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Outcome and costs of homoeopathic and conventional treatment strategies: A comparative cohort study in patients with chronic disorders[☆]

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KEYWORDS

Homeopathy;
Health economics;
Chronic disease;
Costs;
Outcomes

Summary

Objectives: To evaluate the effectiveness of homoeopathy versus conventional treatment in routine care.

Design: Comparative cohort study.

Setting: Patients with selected chronic diagnoses were enrolled in medical practice.

Interventions: Conventional treatment or homeopathy.

Outcome measures: Severity of symptoms assessed by patients and physicians (visual rating scale, 0–10) at baseline, 6 and 12 months and costs.

Results: The analyses of 493 patients (315 adults, 178 children) indicated greater improvement in patients' assessments after homoeopathic versus conventional treatment (adults: homeopathy from 5.7 to 3.2; conventional, 5.9–4.4; $p=0.002$; children from 5.1 to 2.6 and from 4.5 to 3.2). Physician assessments were also more favourable for children who had received homoeopathic treatment (4.6–2.0 and 3.9–2.7; $p<0.001$). Overall costs showed no significant differences between both treatment groups (adults, €2155 versus €2013, $p=0.856$; children, €1471 versus €786, $p=0.137$).

Conclusion: Patients seeking homoeopathic treatment had a better outcome overall compared with patients on conventional treatment, whereas total costs in both groups were similar.

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Introduction

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Homoeopathy, is one of the most widely used forms of complementary medicine in Europe¹ the United States² and in many developing countries.^{3,4} It is based on the principle of curing like with like,⁵ and it is scientifically controversial in part because

the agents purported to be active are highly diluted.⁶

Randomised controlled trials of homoeopathic treatment versus placebo have been conducted to demonstrate that such treatment engenders more than a mere placebo effect. A pioneering meta-analysis of 89 such studies, selected on the basis of their quality, found a statistically significant overall effect in favour of homoeopathy.⁷

An alternative approach is that of outcomes research, which focuses on the results of homoeopathic treatment in everyday medical practice.⁸ This type of research aims to answer, on the basis of comparison with conventional medicine, questions such as what type of patients seek homoeopathic treatment, what benefit they experience, which indications/diagnoses are associated with the greatest benefit (or patient satisfaction), which improvements in quality of life are experienced by the patients and which costs are involved. The results of such trials are of special interest to insurers⁹ and medical service providers^{10,11} because of their economic implications. However, to our knowledge, until now, no study has provided a comprehensive analysis of both the outcome and the costs of treatment.

Thus, in our study we aimed to compare medical outcome, including quality of life and the costs of homoeopathic and conventional treatment, as part of a broad programme in Germany (see Acknowledgements) designed to assess the desirability of offering complementary medicine to the insured.

Methods

Study design

In this prospective, multicentre, parallel group, comparative cohort study, adult and child patients received either conventional or homoeopathic treatment. Patients were first approached at the doctor's practice and had thus already made their own choice of therapy; accordingly, the study was open and non-randomised. Patients were only included after giving written informed consent; the study was compliant with Good Epidemiological Practice (GEP) and relevant data protection laws, and it was approved by the Ethics Committee of our institution.

Patients, physicians and diagnoses

Eligible patients included adults (aged >16 years) presenting with the selected chronic disorders

headache, lower back pain, depression, insomnia or sinusitis, and children (aged 1–16 years) presenting with bronchial asthma, atopic dermatitis or allergic rhinitis. Patients who had been treated previously by the study physician for the study indication were not included. For each diagnosis, further specific entry criteria were defined, so as to exclude patients with very mild or very severe symptoms. Patients were recruited between January 1998 and December 2000.

Homoeopathic doctors interested in participating were selected by reviewers who were members of the central organisation of homoeopathic doctors in Germany (DZVhÄ). Selections were made on the basis of an evaluation questionnaire including a blinded case assessment. Doctors practising conventional medicine were selected from an address list of general practitioners and relevant specialists and informed about the study per mail. Only those who expressed interest, sent back a questionnaire, and were not offering complementary therapies were selected and listed. Participating physicians were recruited on a first come, first served basis.

