

ORIGINAL PAPER

Patients' assessments of the effectiveness of homeopathic care in Norway: A prospective observational multicentre outcome study

A Steinsbekk^{1,*} and R Lüdtkke²

¹Department of Public Health and General Practice, Norwegian University of Science and Technology (NTNU), Trondheim, Norway

²Karl und Veronica Carstens-Stiftung, Essen, Germany

Objective: To evaluate the patient reported effects of homeopathic care 6 months after first consultations.

Methods: Prospective uncontrolled observational multicentre outcome study. All patients visiting 80 homeopaths all over Norway for the first time in eight different time periods from 1996 to 1998 were approached. Patients wrote down their main complaint and scored its impact on daily living on a 100 mm Visual Analogue Scale (VAS) at the first consultation. Six months later they were asked to score again. The homeopaths recorded treatments given for up to two follow-up consultations.

Main outcome measure: Predefined as a reduction of at least 10 mm in the VAS score between the first consultation and follow-up.

Result: Patients 1097 were recruited, 654 completed the follow-up questionnaire. The main complaint improved by at least 10 mm on the VAS for 71% (95% confidence interval 67–74%) of patients. The average reduction was 32 mm (95% CI 30–35 mm). Fifty-one per cent (95% CI 48–55%) of the patients had an improvement in their general well being of more than 10 mm. The mean reduction in the whole group was 14 mm (95% CI 12–16 mm). The proportion of patients using conventional medication reduced from 39% to 16%. Regression analysis showed that lower age and higher baseline score were predictors of better outcome.

Conclusion: In this study, seven out of ten patients visiting a Norwegian homeopath reported a meaningful improvement in their main complaint 6 months after the initial consultation. *Homeopathy* (2005) 94, 10–16.

Keywords: homeopathy; Norway; effectiveness; everyday treatment; outcome study

Introduction

In selecting a treatment, it is likely that a patient wants to know what chance he/she has of getting better

after consulting a practitioner. It is a consistent finding that patients chose a particular homeopathic practitioner after taking advice from relatives or friends,^{1,2} suggesting that patients use such anecdotal information in judging whether homeopathic care is likely to be beneficial. Outcome studies (ie observational studies which follow a specific cohort for a defined time) are a suitable method to document systematically the effectiveness of everyday practice. Several outcome studies of homeopathy have been published. Some are from single practices^{3,4} covering a wide range of health conditions, others on single

*Correspondence: Aslak Steinsbekk, Department of Public Health and General Practice, Norwegian University of Science and Technology (NTNU), MTF5, N-7489 Trondheim, Norway.

E-mail: aslak.steinsbekk@ntnu.no

Received 5 July 2004; revised 9 September 2004; accepted 8 November 2004

conditions like otitis media or headaches.^{5,6} There are studies performed at homeopathic hospitals in the UK.^{7,8} There are also national and international multi-centre studies^{1,9–11} and some involving both general practitioners and homeopaths.^{2,12–14}

The overall effectiveness of treatment by homeopaths according to these studies ranges from 55% to 70% of the patients reporting a clinical valuable improvement. A large majority of these patients have chronic complaints. In Germany 97% of all homeopathically treated adults suffer from chronic diseases with a mean duration of 10.3 years.¹⁰ Most of the homeopathic outcome studies have taken place in homeopathic medical practices. In Norway, most homeopaths do not have a medical degree. Furthermore, there has been no large-scale outcome study in Norway. The primary objective of this study was to estimate the patient-reported effectiveness of homeopathic care in Norway. For this we documented the course of the complaint the patients themselves reported as the main reason for consultation.

Method

This is an uncontrolled, prospective, multicentre observational study of patients visiting homeopathic practitioners in Norway for the first time. The selection of homeopaths was described in a previous publication.¹⁵ Eighty homeopaths volunteered to take part; they were instructed to ask every patient who consulted them for the first time to participate. There was no control of patients who were not asked to participate or patients who refused to participate. The patients were given written information about the purpose of the study and guaranteed anonymity in that only the homeopath would know their identity. To avoid seasonal variations as a confounder and to distribute the workload, recruitment was done by dividing the homeopaths into eight different groups and each group recruited patients in one of eight different time periods (1–2 months) between November 1996 and May 1998.

