
Dansk Homøopatisk Selskab

Jyderup den 5. december 2005

Folketingets Sundhedsudvalg
Christiansborg
1240 København K

Til medlemmer og suppleanter af Folketingets Sundhedsudvalg

Dansk Homøopatisk Selskab har følgende bemærkninger til indenrigs og sundhedsminister Lars Løkke Rasmussen svar vedr. Besvarelse af spørgsmål nr. 2 (ad L 7 forslag til lov m lægemidler), som Folketingets Sundhedsudvalg har stillet til Indenrigs- og Sundhedsministeren den 11. oktober 2005 (bilagt dette brev).

Indenrigs og Sundhedsminister Lars Løkke Rasmussen

Besvarelse af spørgsmål nr. 2 (ad L 7 forslag til lov m lægemidler), som Folketingets Sundhedsudvalg har stillet til indenrigs- og sundhedsministeren den 11. oktober 2005

Spørgsmål nr. 2:

"Hvad er begrundelsen for forskelsbehandlingen i bekendtgørelsen om homøopatiske lægemidler m.v., jf. L 167 bilag 6 (2004-05, 2. samling)?"

Svar:

Jeg forstår spørgsmålet således, at der ønskes en begrundelse for, hvorfor artikel 16, stk. 2, i direktiv 2001/83/EF ikke er implementeret i dansk ret, idet L 167 bilag 6 er høringsvar fra Dansk Homøopatisk Selskab (DHS) til udkast til ny bekendtgørelse om homøopatiske lægemidler. DHS anfører her, at de danske producenter og importører af homøopatiske produkter oplever en stigende skævvridning på markedet, fordi de danske regler for homøopatisk medicin ikke hidtil har udnyttet de rammer, som EU-direktivet har givet mulighed for, mens disse er blevet udnyttet i flere af vore nabolande. Jeg kan henvise til min besvarelse af 11. oktober 2005 af spørgsmål nr. 27 (ad L 167 forslag til lov om lægemidler 2004-05, 2. samling). Som anført heri, omhandler artikel 16, stk. 2, i lægemiddeldirektivet adgang til, at hvert medlemsland på sit område kan indføre eller bibeholde særlige bestemmelser vedrørende prækliniske og kliniske forsøg med homøopatiske lægemidler, som ikke er omfattet af den forenklede registreringsprocedure i artikel 14, stk. 1, i overensstemmelse med de principper og den særlige praksis, der gælder for

Dansk Homøopatisk Selskab

homøopati i det pågældende medlemsland. Jeg oplyste i mit svar, at denne bestemmelse ikke er gennemført i Danmark, idet man ved implementeringen af direktiv 2001/83/EF (oprindeligt direktiv 92/73/EØF, som nu indgår i direktiv 2001/83/EF) vurderede, at der ikke her var behov, tradition og erfaring med homøopatiske lægemidler i et omfang, som gjorde det muligt at udnytte bestemmelsen. Det er Lægemedelstyrelsens vurdering, at der heller ikke i dag er en så etableret empiri (opsamling af erfaringer) eller tradition for homøopatiske lægemidler, at det er muligt at basere nationale bestemmelser på en sådan praksis.

I anledning af spørgsmål nr. 2 ad L 7 har jeg indhentet følgende udtalelse fra Lægemedelstyrelsen, som jeg kan henholde mig til:

Det formodes, at særlige danske principper eller traditioner må være funderet i en homøopatisk litteratur i form af danske referenceværker og håndbøger udarbejdet på baggrund af studier og erfaringsopsamling. Lægemedelstyrelsen har ikke kendskab til sådanne værker. Derimod er Lægemedelstyrelsen bekendt med, at der i visse lande, fx

Tyskland, er indsamlet erfaringer baseret på individuelle behandlinger fra læger, der anvender homøopatiske lægemidler, og at disse erfaringer er samlet i håndbøger. I Danmark har homøopatien formentlig ikke et omfang blandt praktiserende læger, der muliggør en systematisk opsamling af erfaringer med anvendelse til specifikke medicinske indikationer.