Study protocol

At baseline, patients provided socio-demographic information, recorded the severity of their symptoms, and completed the quality of life instrument MOS SF-36 (only in adults). The physicians recorded each diagnosis and its severity, as well as each patient's medical history. Parents responded for their children where appropriate (no distinction is made hereinafter between parents' and patients' own responses). After 6 and 12 months, the patients received standardised questionnaires to provide information on current symptom severity, any perceived side effects of treatment, and quality of life. After 12 months, the study physicians also recorded the current severity of the initial diagnosis using standardised questionnaires.

The principal outcome variables were (1) severity of symptoms, as assessed by the patient on a numerical rating scale (NRS; from 0 to 10),¹² (2) severity of symptoms, as assessed by the physician using also the NRS, (3) quality of life, as assessed by the MOS SF-36 questionnaire for adults.^{13,14}

The variables were classified into 'overall costs' including doctor visits, medication, physiotherapy, hospital stay, sick pay, other remedies/devices and 'medication costs'. For patients in the homoeopathic group, medication was further sub-classified into conventional and homoeopathic medication. Economic analyses were performed only in patients

whose insurance companies provided cost data. Costs not reported by these insurers (e.g. over-the-counter medication purchased privately) were not taken into account.

Statistical methods

For adults, the statistical analysis was performed in three steps. (A) The treatment cohorts were tested for significant differences in age, sex, education, and duration of symptoms, using *t*-tests or chi-squared tests, as appropriate. Lost to follow up rates were compared by chi-squared tests. (B) Repeated measurement analysis of variance (ANOVA) models were fitted to the follow-up data. In an initially saturated model with the factors 'treatment', 'diagnosis' and 'time', the following questions were asked: (i) Are there diagnosis-specific differences in the result between the treatment cohorts (significant interaction term $\text{time} \times \text{treatment} \times \text{diagnosis}$)? If not, then this interaction term was removed from the model. (ii) Are there overall differences between the treatment cohorts (significant interaction term $\text{time} \times \text{treatment}$)? If so, the differences were displayed, with additional tests as appropriate. (iii) Are there overall differences between the diagnoses (significant interaction term $\text{time} \times \text{diagnosis}$)? If so, the differences were displayed. (C) The initial model of step B was extended to include the covariates mentioned in step A (ANCOVA). A test was performed to see whether diagnosis-specific adjustment was necessary. Step B was repeated for the resulting model. For each outcome variable, treatment group-specific marginal means are reported, resulting from the last adjusted model.

For children, the same tests were performed, but with a preliminary examination of whether any significant differences existed between the two age groups (1–7 and 8–16), and, if appropriate, with the inclusion of age group as an additional factor.

For the analysis of costs during the study observation period, two sample *t*-tests (unadjusted analyses) and classical ANOVA models including the same set of covariates as described above (adjusted analyses) were applied. In a second step, the costs from the 12-month period before inclusion were added, and cost increases were analysed by applying repeated measurement ANOVA models as described above.

Finally, a propensity score was calculated from the baseline characteristics of each patient. The results of the analyses did not change qualitatively

if the propensity score was used for adjustment; details are, therefore, not reported here.

Results

Patients

Of those patients eligible to participate, 79% consented and were recruited. A total of 493 patients were enrolled by 101 homoeopathic and 59 conventional study physicians; these are shown according to age group, diagnosis and treatment strategy in [Table 1](#). Of all patients in the study, 90% provided questionnaires after 6 months and 80% after 12 months. Health economic data were obtained for a subgroup of 38% of the patients.

Basic socio-demographic variables and data on previous use of medical resources are summarised in [Table 1](#). Adult patients seeking homoeopathic treatment were more likely to have had 12 or more years of education than those seeking conventional treatment. In children, only the medical services used in the previous 12 months differed significantly between the groups.

Patient assessment of symptom severity

The adults' assessment of symptom severity at study entry did not yield significant differences between the diagnosis groups. Nor did it show any overall or diagnosis-specific differences between the treatment cohorts. The two cohorts were, therefore, regarded as equivalent in respect to patient assessment of symptom severity at baseline.

For adults, the change in severity of symptoms differed clearly between the two treatment cohorts ($p=0.002$, [Fig. 1](#)); the difference was highly significant during the first 6-month period ($p=0.004$), and not significant in the second 6-month period ($p=0.558$). For children, the outcome analysis yielded results that were qualitatively similar to the adult analysis ([Fig. 1](#), $p=0.029$).

