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ORIGINAL PAPER

An exploratory retrospective study of people suffering from hypersensitivity illnesses who attend medical or classical homeopathic treatment

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The objective of this study is to describe patients who had treatment for hypersensitivity illnesses by general practitioners (GPs) or classical homeopaths (CHs) and the patients' self-reported effectiveness of the treatment received. The data stems from an exploratory retrospective study amongst 88 Danish patients (response rate 58%) suffering from hypersensitivity illnesses, who chose treatment from one of six GPs or one of 10 CHs who participated in the project. The patients themselves selected their treatment. The GPs or the CHs considered that the patient's treatment was complete or that the patient was in a situation of current 'maintenance treatment'. The patients' primary reason for consulting the GP or the CH was that they were suffering from hypersensitivity illnesses.

No significant difference was found between the two groups of patients in relation to age, education and duration of hypersensitivity symptoms. The CH patients were more likely to be employed in teaching, research, health care or the social sector compared to GP patients. The two groups of patients were similar in respect of their health at the start of the treatment, 57% of the patients who consulted a CH experienced an improvement of their state of health compared to 24% of the GP patients. Both groups of patients experienced an improvement of their psychological health after treatment. Logistic regression analysis showed that the GP or CH was the only significant effect variable. The results are based on the patients' retrospective, self-reported effectiveness of the treatments. *Homeopathy* (2006) **95**, 73–80.

Keywords: retrospective study; user-evaluation study; outcome assessment; health care

Introduction

There is an increase in the prevalence of hypersensitivity illnesses (a collective term for asthma, allergic rhinoconjunctivitis, atopic eczema, contact dermatitis and food allergy) both in relation to self-reported symptoms and objectively measurable signs.[1–11] The consumption of asthma medication is increasing.[12] A European survey of patients suffering from allergy, including 502 Danish patients, shows that for 70% of

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these patients allergy caused physical limitations in their every-day life.[13]

Most patients with asthma are treated by general practitioners (GPs). Homeopathy is frequently used in the treatment of hypersensitivity illnesses.[14–20] In Denmark homeopathic medicines are used in alternative forms of treatment other than classic homeopathy such as biopathy, nutritional therapy, kinesiology and reflexology.

The work of the GPs and the classical homeopaths (CHs) who participated in the study described here is based on different treatment models including different understandings of illness, different ways of diagnosing and treating illness and different comprehension of how the treatment works.[21] The main difference between the GPs and the CHs was found in relation to their comprehension of how the treatment should work. For GPs the comprehension of how medical treatment should work was to neutralize or curb the *symptoms* directly. For CHs the apprehension of how the homeopathic treatment should work was to set a recovery process into motion by stimulating the *person's* self-healing powers or vital force.[21] The differences in treatment models make it important to know more about what GP patients and CH patients report regarding the effectiveness of the two forms of care. Research-based knowledge about patients' self-reported effectiveness of treatment by GPs compared to treatment by CHs is still limited. The GPs and the CHs participating in this study emphasized the need for the subjective dimension in assessing improvement or cure. GPs and the CHs agreed that objective improvement was not sufficient to say whether or not a treatment is effective for a patient.[21]

The research question of the present study is: What characterizes patients who attended treatment for hypersensitivity illnesses by GPs and CHs and what are the patients' self-reported effectiveness of the treatment received? The study is based on the patients' experience with the treatments. We assume that these primary experiences will be decisive in the patients' future choice of treatment. Compared to randomized controlled trials of homeopathy medicines or of conventional medicines the approach used in this study focuses on the GPs' and CHs' everyday clinical practice.

Material and method

An explorative retrospective study was conducted, between May and October 2001 in Denmark. The Committee for Research Ethics considered the project outside their area of competence.

GPs and CHs

One hundred and four GPs were contacted by mail and asked to participate in the project, six agreed. The GPs were aged between 40 and 50, three men and three women. At first we made contact with GPs in two Danish municipalities in one county, but none of these GPs wished to take part in the project. After realizing how difficult it would be to recruit medical doctors to the project, we wrote to all GPs on Zealand. The project was mentioned in the medical journal 'Practicus', circulated to all GPs.

We contacted the GPs in the two Danish municipalities asking for their reasons for not wanting to participate. The reasons mentioned were lack of time and an understanding that it would overstep certain limits or be too much of a transboundary move to get involved in a dialogue with CHs.

The 11 CHs who were asked to participate all agreed to do so. They were recruited through The School of Classic Homeopathy in Denmark. The CHs who participated fulfilled the following inclusion criteria: completed training in classic homeopathy; a minimum of 2 years clinical practice; experience with treating people with hypersensitivity illnesses. One of the CHs subsequently withdrew because of maternity leave before recruiting any patient. The CHs were aged between 35 and 64; five men and six women.