Udover muligheden for eventuelle indikationer for homøopatiske lægemidler, giver en implementering af artikel 16, stk. 2, i direktiv 2001/83/EF principielt mulighed for at tillade andre lægemiddelformer eller andre fortyndinger end de, der kan registreres efter den forenklede procedure. Lægemedelstyrelsen vil derfor i den kommende periode lægge op til dialog med branchen om hvilke begrænsninger, der kan ligge i den nuværende situation og hvilke ønsker branchen måtte have til supplerende muligheder for markedstilladelse til homøopatiske lægemidler inden for rammerne af artikel 16, stk. 2, i direktiv 2001/83/EF.

Det er Lægemedelstyrelsens vurdering, at det vil være nødvendigt med en præcis redegørelse af behov, omfang og konsekvenser, inden der eventuelt tages skridt til ændring af bekendtgørelsen.

Hertil kan jeg supplerende oplyse, at forslag til § 34, nr. 2 og nr. 3 i L 7 der er en videreførelse fra gældende lægemiddelov - alene indeholder en bemyndigelse til indenrigs- og sundhedsministeren til at fastsætte regler om særlige betingelser for henholdsvis udstedelse af markedsføringstilladelse til og for registrering af homøopatiske lægemidler. De nærmere regler fastsættes i bekendtgørelse om homøopatiske lægemidler m.v. Såfremt Lægemedelstyrelsens ovennævnte dialog med branchen viser, at der er et fagligt grundlag for en ny eller ændret regulering af området, vil jeg være indstillet på at overveje gennemførelse heraf.

Selskabets bemærkninger.

Dansk Homøopatisk Selskab

Selskabet har følgende bemærkninger til ministerens svar til de af Sundhedsudvalget stillede spørgsmål.

Konkluderende. Dansk Homøopatisk Selskab ønsker hermed at opfordre Sundhedsudvalget til at pålægge Sundhedsministeren at sikre at direktivets artikel 16.2 umiddelbart implementeres i "bekendtgørelse om homøopatiske lægemidler mv."

Dette har følgende begrundelse:

Homøopatien er af EU indlagt i lægemiddeldirektivet 2001/83/EF, men i Danmark er det kun i begrænset omfang læger som anvender homøopatisk medicin. I f.eks. Belgien udskrives 90% af al homøopatisk medicin af læger. I Tyskland og Frankrig anvender 40% af alle læger regelmæssigt homøopatisk medicin. I Danmark anvendes homøopatisk medicin af ca. 3000 alternative behandlere og måske 100 læger, tandlæger og dyrlæger.

Den homøopatiske tradition bæres således i Danmark ikke af læger, men af ca. 3000 alternative behandlere som behandler 100.000'er af danskere for alskens genvordigheder - med gode resultater. Det er således ikke rimeligt når Lægemiddelstyrelsen kræver, at det er læger som skal skrive redegørelser om anvendelsen af homøopati - for at Lægemiddelstyrelsen kan gennemføre artikel 16.2 i dansk lov.

Den udbredte anvendelse af homøopati i Danmark er en realitet – det er vores opfattelse at lovgivningen skal regulere denne realitet på bedste måde.

Netop fordi de homøopatiske lægemidler som kan registreres efter artikel 16.2 er den mest veldokumenterede form for homøopati, er det uforståeligt for os at Lægemiddelstyrelsen ikke ønsker at få denne form for homøopatisk medicin ind på det danske marked.

I 2004 fik alle medlemmer af Folketingets Sundhedsudvalg fremsendt et eksemplar af bogen "Allergi Årsager og Behandling". Denne bog er et udmærket stykke dokumentation på, at den homøopatiske tradition trives aldeles udmærket i Danmark. Sundhedsudvalget har i forbindelse med selskabets foretræde også fået forelagt en lille del af den internationale videnskabelige dokumentation. Som supplement har vi vedlagt en helt nyudgivet artikel fra England som viser at ca. 70 % af patienter med kroniske sygdomme vurderer at de får det "bedrer" eller "meget bedre" efter homøopatisk behandling på sygehuset i Bristol.