Physician assessment of symptom severity

For adults, the change in symptom severity did not differ between the two treatment groups ($p=0.251$), but there was a significant reduction in the severity of symptoms for each group (both $p < 0.001$, [Fig. 2](#)). For children, the change in symptom severity was significantly different between the two treatment cohorts ($p < 0.001$; [Fig. 2](#)). There were no significant differences in 'overall

Table 1 Baseline characteristics.

Age group	Parameter	Homoeopathy	Conventional	<i>p</i> -Value, if <0.05
Adults (>16 years)	Age (years; mean ± S.D.)	41.8 ± 11.1	48.5 ± 13.9	<0.001
	Sex (%)			
	Male	18	26	
	Female	82	74	
	School education > 12 years (%)	48	17	<0.001
	Medical services used (12 months) (%)			
	Medicines	89	92	
	Visit to doctor	94	98	
	Stay in hospital	18	13	
	Operation(s)	14	11	
	Diagnosis (<i>n</i> (%))			
	Homoeopathy	Conventional	Total	
All five indications	174 (100)	141 (100)	315	
Headache	70 (40)	42 (30)	112	
Low back pain	22 (13)	50 (36)	72	
Depression	47 (27)	16 (11)	63	
Insomnia	12 (7)	23 (16)	35	
Sinusitis	23 (13)	10 (7)	33	
Age group	Parameter	Homoeopathy	Conventional	<i>p</i> -Value, if <0.05
Children (1–16 years)	Age (years; mean ± S.D.)	6.5 ± 4.1	7.2 ± 4.1	
	Sex (%)			
	Male	63	58	
	Female	37	43	
	Medical services used (12 months) (%)			
	Medicines	81	89	<0.001
	Visit to doctor	96	99	
	Stay in hospital	7	10	
	Operation(s)	3	8	
		Diagnosis (<i>n</i> (%))		
	Homoeopathy	Conventional	Total	
All three indications	91	87	178	
Atopic dermatitis	54 (59)	64 (74)	118	
Allergic rhinitis	20 (22)	11 (12)	31	
Asthma	17 (19)	12 (14)	29	

assessment of therapeutic success' or in 'satisfaction' between the treatment groups (data not shown).

Quality of life

There were major differences between the results for the physical component scores (PCS) and the mental component scores (MCS) of SF-36 (Table 2). For PCS, there were both global ($p=0.026$) and diagnosis-specific ($p<0.001$) differences between the treatment groups at baseline. These differences were still present after adjustment, although they were no longer statistically significant. Overall, the PCS for the homoeopathically treated

patients showed a marked increase, whereas that for conventionally treated patients hardly changed at all (Fig. 3). The change in the first 6-month period differed significantly between the treatment groups, but the change in the second 6-month period did not ($p=0.016/0.649$; Fig. 3).

For MCS, there were no global or diagnosis-specific differences between the treatment groups at baseline. In both 6-month periods, a greater increase was seen for the homoeopathically treated patients than for the conventionally treated ones (Fig. 3), but the difference between the treatment groups was not statistically significant ($p=0.273$). The results for the SF-36 subscales are displayed in Table 2.

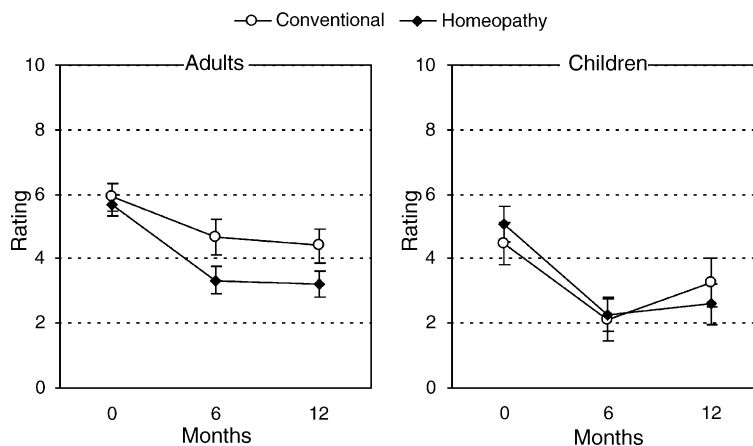


Figure 1 Patients' assessment of the severity of symptoms on a numerical rating scale (0–10). Means from repeated measurement models adjusted for additional covariates and confidence interval (adjusted for: gender, age, educational level, logarithm of symptom duration and interaction age × gender).

