and only 4% had days lost at work outside the given range for 2 years after the first acupuncture cycle.

A very similar picture emerged for homoeopathy: 59% had no work days lost 2 years before the first consultation and 7% lay outside the range. In the year of treatment,

42% showed no days lost to work, but 9% were outliers. 2 years after treatment, 8% still lay outside the given range. The higher rate of outliers and the lower number of patients with no days absent from work shows that regression to the mean is not a very likely explanation for the decline in work days lost after treatment.

The costs of the alternative treatments offered within the test phase are clear-cut: Neither homoeopaths nor acupuncturists employ fancy technical products. They do not order a large number of diagnostics, and the number of sessions taken to achieve the results are modest: On average, 10 acupuncture and 2 to 3 homoeopathy sessions were necessary to achieve the effects with stability over four years, which translates to a rough estimate of €300 per patient, with no hidden costs for expensive drugs. To treat a migraine patient suffering 2 attacks a month over the course of one year, using an effective triptane would cost at least the same in one year, taking only the drug costs into account and without including the cost of visits to the doctor and the cost of diagnostics. Thus, here we have a potential for cost-saving warranting further and more intricate exploration.

Conclusions

The types of homoeopathy or acupuncture we studied were fairly mundane. While we also had some experienced doctors in our sample, most of the doctors in the study had undergone training 5 to 10 years previously. Thus, we documented what subjective benefit patients can expect from an average homoeopathic doctor or acupuncturist in Germany and probably elsewhere. Even so, the recommendation based on the summary of our data would be that both homoeopathy and acupuncture seem to be effective practices that satisfy patients, and help the majority to a sufficient degree. Our study is a very first hint in that direction and provides material for further and more in-depth scrutiny. Future studies should place emphasis on careful documentation of the cost and effects of conventional treatment as compared to CAM treatment.

Competing interests

None declared.

Authors' contributions

CG was the study manager, she was also responsible for data analyses and drafted the manuscript.

OL entered the data and ran plausibility checks

HW designed the study, was the principal investigator, participated in interpreting the data and in writing the manuscript.

Acknowledgements

The study (CG, OL) was funded by the Bundesverband der Innungskrankenkassen (IKK), Bergisch Gladbach, Germany and by IKK Sachsen, Dresden, by IKK Baden-Württemberg, Ludwigsburg, and by IKK Sachsen-Anhalt, Magdeburg. We are grateful to the persons responsible in the insurance company for their understanding and help with funding in times of financial restraints, and for their openness. The help we received from the doctors' self-administrative agencies (Kassenärztliche Vereinigung) in several regions proved extremely helpful in establishing cooperation with doctors: KV Südbaden, KV Nordbaden, KV Südwürttemberg, KV Sachsen, KV Sachsen-Anhalt.

Harald Walach was funded by the Institut für Grenzgebiete für Psychologie (IGPP), Freiburg, during the first years of the study through other projects, and during the last two years by the Samueli Institute.

We are grateful to Anke Brednich and Stefanie Schüller, who were the first study managers and who helped set up the study, as well as to our research assistants Roland Krupke and Andreas Lips, who were in charge of data monitoring. Over the years we also received support from numerous other assistants, who helped with data entry and other aspects of study management and coordination, among them especially Michael Roth. Wilfried Truckenmüller was in charge of data-base management for many years and assured the quality of the data.