Når Lægemiddelstyrelsen stiller krav om at der skal foreligge dansk akademisk litteratur om homøopati før de har grundlag for at ændre holdning, er der ringe udsigt til at en dialog mellem DHS og Lægemiddelstyrelsen vil føre til et konstruktivt resultat for homøopati i Danmark. Dette krav om "dansk dokumentation" er endvidere i diametral modsætning til de krav samme Lægemiddelstyrelse gør gældende i forbindelse med registrering af "plantelægemidler" og "naturlægemidler"

Dansk Homøopatisk Selskab

med traditionel anvendelse" hvor lægemiddelstyrelsen anerkender foreliggende international dokumentation.

På den baggrund er det - uanset ministerens gode hensigt med en dialog mellem DHS og Lægemiddelstyrelsen - udelukkende en politisk beslutning som pålægger Ministeren at implementere direktivets artikel 16.2 i homøopatibekendtgørelsen, som kan sikre denne udvikling.

Således vil lovgivningen om homøopati i Danmark kunne komme til fornyet gavn for patienterne, behandlerne, konkurrencevilkårene for branchen, og så sandelig også for det danske sundhedsbudget idet de positive behandlingsresultater opnås uden statstilskud.

Gunnar Hvass

Formand.

Homeopathic Treatment for Chronic Disease: A 6-Year, University-Hospital Outpatient Observational Study

DAVID S. SPENCE, M.B., B.S., F.F.Hom., M.R.C.S., L.R.C.P., D.R.C.OG.,¹
ELIZABETH A. THOMPSON, B.A., M.B., B.S., M.R.C.P., F.F.Hom.,² and S.J. BARRON, B.Sc.¹

ABSTRACT

Objective: The aim of this study was to assess health changes seen in routine homeopathic care for patients with a wide range of chronic conditions who were referred to a hospital outpatient department.

Design: This was an observational study of 6544 consecutive follow-up patients during a 6-year period.

Setting: Hospital outpatient unit within an acute National Health Service (NHS) Teaching Trust in the United Kingdom.

Participants: Every patient attending the hospital outpatient unit for a follow-up appointment over the study period was included, commencing with their first follow-up attendance.

Main outcome measure: Outcomes were based on scores on a 7-point Likert-type scale at the end of the consultation and were assessed as overall outcomes compared to the initial baseline assessments.

Results: A total of 6544 consecutive follow-up patients were given outcome scores. Of the patients 70.7% ($n = 4627$) reported positive health changes, with 50.7% ($n = 3318$) recording their improvement as better (+2) or much better (+3).

Conclusions: Homeopathic intervention offered positive health changes to a substantial proportion of a large cohort of patients with a wide range of chronic diseases. Additional observational research, including studies using different designs, is necessary for further research development in homeopathy.

INTRODUCTION

Homeopathic medicine is a system of therapeutics that appears to work by stimulating the body's autoregulatory mechanisms using microdoses of toxins.¹ The principle was first expounded by Hippocrates, the so-called father of medicine, in 450 BC and was rationalized into a clinical system by a German physician, Samuel Hahnemann, in the late 18th century. Its clinical use spread widely through western Europe in the 19th century and then to the rest of the world. Homeopathy is extremely popular with patients and its use has steadily increased in recent years.

Much skepticism within the medical profession has always existed because the exact mechanism of action of homeopathic medicines is not fully understood, and any beneficial action has often been attributed to the placebo response.² However well-designed, randomized controlled tri-

als³⁻⁵ have suggested that the effects cannot be entirely explained this way, and meta-analyses or systematic reviews of substantial numbers of randomized controlled trials⁶⁻¹⁰ have further endorsed this assertion. Some recent studies^{11,12} of homeopathic treatment in specific conditions have suggested a lack of efficacy, but the design of these studies has been flawed^{13,14} and therefore the results cannot be regarded as reliable.