Health economics

Overall unadjusted costs during homoeopathic and conventional therapy, respectively, were €1764 and €2696 ($p=0.157$) for adults and €1392 and €814 ($p=0.176$) for children. After adjustment, the corresponding overall costs for patients with homoeopathic and conventional treatment showed no significant differences for adults (€2155 and €2013; $p=0.856$) or children (€1471 and €786, $p=0.137$).

Overall unadjusted cost *increases* (as compared to the 12 months before inclusion) during homoeopathic and conventional therapy were €1226 and €1067 for adults ($p=0.831$) and €1015 and €371 for children ($p=0.128$). After adjustment, the corresponding overall cost increases for patients with homoeopathic and conventional

showed no significant difference (adults: €1446 and €912; $p=0.573$; children: €1049 and €366, $p=0.129$).

Half of the homoeopathically treated patients (54%) used additional conventional treatments; in this group, the homoeopathic costs accounted for approximately 10% of the overall costs.

Unadjusted medication costs during homoeopathic and conventional therapy were €197 and €812, respectively, for adults ($p=0.001$) and €299 and €362 for children ($p=0.685$). After adjustment, the corresponding medication costs for patients with homoeopathic and conventional treatment showed no significant differences (adults: €270 and €639; $p=0.117$; children: €334 and €424, $p=0.637$).

Unadjusted medication cost *increases* (as compared to the 12 months before inclusion) dur-

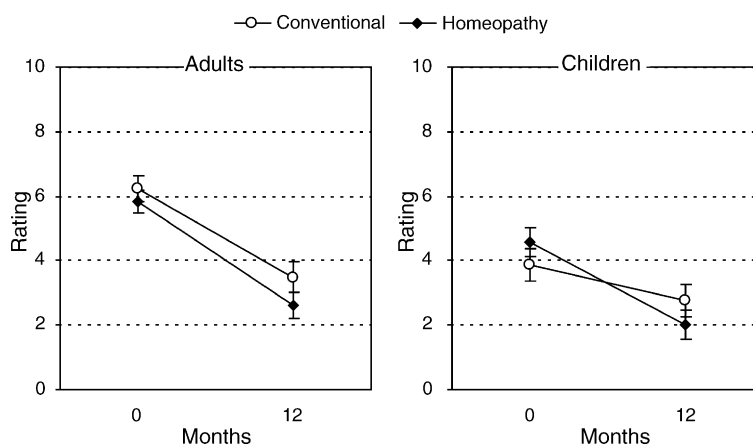


Figure 2 Physicians' assessment of severity of symptoms on a numerical rating scale (0–10). Means from repeated measurement models adjusted for additional covariates and confidence interval (adjusted for: gender, age, educational level, symptom duration and interaction age × gender).

Table 2 Quality of life data (SF-36) for adults.