The patients completed a one-sided questionnaire during the first consultation. The homeopaths collected this and returned it to the study centre. The patients were asked:

- ‘Write in your own words the main complaint you hope the homeopath can help you with.’
- ‘How much does this complaint affected your daily living?’. This was scored on a 100 mm visual analogue scale (VAS) with end points ‘No effect’ (0 mm)—‘greatly affected’ (100 mm).
- ‘Have you used conventional drugs prescribed by a medical doctor during the last month for this complaint?’ (‘yes’/‘no’).
- ‘How is your general well being?’. This was scored on a 100 mm VAS with end points ‘Very good’ (0 mm)—‘Very bad’ (100 mm).

The homeopaths registered the patient’s gender, occupation, year of birth, prescribed treatment and confidence in the prescription (0–100%). Two follow-up consultations were recorded. Complaints were coded by the first author using International Classification of Primary Care (ICPC).¹⁶

After 6 months, the patients were sent a follow-up questionnaire and prepaid return envelope by post. To ensure the anonymity of the patients, the homeopaths did this. The completed questionnaire was sent by the patient directly to the study centre. The patients received one reminder. The complaint the patients wrote on the first questionnaire was pre-printed on the follow-up questionnaire to make sure that the patients remembered which complaint they sought help for. The patients were asked the same questions as on the first questionnaire, except the question on use of conventional drugs:

- ‘Do you use conventional drugs prescribed by a medical doctor for this complaint now?’ (‘yes’/‘no’).

They were not informed about their previous score on the VAS. Outcome of treatment was assessed by the change in the VAS score between the first consultation and the 6 months follow-up for the main complaint. Improvement was pre-defined to be a reduction in VAS of at least 10 mm from the first consultation.

Statistics

This study was designed to detect predefined differences between any two subgroups, if each included at least 5% of recruited patients. It was calculated that an unpaired *t*-test required at least 37 patients in each subgroup to detect a difference of 10 mm on the VAS at a significance level of 5% with a power of 80%, assuming that the common standard deviation was 15 mm. These 37 patients were multiplied by a factor of 20 (corresponding to the 5% coverage rate) and again by a factor of 1.33 (representing an assumed non-response rate of 25%). Thus the aim was to include 1000 patients.

Comparison between those who returned the follow-up questionnaires and those who did not were done by non-parametric two sample tests (Wilcoxon and χ^2 tests). Effectiveness analyses were performed by multiple linear regression analyses modelling the change of the VAS scales as a function of age, baseline, confidence in prescription, prescribed remedy (5 most frequent), ICPC group (10 most frequent) and the need for conventional treatment at baseline. We explored the relationship between age and treatment success more extensively by fitting fractional polynomial regression models to the data.¹⁷ The software packages SPSS v. 11.5¹⁸ and SAS 8.2,¹⁹ were used.

Results

The first questionnaire was completed by 1097 Patients. As two homeopaths did not participate further only 1065 patients were sent the follow-up questionnaire. Six hundred and fifty-four (61.4%) of the patients returned the follow-up questionnaire (Figure 1). Six hundred and thirty-one patients scored the question on effect of the complaint on daily living in both questionnaires. Details on the characteristics of the initial 1097 patients and their complaints and the characteristics of the participating homeopaths has been published elsewhere.^{15,20} The average age of the patients was 30 years, 63% were female; children under 10 constituted 26% of all patients. The mean baseline symptom score was 69 mm (95% confidence interval 67–70 mm) and the mean well being score was 42 mm (95% CI 40–44 mm).

Of the 80 participating homeopaths, 86% were female and the average time since qualification was 5 years. All homeopaths had at least 5 year part-time education covering both homeopathic and conventional medical subjects. None of the homeopaths was a medical doctor.

Return of follow-up questionnaire

Those who returned the follow-up questionnaire differed in some variables from those who did not (Table 1). Those returning were slightly younger ($P < 0.001$, Wilcoxon test) and more often female ($P = 0.023$, χ^2 test). 63.9% of those returning compared to 43.6% of those not returning had two or more follow-up consultations. There was no significant difference between them for the following variables: homeopath's gender ($P = 0.111$), most frequent ICPC group ($P = 0.447$), occupation ($P = 0.572$), medication prescribed by a medical doctor last month for same complaint ($P = 0.227$), and homeopath's confidence in prescription ($P = 0.837$).