A recent paper giving an overview of current research in the field of homeopathic medicine¹⁵ concluded that "more and better research is needed unobstructed by belief or disbelief in the system," and that "homeopathy deserves an open-minded opportunity to demonstrate its value."

Many clinicians in everyday conventional medical practice have expressed their skepticism about clinical trials and whether the results of trials transfer to clinical care. In some recent studies clinical treatment protocols using large co-

¹Directorate of Homeopathic Medicine, United Bristol Healthcare, National Health Service Trust, Bristol, United Kingdom.

²University Department of Palliative Medicine, University of Bristol, Bristol, United Kingdom.

horts of patients and long periods of follow-up have been used to monitor the "real-world" effectiveness of treatments in everyday clinical practice.¹⁶ Observational studies can provide useful information,¹⁷⁻¹⁹ but chance must be minimized by ensuring that sufficiently large numbers of patients are studied,²⁰ as large amounts of information are needed to overcome random effects in estimating the direction and magnitude of treatment effects.²¹ Outcome studies of homeopathic treatment for chronic disease in hospital outpatient departments have shown positive trends,²²⁻²⁴ as have some observational studies in primary care settings.²⁵⁻²⁹

This paper presents the results of a large, longitudinal, observational study assessing the health changes reported by patients with a wide range of chronic diseases, who were referred to a busy homeopathic hospital outpatient department in a major university teaching hospital in the United Kingdom (UK).

METHODS

Between November 1, 1997, October 31, 2003, overall outcomes were recorded for 6544 patients who were followed-up with a total of 23,473 outpatient attendances, an average of three or four attendances per patient. Data are available in this study only for follow-up patients. Data provided by the Information Management and Technology Directorate of the United Bristol Healthcare National Health Service (NHS) Trust (UBHT) show that the drop-out rate after first appointments is <5%. There are no data on the reasons why patients did not attend for their first follow-up appointments. All patients were referred by their general practitioners or by hospital consultants in other specialties. All patients had chronic disease and many had already been treated by one or more hospital specialists in the secondary care sector. The aims of treatment were to enhance general health and well-being, to improve symptom control and to reduce the frequency and/or severity of acute-on-chronic exacerbations of patients' conditions. All patients had 45-minute, new-patient appointments followed by 15-minute follow-up appointments.

TABLE 1. OUTCOME SCALE

Much better	+3
Better	+2
Slightly better	+1
No change	0
Slightly worse	-1
Worse	-2
Much worse	-3
Could not score	"99"
Outside effects	"x"

The scores "99" and "x" were assigned for these categories.

TABLE 2. NEW PATIENT REFERRALS AS PERCENTAGES BY SPECIALTY

Specialty	%	Specialty	%
Dermatology	19	Oncology	7
Neurology ^a	16	Gynaecology	6
Rheumatology	10	Other ^b	6
Gastroenterology	9	Respiratory	6
Psychiatry	9	Cardiovascular	2
Ear, nose, and throat	8	Genitourinary	2

^aIncludes chronic fatigue syndrome.

^bIncludes endocrinology, ophthalmology, and "polysymptomatology."

Baseline and outcome assessment

During the 6 years of the study the clinical work in the unit has been undertaken by 12 different physicians, all medically qualified for at least 15 years and also, as a minimum standard, having passed the postgraduate medical Membership examination of the Faculty of Homeopathy, a statutory medical body incorporated by a U.K. Act of Parliament in 1950.

At the first consultation the current state of health and the nature and severity of each patient's symptoms were evaluated and recorded in detail. These details provided the baseline from which treatment was commenced. At each subsequent consultation the outcome score was assessed as an overall outcome compared with that initial baseline assessment (i.e., the perceived change since that first attendance). At every consultation a data form was completed containing the patient's demographic details, hospital registration number, clinical diagnosis together with its International Center for Disease 10 coding, treatment given, and overall outcome score. The scale used for the outcome score is shown in Table 1.