Patients

The researchers delivered 194 questionnaires to the GPs and CHs (Figure 1). The number of questionnaires was based on what the GPs and the CHs considered to be realistic in terms of numbers of patients suffering from hypersensitivity illnesses. The GPs and the CHs were responsible for sending or handing out questionnaires to all their patients whose primary reason for consultation was hypersensitivity illnesses; had been treated within the last 3 years; treatment finished or current 'maintenance treatment'. The exclusion criteria were: not Danish-speaking; diagnosis of cancer; 17 years old or younger. The questionnaires were returned to the researchers.

The patients were recruited consecutively: the GPs and the CHs started from 'today' and were instructed to go back in time without excluding any patient, until they had distributed all the questionnaires they had received from the researchers. To ensure the anonymity of the patients, we chose not to enable ourselves to send a reminder to patients who did not return the questionnaire. As shown in Figure 1 the response rate was similar among the GP patients and the CH patients. Figure 1 also illustrates that the CHs distributed 89% of the questionnaires they asked for while the GPs distributed 67%.

Questionnaire

The questionnaire contained the following social and health-related variables: age, education and occupation at the time of completion of the questionnaire, self-reported hypersensitivity illnesses, other illnesses, duration of symptoms/course of hypersensitivity illnesses before consulting the GPs or the CHs, point in

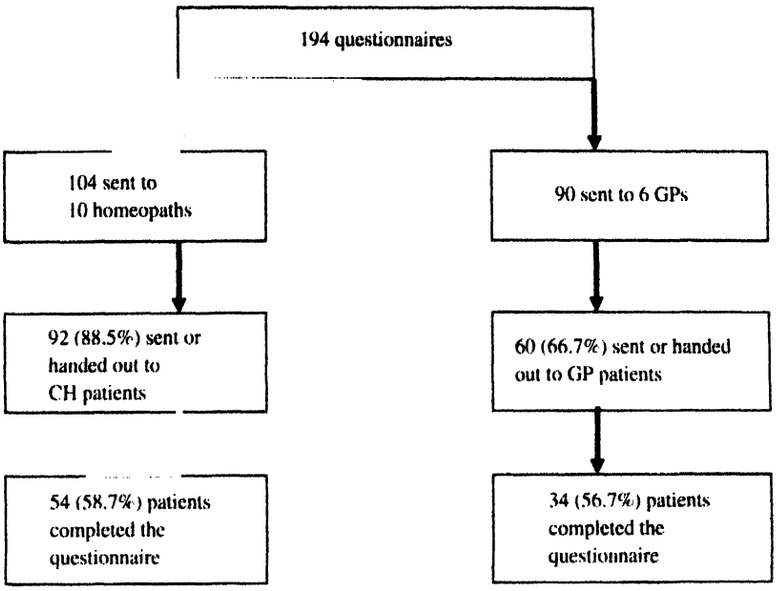

Fig. 1 Summary of the distribution of questionnaires and response rate.

time for first consultation, and a self-assessment of a range of psychological conditions before and after treatment. The parameters were developed in collaboration with the GPs and CHs in order to address their needs for an assessment of their treatment models.[21]

Respondents' understanding of the different questions and response categories was examined by carrying out qualitative interviews with five patients suffering from hypersensitivity illnesses. This was done to ensure that the respondents and the researchers had the same understanding of the questions and the response categories. The questions and response categories in the questionnaires were subsequently revised.

The patients' self-reported effectiveness of the treatment by the GP or CH was explored through the following variables:

1. The time between receiving treatment and experiencing any effect of the treatment.
2. Changes in symptoms.
3. The emergence of previous symptoms.
4. Changes in the use of conventional medicine.
5. Use of conventional medicine at the time of questionnaire response.
6. Patient-experienced consequences of stopping the intake of conventional medicine.
7. State of health 'today' compared to 12 months ago.
8. Quality of life 'today' compared to 12 months ago.
9. Self-assessment of psychological conditions (self-confidence, joy of life, ideas to act in new ways, energy, anxiety, optimism, irritation, general well-being, feeling of freedom, the need to avoid certain things or situations, feeling of anger) (An example of a question: "How much self-confidence did you have before treatment and after the treatment?" The patient was asked to answer on a scale from 0 to 10 regarding both before treatment and after the treatment (0 indicated no self-confidence and 10 indicated great self-confidence).

To compare the change in self-assessed psychological conditions we computed for each patient the improvement as the difference between scores before and after treatment with a negative sign for the worsening parameters.