Quality of life (SF-36)	Baseline, mean (95% CI)		After 6 months, mean (95% CI)		After 12 months, mean (95% CI)	
	Homeopathy	Conventional	Homeopathy	Conventional	Homeopathy	Conventional
Physical functioning	-0.16 (-0.35 to 0.04)	-0.35 (-0.60 to -0.10)	-0.02 (-0.20 to 0.16)	-0.25 (-0.49 to -0.01)	0.09 (-0.10 to 0.27)	-0.34 (-0.58 to -0.10)
Role physical	-0.66 (-0.91 to -0.42)	-0.74 (-1.06 to -0.42)	-0.16 (-0.39 to 0.07)	-0.58 (-0.88 to -0.28)	-0.30 (-0.54 to -0.05)	-0.51 (-0.83 to -0.20)
Bodily pain	-0.91 (-1.12 to -0.69)	-1.11 (-1.39 to -0.83)	-0.30 (-0.51 to -0.10)	-0.90 (-1.16 to -0.63)	-0.24 (-0.44 to -0.03)	-0.80 (-1.07 to -0.53)
General health perceptions	-1.02 (-1.22 to -0.82)	-0.90 (-1.16 to -0.64)	-0.57 (-0.78 to -0.36)	-0.93 (-1.20 to -0.65)	-0.48 (-0.69 to -0.27)	-0.76 (-1.03 to -0.49)
Vitality	-1.09 (-1.26 to -0.92)	-0.85 (-1.07 to -0.63)	-0.37 (-0.55 to -0.19)	-0.56 (-0.79 to -0.33)	-0.33 (-0.51 to -0.14)	-0.46 (-0.70 to -0.22)
Social functioning	-0.76 (-0.99 to -0.52)	-0.68 (-0.99 to -0.38)	-0.11 (-0.33 to 0.10)	-0.40 (-0.68 to -0.12)	-0.23 (-0.47 to 0.00)	-0.27 (-0.58 to 0.04)
Role emotional	-0.69 (-0.94 to -0.45)	-0.51 (-0.83 to -0.19)	-0.29 (-0.53 to -0.05)	-0.29 (-0.60 to 0.01)	-0.04 (-0.29 to 0.20)	-0.34 (-0.65 to -0.02)
Mental health	-0.93 (-1.12 to -0.73)	-1.00 (-1.26 to -0.75)	-0.58 (-0.77 to -0.38)	-0.77 (-1.02 to -0.51)	-0.47 (-0.68 to -0.26)	-0.64 (-0.91 to -0.37)
Physical component score	-0.53 (-0.73 to -0.33)	-0.68 (-0.94 to -0.42)	-0.14 (-0.33 to 0.05)	-0.62 (-0.86 to -0.37)	-0.16 (-0.35 to 0.04)	-0.57 (-0.83 to -0.32)
Mental component score	-0.99 (-1.21 to -0.77)	-0.80 (-1.09 to -0.51)	-0.45 (-0.67 to -0.24)	-0.51 (-0.79 to -0.22)	-0.34 (-0.58 to -0.09)	-0.41 (-0.73 to -0.09)

Subscales and summary scales compared to the German standard population (defined by the German version of the SF-36). Means from repeated measurement models adjusted for additional covariates and confidence interval (adjusted for: gender, age, educational level, symptom duration and interaction age × gender).

ing homoeopathic and conventional therapy were €39 and €508 for adults ($p < 0.001$) and €128 and €142 for children ($p = 0.940$). After adjustment, the respective medication cost increases showed a significant difference for adults but not for children (adults: €18 and €478; $p = 0.027$; children: €152 and €206, $p = 0.794$).

Discussion

This study is, to our knowledge, the first prospective study to compare both the outcome and the costs for patients seeking homoeopathic or conventional treatment. In order to find a balance between the representativeness and comparability of the treatment groups, we decided to recruit patients who presented for the first time with one out of eight common chronic diagnoses that are usually defined in a similar way by conventional and homoeopathic physicians. However, because patient self-selection or differences in recruitment strategies resulted in differences in the baseline characteristics of the patients, additional adjusted analyses were needed. While this reduced hidden bias to a minimum, it cannot be excluded with the same certainty as is the case with the randomised trials reviewed by Linde et al.⁷ On the other hand, the design chosen closely reflects regular clinical practice, so that outcome and cost measurements provide a more realistic picture than can be expected in a randomised trial. Thus, the study design chosen can be regarded as supplementing, rather than challenging, the perspectives offered by randomised controlled trials.

An important feature of the present study can be seen in the fact that the reference therapy was not placebo (as would be the case in a trial intended to find out whether homoeopathic treatment has any curative value at all). Instead, the reference therapy was the respective conventional treatment that would be prescribed under normal clinical conditions by a conventional practitioner of the patient's choice.

Because conventional therapy can be viewed as an active control, there was the initial possibility that homoeopathic treatment might be found significantly inferior to conventional therapy. Thus, it is remarkable that homoeopathic treatment was never shown to be inferior in this study. Nonetheless, it must be kept in mind that this study was not designed as an efficacy study to test a formal non-inferiority hypothesis, but rather as an investigation of different aspects of the real-world performance of different therapeutic approaches.