The outcome score was assessed during the consultation, with patients being asked to rate their overall improvement or deterioration compared to their status at first visit. Objective parameters were incorporated in the assessment whenever possible (e.g., alteration in conventional medication, changes in forced expiratory volume, measurable changes in mobility or exercise tolerance, or changes in results of investigations). If patients could not score their outcome, they were given a score of "99" and if their conditions had been affected by obvious external factors (e.g., other treatments), this was scored as an "x."

RESULTS

A very wide range of morbidities are referred to the homeopathic outpatient unit. A study of the distribution of the main clinical specialties is shown in Table 2. The age range of patients is shown in Table 3, the majority (62.5%) of pa-

TABLE 3. AGE RANGE OF PATIENTS SEEN

Age group (years)	%	Age group (years)	%
<16	19.4	49-64	27.3
16-32	17.1	65-80	9.1
33-48	26.0	>80	1.1

tients being <48 years of age. Patients scored their outcomes at every follow-up consultation, and data are presented here only for their outcome scores at their most recent follow-up attendance (i.e., the perceived change between their most recent attendance and their first attendance). Outcome scores from the total patient population are shown in Table 4. Of the patients, 50.7% rated their overall health change as better or much better. Some degree of improvement was seen in 70.7% of patients. Overall 23.1% of patients reported no change during treatment, and 3.1% reported deterioration. Another 3.1% were given either a "99" or an "x" score. Table 5 shows the changes for children. In 65.8% of children health changes were reported as better or much better; and in 80.5% of children some degree of improvement was seen. Table 6 shows the outcomes observed and the numbers of patients seen with some of the diagnoses most commonly referred to the hospital.

DISCUSSION

The burden of chronic disease management is one of the challenges that health services increasingly face today, and this burden will increase.³⁰ All the patients referred to the unit had chronic disease and in many cases this was of several years' duration. Younger age groups (<48 years of age) formed the majority of the referrals (62.5%). Any health gain offered by homeopathic treatment would therefore be of considerable value to the healthcare system in managing this increasing burden. The inexpensive nature of homeopathic drugs is another important factor to be considered.

Concurrent with the study reported here, two independent surveys were run by the Consumer Involvement Unit of the United Bristol Healthcare NHS Trust in randomly selected samples of patients attending the homeopathic hospital outpatient unit. The first sample of 160 patients was taken during year 1 of the study and the second sample of 242 patients during year 3 of the study. Each sample of patients

was sent a questionnaire about various aspects of their treatment in the homeopathic outpatient unit, and the questionnaire included qualitative questions concerning health changes. Both of these independent surveys confirmed the health gain reported by the patients in this study (available as an internal NHS audit). During year 5 of the study, 59% of 116 patients in another independent audit described improvement in their symptoms after just one visit.³¹

The results of this study also concur with the positive outcomes reported in smaller observational studies from two other NHS Homeopathic Hospital outpatient units in the U.K.^{22,23} where overall clinical improvement was seen in 74% of 1372 patients and in 76.6% of 1100 patients respectively. Neither of these studies is exactly comparable to the current study, as both excluded certain diagnoses, especially the latter study, which excluded cancer patients, who form a significant part of the workload in the current study. However patients reporting better/much better (+2/+3) health gain in these previous two studies were 55% and 59.2% respectively. An additional finding of the present study was the larger positive health change observed in children, with 65.8% reported as being better or much better (+2/+3) and 80.5% as having some degree of improvement.