The mean baseline score for the effect of the complaint on daily living was equal for those returning and not returning, both scoring a mean 68 mm ($P = 0.867$, Wilcoxon test). The general well being was scored at 41 mm (95% CI 39–43 mm) by those

Table 1 Characteristics for those who did and those who did not return the follow-up questionnaires after six months (N = 1065)

	Returned questionnaire		P-value*
	No	Yes	
Gender	(397)	(654)	
Female	58.4	65.4	0.023
Male	41.6	34.6	
Age group (year)	(394)	(643)	
0–9	20.6	28.9	0.005
10–19	8.1	10.1	
20–29	13.7	14.2	
30–39	20.6	18.4	
40–49	13.5	12.6	
50–59	9.6	6.2	
60–69	6.9	5.9	
70–79	5.1	3.4	
+80	2.0	0.3	
Number of follow-ups (max 2 recorded)	(403)	(643)	
0	24.3	8.6	<0.001
1	28.5	26.4	
2	47.1	65.0	

Percentage. () = absolute numbers. The number of patients varies slightly between the different variables due to the actual response to each question. *P-values calculated by Wilcoxon test.

returning and 43 mm (95% CI 40–46 mm) by those not returning ($P = 0.228$).

Outcome

For those who returned the follow-up questionnaire, 65.4% were women and the mean age was 28 years. The most frequent diagnostic group was respiratory complaints (ICPC group R) (18%), followed by skin problems (group S) and general symptoms (including allergies, group A). The most often frequent ICPC code was allergy (66 entries), followed by eczema (45 entries), and upper respiratory tract infection and otitis media (each 20 entries).

71% (95% CI 67–74%) of the patients improved with a reduction of more than 10 mm in the VAS score of how much the complaint affected their daily living. The average reduction in how much the complaint affected their daily life was 32 mm (95% CI 30–35 mm). 51% (95% CI 48–55%) of the patients had an improvement in their general well being of more than 10 mm, with a mean reduction of 14 mm (95% CI 12–16 mm). The proportion of patients using conventional medication reduced from 39% to 16% 6 months later.

Crude analyses show that 86% of patients under the age of 10 years improved (Table 2). This proportion decreases with age but increases again in patients over 70. The fractional polynomial models confirmed this age-dependency. There was no statistical difference in the proportion of patients with improvement with the number of consultations. Ear and respiratory

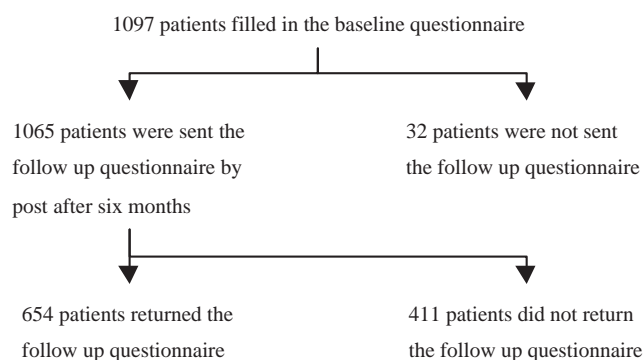


Figure 1. Flow chart of patients participating in the study.

Table 2 Proportion of patients with improvement for gender, age, use of conventional medication prescribed by a medical doctor for the presenting complaint during the last month and number of follow up consultation (max two recorded)

	No. in each group	% of group improved	P-value*
Gender	(631)		
Female	412	70.4	0.117 0.732
Male	219	71.7	
Age group (year)	(621)		
0–9	181	82.9	28.087 0.001
10–19	63	74.6	
20–29	89	70.8	
30–39	116	61.2	
40–49	79	64.6	
50–59	38	68.4	
60–69	36	52.8	
70+	19	72.2	
Use conventional medication	(631)		
No	393	72.0	0.691 0.406
Yes	238	68.9	
Number of follow-ups (max 2 recorded)	(621)		
0	52	65.4	5.016 0.081
1	168	77.4	
2	401	68.8	

Percentage. () = Total numbers in each group.
The number of patients varies slightly between the different variables due to the actual response to each question.
*P-values calculated by Pearson Chi Square

complaints had the highest success rates (Table 3). There was a difference in the proportion of patients that improved for the two most frequent single complaints: patients with allergy did better than patients with eczema. Outcomes did not vary according to the homeopathic medicine prescribed at the first consultation, nor with the homeopaths' confidence in their prescription (Table 4).

Multiple linear regression analysis showed that baseline severity is a strong predictor of outcome; prescription confidence, conventional treatment at baseline, and prescribed homeopathic medicine were not (Table 5). Outcome worsened with age ($P = 0.001$) and differed between ICPC groups ($P = 0.0016$): Musculoskeletal, neurological and skin complaints responded worse than other groups of complaints.