Statistical methods

The questionnaire responses were coded and the data entered in the SPSS and the SAS statistical programs, by which the analyses were also performed. In the statistical analysis of frequency tables the Pearson Chi-square test was used for tables with categorical responses, while the Gamma test[22] was used for tables with ordinal responses. One and two sample *t*-tests were used to analyse changes in self-assessed psychological parameters. The level of significance was chosen at 5%. In some of the analyses the conditions for using Pearson Chi-square are not fulfilled. In these cases a supplementary exact test was carried out.

Results

Patients

Table 1 shows the baseline characteristics of the GP patients and the CH patients. No significant difference between the two patient groups in age, school education and duration of hypersensitivity symptoms was found. A significant difference was found in occupation. More CH patients than GP patients were employed in the teaching, research, health care and the social sector.

Table 1 Baseline characteristics—GP patients and CH patients

	GP patients	*CH patients*	*Total number of patients*	*Frequency missing*	*P-value*
Age					
<30	15.63	18.00			
30–9	34.38	20.00			
40–9	18.75	32.00			
50 and >	31.25	30.00			
N	32	50	82	6	0.4032
School education					
<10 years	30.30	16.98			
10 years	33.33	20.75			
>10 years	36.36	62.26			
N	33	53	86	2	0.0640
Occupation					
Private sector	57.58	26.42			
Teaching, research, health care and social sector	21.21	47.17			
Other kinds of public services and administration	15.15	20.75			
Other responses	6.06	5.66			
N	33	53	86	2	0.0270

Table 2 The use of conventional medicines among GP patients and CH patients 'today'

			Using conventional medicine		*Total*
			Yes	*No*	
GP or CH	GP	Count	34	0	34
		% within GPs	100	0.0	100
	CH	Count	38	14	52
		% within CHs	73.1	26.9	100
Total		Count	72	14	86
		% within GPs or CHs	83.7	16.3	100

P-value for Pearson $\chi^2 < 0.001$.
Two patients had missing values for *use of conventional medicine*.

There are no significant differences in the GP and CH patients' self-reported symptoms and their reports of medically diagnosed symptoms. Of all patients 48% had seasonal allergic rhinitis; 32% perennial rhinitis; 55% asthma; 30% allergic eczema; 17% asthmatic eczema, 17% urticaria, 14% allergic reactions in the gastrointestinal tract, and 21% other allergic/asthmatic symptoms. Several patients had a combination of symptoms. Analysis of the occurrence of other illnesses did not show any significant differences.

There is no significant difference between the GP and CH groups in the length of time between receiving treatment improvement in their conditions. Table 2 shows that all the GP patients were using conventional medicine at the time of answering the questionnaire, compared to 73% of the CH patients ($P < 0.001$).

Self-reported effectiveness of treatment by GPs and CHs

Patients (43) who had stopped using conventional medicine for their hypersensitivity illnesses for shorter or longer periods of time, were asked what consequences they experienced from not taking the conventional medicine. Table 3 shows that the consequences are significantly different between CH patients and GP patients ($P = 0.002$). While most of the GP patients found that their symptoms worsened, about 1/3 of the CH patients experienced the same. Only one of the GP patients reported a reduction in symptoms, while about 2/3 of the CH patients experienced a reduction.

The patients' self-reported improvement in their general state of health showed a significant difference ($P = 0.004$) between GP patients and CH patients. Of the GP patients 24% assessed that they had an improvement in their state of health compared to 57% of the CH patients (Table 4).

The scores of the psychological health index before treatment were statistically significantly different ($P = 0.020$) between the two patient groups. Table 5 (columns 4 and 7) shows that both GP and CH patients experienced improvement after undergoing treatment when combining all psychological parameters ($P = 0.03$ for GP patients, $P = <0.0001$ for CH patients, one sample *t*-test).

Column 8 shows that CH patients experience a larger improvement than GP patients in all variables.

Table 3 GP patients' and CH patients' self—reported consequences of stopping the intake of conventional medicine in shorter or longer period of time

			Consequences of stopping the intake of conventional medicine			*Total*
			Reduction of symptoms	*Disappearance of symptoms*	*Worsening of symptoms*	
GP or CH	GP	Count	1		9	10
		% within GPs	10		90	100
	CH	Count	12	11	10	33
		% within CHs	36.4	33.3	30.3	100
Total		Count	13	11	19	43
		% within GPs or CHs	30.2	25.6	44.2	100

P-value for gamma = 0.002.