Apart from the placebo response (*vide supra*), two major reasons cited as explanations of any beneficial effects of homeopathic treatment are money and time. Many patients use homeopathy in the independent sector and the fact that they are paying for their treatment is cited as a reason why they report benefit. As this is an entirely NHS hospital unit there are no charges for treatment (other than the standard NHS prescription charges for medicines). It is also cited that patients are given great amounts of time during homeopathic treatment, and this is a reason why they report positive outcomes. The allocated appointment times in the homeopathic unit are *de facto* very similar to those for other chronic disease specialties within the UBHT. Data provided by the Information Management and Technology Directorate at UBHT show that appointment times for homeopathy align closely with those for such areas as rheumatology, neurology, and respiratory medicine and are substantially shorter than for psychiatry.

Methodologic issues for improving the quality of clinical trials to evaluate homeopathy in the treatment of chronic diseases include the need for more observational data from real-world homeopathic practice.¹⁷⁻¹⁹ Selection of outcome measures must also reflect the real-world circumstances. Outcomes of importance to patients must be the primary

TABLE 4. OVERALL OUTCOME FOR 6544 PATIENTS

	-3	-2	-1	0	+1	+2	+3	"99"	"x"
%	0.1	0.5	2.5	23.1	20.0	25.7	25.0	2.8	0.3
n	6	33	163	1512	1309	1682	1636	183	20

TABLE 5. OUTCOMES FOR CHILDREN (<16 YEARS), ADULT WOMEN AND ADULT MEN

Subjects	-3	-2	-1	0	+1	+2	+3	"99"	"x"
Children (n = 1270)	0 (0)	0.3 (4)	1.5 (19)	14.8 (188)	14.7 (187)	24.7 (313)	41.1 (522)	2.6 (33)	0.3 (4)
Adult women (n = 4194)	0.1 (4)	0.4 (17)	2.4 (101)	24.3 (1019)	21.2 (889)	26.0 (1090)	22.0 (923)	3.2 (134)	0.4 (17)
Adult men (n = 1080)	0 (0)	1.2 (13)	4.0 (43)	28.1 (303)	21.2 (229)	25.9 (280)	18.2 (197)	1.3 (14)	0.1 (1)

concern of clinicians, and both specific and nonspecific outcome measures with lengthy follow-up are needed to encompass this adequately.³² Additional research is needed combining observational quantitative and qualitative research methods³³ to explore further patients' perceptions of their health changes during homeopathic treatment.

Study limitations

This study was designed as a longitudinal observational study that set out to examine a large cohort of patients (with no exclusions) to try to assess the health changes experienced by patients undergoing homeopathic treatment in real-world circumstances. Comparison groups were not included by design, although such a design has been successfully implemented in homeopathy research.³⁴ Issues concerning observational study design are well known and are documented elsewhere.³⁵

The limitations of this study include potential bias introduced by a "patient-with-doctor" generated measure, an issue that has been examined in other fields of medicine³⁶; some evidence would suggest that both the views of the ob-

server and the patient looking at the overall changes might be the preferred method.³⁷ The particular tool used in this study is modeled on the 7-point Likert-type scale, which has been validated elsewhere.³⁸ Such a large cohort of patients, all referred independently by hundreds of other medical practitioners in both primary and secondary care, minimizes the possibility of selection bias. Independent surveys, involving cohorts of randomly selected patients and run in years 1, 3, and 5 of the study, help to validate the reported effects. The study also reflects real-world circumstances in everyday clinical practice in a busy NHS outpatient unit. As a consequence of regular updated reporting of this study during its progress, similar ongoing monitoring of clinical outcomes in routine practice has now been recommended by the UBHT Clinical Governance Committee for other specialties in this Teaching Hospital Trust.