Discussion

Seven out of ten patients visiting a Norwegian homeopath can expect to have an improvement in their main complaint 6 months after the first consultation. This rate lies in the range as found in other outcome studies. Our results strengthen the impression that

Table 3 Proportion of patients with improvement for all ICPC groups and for the ten most frequent ICPC codes

	No. in each group	% of group improved	P-value*
ICPC group	(631)		
A General (incl. allergy)	107	77.6	42.051, 0.001
B Blood	3	33.3	
D Digestive	40	77.5	
F Eye	9	44.4	
H Ear	33	90.9	
K Circulatory	7	42.9	
L Musculo- skeletal	50	62.0	
N Neurological	35	57.1	
P Psychological	71	74.6	
R Respiratory	116	80.2	
S Skin	108	59.3	
T Metabolic, endocrine, nutr	8	37.5	
W Pregnancy, childbearing	14	78.6	
U Urinary	6	66.7	
X Female genital	23	69.6	
Y Male genital	1	0.0	
Z Social	0	—	
ICPC code	(631)		
A12 Allergy	66	78.8	21.174, 0.020
S87 Eczema	45	60.0	
P06 Sleep	22	72.7	
R74 Upper respiratory tract infection	20	90.0	
H74 Otitis media	20	90.0	
N01 Headache	18	72.2	
P01 Anxiety	18	72.2	
A04 Fatigue	16	56.3	
R75 Sinusitis	15	100.0	
R96 Asthma	14	64.3	
Other codes	377	68.2	

Percentage. () = Total numbers in each group
*P-values calculated by Pearson Chi Square

homeopathic treatment is beneficial for patients' health regardless of cultural differences within Europe.

Selection

The participating homeopaths in this study are representative of Norwegian homeopaths as a whole. They match in gender, year and place of graduation,²⁰ and their practices are geographically distributed all over Norway. This suggests that the sample of homeopaths is not biased and that the selection of patients (each patient presenting for the first time was selected) can therefore be assumed to be valid, even if we cannot exclude that some deviations from the study protocol in patient enrolment may have occurred.

The response pattern among the patients may still lead to a severe bias. Those returning the follow-up questionnaire had significantly more consultations than those who did not return it. But since the number of consultations did not influence the outcome, it is not likely to have distorted the estimate for the

Table 4 Proportion of patients with improvement for the 12 homeopathic medicines prescribed to more than ten patients, the homeopaths confidence in their prescription, for changing the prescribed homeopathic medicine at the first follow-up consultation and homeopaths gender

	No. in each group	% of group improved	P-value*
Prescribed	(614)		
Sulph	81	71.6	9.370, 0.671
Calc	65	73.8	
Nat-m	50	66.0	
Puls	46	78.3	
Lyc	31	77.4	
Phos	31	71.0	
Nux-v	22	54.5	
Sil	21	71.4	
Sep	17	58.8	
Carc	16	87.5	
Tub	12	75.0	
Rhus-t	11	63.6	
Others	211	70.1	
Confidence in prescription (100 mm VAS)	(610)		
0-69	118	71.2	1.273, 0.736
70-79	155	67.7	
80-89	168	72.6	
90-100	169	72.8	
Changed prescription at first follow-up	(631)		
No	470	71.7	5.742, 0.017
Yes	161	68.3	
Homeopaths gender	(631)		
Female	511	70.3	0.446, 0.504
Male	120	73.3	

Percentage. () = Total numbers in each group. The number of patients varies slightly between the different variables due to the actual response to each question.
*P-values calculated by Pearson Chi Square

main outcome measure. Because those returning the follow-up questionnaire were younger and because younger patients had a better outcome, our results might be too optimistic. We expect this overestimation to be small, because the age effect on outcome itself is rather small (although statistically significant) and only becomes relevant when large age differences were compared.

Validity of outcome

The outcome was measured on the complaint the patient gave as his/hers main complaint instead of using a conventional diagnosis. This was done because patients are likely to use everyday language when talking to others about their complaints and the effect of a treatment on it. It also better meets the need of homeopathy where generally treatment decisions are based on symptoms rather than diagnoses.