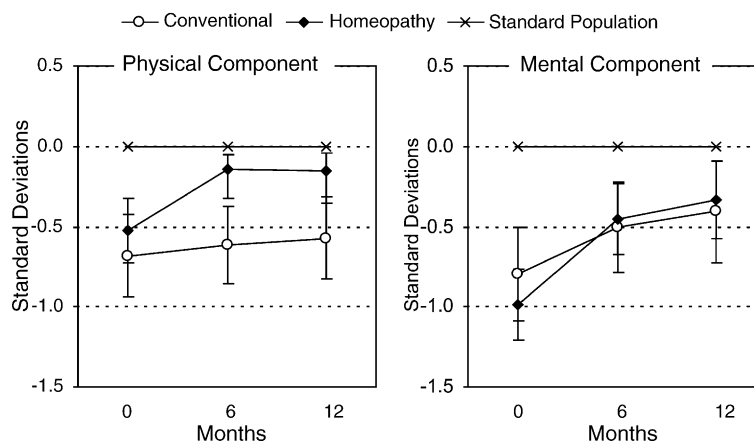


Figure 3 Quality-of-life scores for adults. Physical Component Summary Scale and Mental Component Summary Scale compared to the German standard population (defined by the German version of the SF-36). Means from repeated measurement models adjusted for additional covariates and confidence interval (adjusted for: gender, age, educational level, symptom duration and interaction age \times gender).

Significant differences between the treatment groups were observed in respect to several key factors. The study showed that the assessments by both adult and child patients (evaluated separately) were more favourable 6 or 12 months after diagnosis and initiation of homeopathic treatment than for conventional treatment. A similar apparent superiority of homeopathic treatment was also seen in the physicians' assessments for the children, although not for the adults. These differences are not easily accounted for by sources of bias (such as self-selection) alone, because our statistical analyses allowed for self-selection by adjustment for baseline characteristics. In addition, the patients (or their parents) made their own choice of physician and therapy before knowing that they would participate in a trial. This is expected both to eliminate any inducement (such as may be expected, for example, when additional free insurance cover is offered)¹⁵ and to compensate for any 'anticipation' or 'eagerness to please' that might otherwise have biased the results towards a preferred therapy.

To prevent a potential bias by selecting conventional physicians who might be favourably inclined to homeopathy, we only selected doctors who did not offer complementary or alternative treatments as part of their services. To ensure that physicians in both groups used the same inclusion criteria for each diagnosis, we also established formal inclusion and exclusion criteria for each diagnosis. All physicians received training prior to study initiation and were monitored during the study period.

The quality of life analysis of the component scales revealed statistically significant differences, again in favour of the homeopathic approach.

However, this was seen for the PCS component only. To our knowledge, there have been no comparable studies to include a conventional control group. Prospective observational studies on homeopathy have shown improvements in quality of life. For example, a health insurance company project including 900 patients treated with homeopathy in routine care as part of a prospective observational study showed improvements in quality of life and in physician assessment.⁹ Anelli et al.¹⁶ and Muscari-Tomaioli et al.,¹⁷ also using SF-36, demonstrated a beneficial outcome of homeopathic treatment.

In the present study, there were no significant differences between the overall costs incurred by patients according to the homeopathic or conventional treatment strategies. Due to small sample sizes and a high variability in the cost data, differences between both treatment groups, which seem large at first glance, remained non-significant. However, in adults, medication costs in particular were significantly higher with conventional treatment even after adjusting for baseline differences. The cost analyses were performed only for a subgroup of patients due to the fact that cost data could be obtained from only two insurance companies.

Being inevitably open and non-randomised, the present study does not provide firm data on the comparative efficacy of conventional and homeopathic treatments. Rather, it provides an 'as is' comparison of the outcome and costs of treatment by conventional and homeopathic methods. While the study demonstrates differences in favour of homeopathic therapy, it cannot explain what actually 'drives' these results. Homeopathy may inherently be more effective for the diagnoses

under investigation compared to conventional treatment. It may also be that compliance in homeopathically treated patients is better than in conventionally treated ones. Finally, a methodical limitation of our study is the unblinded severity rating that might contribute to the observed results. To our knowledge, the present study is the first comparative study to compare homeopathy and conventional therapy in general medical practice while including patients with several different diagnoses. For future studies, it would be advantageous to concentrate on a single diagnosis, to use a more specific measurement instrument and to provide a blinded reading. Another interesting option for future research would be a pragmatic randomised study design comparing a conventional treatment including homeopathy versus a treatment without homeopathy, as it has recently been done correspondingly in two different acupuncture studies.^{18,19} From a community perspective, the differences observed in the present study appear to support the use of homeopathic treatment. Thus, the global trends seen here could, if confirmed by further studies, influence the reimbursement policies of medical insurers towards the coverage of homeopathic treatment strategies.

Acknowledgements

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