CONCLUSIONS

This observational study has demonstrated positive health changes seen in routine homeopathic hospital practice for a

TABLE 6. OUTCOMES FOR THE MOST COMMONLY REFERRED DIAGNOSES

Number of patients	Diagnosis	Outcome score								
		-3	-2	-1	0	+1	+2	+3	"99"	"x"
448	Eczema <16 years	0%	1%	1%	15%	14%	23%	45%	1%	0%
195	Asthma <16 years	0%	0%	2%	6%	14%	26%	49%	3%	0%
163	Migraine	0%	1%	1%	22%	21%	27%	26%	1%	1%
225	IBS	0%	0%	1%	26%	16%	25%	30%	2%	0%
152	Menopausal problems	0%	0%	1%	18%	15%	27%	35%	3%	1%
112	Inflammatory bowel disease UC/Crohn's disease	0%	0%	7%	17%	15%	24%	37%	0%	0%
354	ME/CFS	0%	1%	2%	25%	29%	25%	18%	0%	0%
301	Cancer	1%	1%	8%	15%	20%	27%	26%	2%	0%
201	Depression	0%	0%	1%	23%	18%	34%	19%	4%	1%
245	Arthritis	0%	1%	4%	23%	21%	30%	19%	2%	0%

IBS, irritable bowel syndrome; UC, ulcerative colitis; ME, myalgic encephalomyelitis; CFS, chronic fatigue syndrome.

wide range of conditions. Greater improvements were noted in children. The study results show that homeopathic treatment is a valuable intervention. Although there are limitations to the inferences that can be drawn from this kind of observational study, it offers an important strand of evidence in favor of the effectiveness of homeopathy in the management of a wide range of chronic diseases.

ACKNOWLEDGMENTS

The authors thank the medical, nursing, administrative, and clerical staff of the hospital unit for their cooperation throughout the 6 years of the study.