References

- Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, Van Rompay M *et al.*: **Trends in Alternative Medicine Use in the United States, 1990–1997.** *JAMA* 1998, **280**:1569-1575.
- Thomas KJ, Nicholl J, Coleman P: **Use and expenditure on complementary medicine in England: a population based survey.** *Complement Ther Med* 2001, **9**:2-11.
- Wootton JC, Sparber A: **Survey of complementary and alternative medicine: Part I General trends and demographic groups.** *Journal of J Altern Complement Med* 2001, **7**:195-208.
- Albrecht H: **Alternative medicine in Germany: Personal views of a critical observer.** In *Medical Challenges for the New Millenium. An Interdisciplinary Task* Edited by: Willich SN, and Elm S. Amsterdam. Kluwer Academic Publishers; 2001:39-46.
- Haag G, Walach H, Erbe C, Schrömgens H: **Unkonventionelle medizinische Verfahren. Verbreitung und Verwendung bei niedergelassenen Ärzten – Ergebnisse einer Fragebogenumfrage.** *Zeitschrift für Allgemeinmedizin* 1992, **68**:1184-1187.
- Linde K, Clausius N, Ramirez G, Melchart D, Eitel F, Hedges LV, Jonas WB: **Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials.** *Lancet* 1997, **350**:834-843.
- Linde K, Jobst K, Panton J: **Acupuncture for chronic asthma.** *Cochrane Database Syst Rev* 2000. CD000008. Review
- Linde K, Jobst KA: **Homeopathy for chronic asthma [Cochrane review].** *Cochrane Database Syst Rev* 2000. CD000353. Review
- Walach H: **Das Wirksamkeitsparadox in der Komplementärmedizin.** *Forsch Kompmed* 2001, **8**:193-195.
- Kalauokalani D, Cherkin DC, Sherman KJ, Koepsell TD, Deyo RA: **Lessons from a trial of acupuncture and massage for low back pain.** *Spine* 2001, **26**:1418-1424.
- Walach H, Jonas WB, Lewith G: **The role of outcomes research in evaluating complementary and alternative medicine.** In *Clinical Research in Complementary Therapies: Principles, Problems, and Solutions* Edited by: Lewith G, Jonas WB, and Walach H. London: Churchill Livingstone; 2002:29-45.
- Lewith G, Walach H, Jonas WB: **Balanced research strategies for complementary and alternative medicine.** In *Clinical Research in Complementary Therapies: Principles, Problems, and Solutions* Edited by: Lewith G, Jonas WB, and Walach H. London: Churchill Livingstone; 2002:3-27.
- Bullinger M, Kirchberger I, Ware J: **Der deutsche SF-36 Health Survey.** *Zeitschrift für Gesundheitswissenschaften* 1995, **3**:21-36.
- Bullinger M, Kirchberger I: *SF-36 Fragebogen zum Gesundheitszustand.* Göttingen: Hogrefe; 1998.
- Walach H, Brednich A, Heinrich S, Esser P: **Das Erprobungsverfahren der Innungskrankenkassen zu Homöopathie und Akupunktur. Evaluationskonzept und erste Erfahrungen.** *Forsch Kompmed* 1996, **3**:12-20.
- Güthlin M, Walach H: **Valid results despite missing data? [Poster presentation].** In *8th Annual Conference of the International Society for Qual Life Res: Amsterdam*. November 7–10 2001
- Cohen J: *Statistical Power Analysis for the Behavioral Sciences* Hillsdale: Lawrence Erlbaum; 1987.
- Lydick E, Yawn BP: **Clinical interpretation of health-related quality of life data.** In *Quality of Life Assessment in Clinical Trials. Methods and Practice* Edited by: Staquet MJ, Hays RD, and Fayers PM. Oxford: Oxford University Press; 1998:299-314.

Pre-publication history

The pre-publication history for this paper can be accessed here:

<http://www.biomedcentral.com/1471-2458/4/6/prepub>

Publish with **BioMed Central** and every scientist can read your work free of charge

"BioMed Central will be the most significant development for disseminating the results of biomedical research in our lifetime."

Sir Paul Nurse, Cancer Research UK

Your research papers will be:

- available free of charge to the entire biomedical community
- peer reviewed and published immediately upon acceptance
- cited in PubMed and archived on PubMed Central
- yours — you keep the copyright

Submit your manuscript here:
http://www.biomedcentral.com/info/publishing_adv.asp