Table 4 The GP patients' and the CH patients self—reported general state of health "today" compared to 12 months ago

			General state of health 'today' compared to 12 months ago			*Total*
			Better	*Mainly unchanged*	*Worse*	
GP or CH	GP	Count	8	25	1	34
		% within GPs	23.5	73.5	2.9	99.9
	CH	Count	30	20	3	53
		% within CHs	56.6	37.6	5.7	100
Total		Count	38	45	4	87
		% within GPs or CHs	43.7	51.7	4.6	100

P-value for gamma < 0.001.
One CH patient had a missing value for quality of life 'today' compared to 12 months ago.

Table 5 GP patients' and the CH patients' self-reported improvement on psychological parameters

Psychological parameter	*CH patients*			*GP patients*			*Difference in improvement*	*Confidence interval for difference*
	Before	*After*	*Improvement*†	*Before*	*After*	*Improvement*†		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Self-confidence	6.17	7.75	1.58	6.89	7.82	0.93	0.65	(−0.30, 1.62)
Joy of life	5.81	8.27	2.46	7.21	8.21	1.00	1.46	(0.30, 2.64)
New ideas	5.91	7.17	1.26	6.64	6.78	0.14	1.12	(0.19, 2.04)
Energy	4.83	7.75	2.92	5.29	6.43	1.14	1.78	(0.47, 3.08)
Optimism	5.83	7.85	2.02	6.81	6.85	0.04	1.98	(0.62, 3.34)
General well-being	5.13	8.04	2.91	5.25	6.82	1.57	1.34	(−0.10, 2.78)
Freedom	6.52	8.11	1.59	6.97	7.43	0.46	1.13	(0.02, 2.22)
Anxiety	5.57	4.74	0.83	3.57	3.43	0.14	0.69	(−0.67, 2.05)
Irritation	5.45	3.94	1.51	5.33	4.48	0.85	0.67	(−1.00, 2.33)
Avoiding things	4.69	4.27	0.42	3.63	3.26	0.37	0.05	(−1.43, 1.54)
Anger	4.32	2.60	1.72	3.39	3.18	0.21	1.51	(0.29, 2.73)
Mean improvement			1.86**			0.62*	1.24**	(0.37, 2.12)

Mean improvement is significantly different from 0 for both the GP and CH patients ($P = 0.03$ for GP, $P < 0.0001$ for CH). The difference between the CH and GP patients is also significant ($P = 0.006$).

*Significant at 5% level;

**Significant at 1% level.

†For GP's between 5 and 8 patients were omitted due to missing values when computing improvement on the individual psychological parameters. For CH's between 6 and 9 were omitted.

Column 2 shows 95% confidence limits equivalent to a *t*-test for each mental parameter. However, these should be regarded with reservation because variables are associated. Comparing the mean improvement for GP and CH patients respectively, the CH patients report a significantly larger improvement ($P = 0.006$, two sample *t*-test).

The finding is confirmed by Table 6 showing a significant difference between the GP patients' and the CH patients' assessment of changes in their quality of life. Of the GP patients 15% felt that their quality of life had improved, compared to 53% of the CH patients.

In Table 5 we compared mean improvement between GP patients and CH patients. To ensure comparability all patients with missing values on one or more of the psychological parameters were omitted. Table 6 shows the patients' assessment of their quality of life 'today'

Table 6 The GP patients' and the CH patients' self-reported quality of life today compared to 12 months ago

			Quality of life 'today' compared to 12 months ago			*Total*
			Better	*Mainly unchanged*	*Worse*	
GP or CH	GP	Count	5	27	2	34
		% within GPs	14.7	79.4	5.9	100
	CH	Count	28	24	1	53
		% within CHs	52.8	45.3	1.9	100
Total		Count	33	51	3	87
		% within GPs or CHs	37.9	58.6	3.4	100

P-value for gamma < 0.001.
One CH patient had a missing value for *quality of life 'today' compared to 12 months ago.*

Table 7 Odds ratio estimates for regression analysis

Effect variables	*Value*	*Point estimate*	*95% Wald confidence limits*	
GP or CH	GP (baseline) HP	10.851	2.521	46.700
Duration of hypersensitivity symptoms	Year	0.997	0.988	1.007
Age	Year	0.999	0.998	1.001
School education	> 10 years (baseline) 10 years	1.609	0.449	5.763
	< 10 years	0.493	0.103	2.367
Occupation	Private sector (/baseline)	0.393	0.102	1.514
	Teaching, research, health care and social sector			
	Other kinds of public services and administration	0.195	0.034	1.126
	Other responses	1.827	0.199	16.744

Dependent variable: quality of life today compared to 12 months ago.

compared to 12 months ago for all patients and for omitted patients (compare Table 4). No-response shows no correlation with change in quality of life (the distribution was the same for GP patients and CH patients). Mean improvement is consistent with change in quality of life for both GP patients and CH patients, but a higher level for CH patients.