REFERENCES

1. Swayne J. Homeopathic Method. Edinburgh, U.K.: Churchill Livingstone, 1998:3.
2. Vickers AJ. Clinical trials of homeopathy and placebo: Analysis of a scientific debate. *J Altern Complement Med* 2000;6:49-56.
3. Reilly DT, Taylor MA, McSharry C, Aitchison T. Is homeopathy a placebo response? *Lancet* 1986;ii:881-886.
4. Reilly D, Taylor MA, Beattie NG, et al. Is evidence for homeopathy reproducible? *Lancet* 1994;344:1601-1606.
5. Taylor MA, Reilly D, Llewellyn-Jones RH, et al. Randomised controlled trial of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *BMJ* 2000;321:471-476.
6. Kleijnen J, Knipschild P, ter Riet G. Clinical trials of homeopathy. *BMJ* 1991;302:316-323.
7. Linde K, Clausius N, Ramirez G, et al. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet* 1997;350:834-843.
8. Linde K, Melchart D. Randomized controlled trials of individualized homeopathy: A state-of-the-art review. *J Altern Complement Med* 1998;4:371-388.
9. Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. *Ann Intern Med* 2003;138:393-399.
10. Mathie RT. The research evidence base for homeopathy: A fresh assessment of the literature. *Homeopathy* 2003;92:84-91.
11. Stevinson C, Devaraj VS, Fountain-Barber A, et al. Homeopathic arnica for prevention of pain and bruising: Randomized placebo-controlled trial in hand surgery. *J R Soc Med* 2003;96:60-65.
12. White A, Slade P, Hunt C, et al. Individualised homeopathy as an adjunct in the treatment of childhood asthma: A randomised placebo controlled trial. *Thorax* 2003;58:317-321.
13. Richardson J, Hughes-Games J, Lewith G, et al. Homeopathic *Arnica* [letter to the editor]. *J R Soc Med* 2003;96:204-207.
14. Dantas F, Brien S, Fisher P, et al. Homeopathy in childhood asthma [letter to the editor]. *Thorax* 2003;58:826-828.
15. Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. *Ann Intern Med* 2003;138:393-399.
16. Lindqvist E, Saxne T, Geborek P, Eberhardt K. Ten year outcome in a cohort of patients with early rheumatoid arthritis: Health status, disease process, and damage. *Ann Rheum Dis* 2002;61:1055-1059.
17. Walach H, Jonas WB, Lewith GT. The role of outcomes research in evaluating complementary and alternative medicine. *Altern Ther Health Med* 2002;8:88-95.
18. Bell I. Evidence-based homeopathy: Empirical questions and methodological considerations for homeopathic research. *Am J Hom Med* 2003;96:17-31.
19. Mathie RT. Clinical outcomes research: Contributions to the evidence-base for homeopathy. *Homeopathy* 2003;92:56-57.
20. Landray MJ, Whitlock G. Evaluating treatment effects reliably. *BMJ* 2002;325:1372-1373.
21. Moore RA, Gavaghan D, Tramer MR, et al. Size is everything—large amounts of information are needed to overcome random effects in estimating direction and magnitude of treatment effects. *Pain* 1998;78:209-216.
22. Clover A. Patient benefit survey: Tunbridge Wells Homeopathic Hospital. *Br Home J* 2000;89:68-72.
23. Richardson WR. Patient benefit survey: Liverpool Regional Department of Homeopathic Medicine. *Br Home J* 2001;90:158-162.
24. Thompson EA, Reilly D. The homeopathic approach to symptom control in the cancer patient: A prospective observational study. *Palliat Med* 2002;16:227-233.
25. Anelli M, Scheepers I, Sermeus G, Van Wassenhoven M. Homeopathy and health related quality of life: A survey in six European countries. *Homeopathy* 2002;91:18-21.
26. Frenkel M, Hermoni D. Effects of homeopathic intervention on medication consumption in atopic and allergic disorders. *Altern Ther Health Med* 2002;8:76-79.
27. Goldstein MS, Glik D. Use of and satisfaction with homeopathy in a patient population. *Altern Ther Health Med* 1998;4:60-65.
28. Van Wassenhoven M, Ives G. An observational study of patients receiving homeopathic treatment. *Homeopathy* 2004;93:3-11.
29. Steinsbekk A, Ludtke R. Patients' assessment of the effectiveness of homeopathic care in Norway. A prospective observational multicentre outcome study. *Homeopathy* 2005;94:10-16.
30. Wagner EH, Groves T. Care for chronic diseases. *BMJ* 2002;325:913-914.
31. Thompson E, Barron S, Spence D. A preliminary audit investigating remedy reactions including adverse events in routine homeopathic practice. *Homeopathy* 2004;93:203-209.
32. Mason S, Tovey P, Long AF. Evaluating complementary medicine: Methodological challenges of randomised controlled trials. *BMJ* 2002;325:832-834.
33. Thompson TD. Can the caged bird sing? Reflections on the application of qualitative research methods to case study design in homeopathic medicine. *BMC Med Res Methodol* 2004;4: Online document at: www.biomedcentral.com/content/pdf/1471-2288-4-4.pdf
34. Witt C, Keil T, Selim D, et al. Outcome and costs of homeopathic and conventional treatment strategies: A comparative cohort study in patients with chronic disorders. *Comp Ther Med* 2005;13:79-86.
35. Concato J, Shah N, Horwitz RI. Randomized, controlled tri-

- als, observational studies, and the hierarchy of research designs. *NEJM* 2000;342:1887-1892.
36. Weinberger M, Oddone EZ, Samsa GP, Landsman PB. Are health-related quality-of-life measures affected by the mode of administration? *J Clin Epidemiol* 1996;49:135-140.
 37. Moller HJ. Rating depressed patients: Observer-vs self assessment. *Eur Psychiatry* 2000;15:160-172.
 38. Gordon S, Ameen V, Bagby B, et al. Validation of irritable bowel syndrome Global Improvement Scale: An integrated symptom end point for assessing treatment efficacy. *Dig Dis Sci* 2003;48:1317-1323.

Address reprint requests to:
*David S. Spence, M.B., B.S., F.F. Hom.,
M.R.C.S., L.R.C.P., D.R.C.O.G.
Directorate of Homeopathic Medicine
United Bristol Healthcare
National Health Service Trust
Bristol BS6 6JU
United Kingdom*

E-mail: David.Spence@ubht.nhs.uk