Table 5 Multiple linear regression analyses of treatment effect (change of complaints' impact measured in mm) on various baseline parameters

	Linear regression analysis	
	Difference in mm VAS score (95% CI)	P-value
Use of conventional drugs at baseline		
Yes vs no	-4 (-10 to -1)	0.092
Complaints impact at baseline		
Each mm	6 (5 to 7)	<0.001
Prescription confidence		
Each % point	0 (-1 to 1)	0.836
Age		
Each 10 years	-2 (-3 to -1)	0.001
Main ICPC ⁺		
General vs other groups	1 (-8 to 11)	0.781
Digestive vs other groups	-7 (-19 to 5)	0.262
Ear vs other groups	10 (-3 to 24)	0.126
Musculo-skeletal vs other	-10 (-21 to 1)	0.072
Neurological vs other	-12 (-25 to 0)	0.055
Psychological vs other	-6 (-17 to 4)	0.236
Respiratory vs other	3 (-7 to 12)	0.575
Skin vs other groups	-10 (-19 to -0)	0.044
Homeopathic ⁺		
Sulphur vs other	-6 (-13 to 2)	0.155
Calcarea carb vs other	0 (-8 to 9)	0.921
Natrium mur vs other	-4 (-13 to 5)	0.383
Pulsatilla vs other	3 (-6 to 12)	0.543
Lycopodium vs other	-2 (-13 to 9)	0.732

A negative number indicates a worse outcome.
⁺Compared to the other groups/medicines.

By asking the patients to score the impact of their complaint at two points in time without having information about their first score when they made the second score, it is likely that the patient focuses more on the present situation than of how he/she judges the treatment. This gives a result that is closer to the actual situation for the patient compared to asking the patient the retrospective question about whether the complaint has improved.

The advantage of using a VAS, compared to the Likert scales most frequently used in other studies, is greater sensitivity to change. This approach also makes the results better comparable to other outcome studies in homeopathy that also have used VAS. The interpretation of the VAS is difficult, as the score does not have the same meaning for all patients and it is not easy to verbalise. We pre defined a reduction of 10mm in the VAS as clinically relevant. This cut-point was set arbitrarily in the study protocol but turned out to be comparable to the results of other surveys. The overall judgement of the outcome measure is that it is a reasonably good tool for this type of study. In retrospect, the similar but validated MYMOP^{21,22} questionnaire would have been a good choice, but MYMOP had not been published when the study was planned.

Effectiveness

As in all uncontrolled observational studies, there is no way of determining to what degree the improvement reported by the patients is attributable to the treatment by the homeopaths and how much to other factors. With this in mind, the next paragraphs will discuss some of the findings in this study.

Without controlling for other variables, a larger portion of the youngest and oldest patients improved than in the other age groups. Since most of those visiting homeopaths do so on advice from friends and relatives,^{1,2} it might be expected that changes in patients populations over time reflect which groups feel that they benefit most from treatment. This could explain why an increasing portion of patients visiting homeopaths in Norway are children under ten,¹⁵ rising from 1 in 10 in 1985 to 1 in 4 in 1998.

If younger patients more frequently consult with acute complaints, this could explain the observed difference in outcome between age groups. Patients with musculo-skeletal, neurological and skin complaints tended to do slightly worse, and this may reflect these complaints being of a more chronic nature.

What was most surprising was that the regression models contributed little to explaining which variables contributes to the improvement. If homeopathy had been a particularly good treatment for a certain group of patients or specific complaints/groups of complaints frequently seen by homeopaths, this would have been seen in a regression model. The absence of such finding can be argued to be an indication for homeopathy having a general effect on the patient and not on specific diseases. This would be in line with the claim made by homeopaths that they 'treat the patient, not the disease'.²³ In other words, homeopathic theory predicts the degree of improvement to be linked to the body's ability to heal itself (the patient's vital force), more than the actual disease. Future studies on the effectiveness of treatment by homeopaths would benefit from including some measure of this vital force to explore this issue.

Four of the five most common reasons for homeopathic consultations match those for general practice.¹⁵ Eighty-five per cent of the homeopathic patients had previously seen a practitioner of conventional medicine for the same complaints for which they visited the homeopath.¹⁵ This indicates that homeopaths in Norway treat patients with mostly chronic complaints similar to those seen in general practice. Moreover, this assures that the effects we report cannot solely be attributed to spontaneous resolution of acute diseases.

Conclusion

In this study, seven out of ten patients visiting a Norwegian homeopath reported a meaningful im-

provement in their main complaint 6 months after the initial consultation.

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