To control for a possible influence of the background variables a logistic regression analysis was performed in SAS with quality of life 'today' compared to 12 months ago as response variable and GP or CH, age, duration of the hypersensitivity symptoms, school education and occupation as regression (effect) variables (compare Table 1). To enhance the power of the tests quality of life 'today' compared to12 months ago was dichotomized as 'better' or 'unchanged/worse'. For school education and occupation the categories from Table 1 was used. GP or CH was the only significant effect variable (Table 7). This did not change when non-significant effects were eliminated either backwards or forwards. This confirms the findings in Table 6.

Conclusion and discussion

The patients participating in the study were defined by their GPs or CHs as having finished their treatment or being on 'maintenance treatment'. Although the two groups of patients are relatively similar in self-reported symptoms and their reports of medically diagnosed symptoms at the start of the treatment, a larger part of the CH patients have reported an improvement in their general state of health after the treatment. Both groups experienced an improvement in psychological conditions. However, the CH patients report a significantly larger improvement perceived as a result of the treatment received.

What causes these results in favour of homeopathic treatment cannot be explained meaningfully on the basis of the social and health-related variables. The patients' state of health before treatment did not differ between the two groups and cannot explain the differences in GP patients' and CH patients' self-assessed effectiveness of the treatments.

It is interesting to note that the conventional medicine used by the GPs are documented to have effects opposite homeopathy medicines where meta-analyses of homeopathy for hypersensitivity illness do not show convincing specific effects.[23 27] This study, unlike RCT, examined normal treatment in everyday clinical practice. The focus is not just on a simple input of a treatment technique but incorporates the whole treatment setting in the clinical practice of both the GPs and the CHs. More research into the whole GP treatment compared to the whole CH treatment and the implication of the treatments within the patients' everyday life situations is needed.

A possible effect of the interaction between patient and therapist may influence how the patients' experience the treatment. We do not know, however, if this effect is larger in CHs' than in GPs' clinical setting. An important research issue is to explore possible over-treatment by GPs so that a reduced use of conventional medicine lead to reduced side effects contributed to the improvement observed by CH treatment.

Looking at the GPs' and the CHs' treatment models the main difference is the practitioners' comprehension of how their treatment should work.[21] Whereas the GPs' understanding is to neutralize or curb the symptoms directly the CHs' understanding is to set a recovery process into motion by stimulating the person's self-healing powers or vital force. We do not know if the patients' self-reported effectiveness of the treatments reflects these different apprehensions. More research is needed to explore the connections between the practitioners' apprehensions of how their treatment should work and treatment outcomes.

The project has some obvious limitations for statistical generalization. The recruitment of GPs to the study was based on self-selection. The GPs' motivation for taking part in the project is a desire to have the weaknesses and strengths of their own methods of treatment evaluated compared to homeopathic treatments. We do not have information concerning the participating GPs' patient-lists compared to patient-lists of other GPs who were unwilling to participate in the study. All the invited CHs agreed to participate.

The GPs and CHs were responsible for distributing the questionnaire to their patients and a biased selection of patients might have occurred especially in relation to the GPs. Only 67% of the questionnaires were distributed by the GPs to their patients compared to 89% for the CHs. The researchers asked the GPs and CHs about any conscious selection of patients. The GPs and CHs told the researchers that they had distributed the questionnaires to patients they considered having the ability to complete the form. This might indicate that GPs had more patients lacking resources to fill out the questionnaire. The GPs' and CHs' arguments for not distributing *all* the questionnaires were that they actually did not have as many patients as they had originally thought, they did not have time, or they had forgotten about it. The consequence of this bias is that the study gives a limited picture of all the patients within the two treatment modalities.

Information bias related to the source of data

Our study is based on the patients' treatment experiences obtained through a treatment course. The results are based on the patients' self-reported effectiveness of the treatments. The patients' assessment was done retrospectively based on the patients' experience and knowledge gained through a treatment course and the outcomes of this treatment course. The patient's retrospective assessment of their initial state of health is assumed to be different from prospective studies. It is not possible to state whether the retrospective assessment is more or less valid than the prospective assessment. It is more a question of the patients' frames of reference for their assessment.

Statistical power

Due to the study's limited size, we cannot expect small differences between groups to result in statistically significant results. We therefore emphasize that non-significant results might represent real, but smaller differences. Conversely, the statistically significant results can be regarded as relatively reliable.

The results of the study have been communicated to and discussed with the GPs and CHs who recruited patients to the project. Neither the GPs and CHs raised any objections to the results.

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