

## ORIGINAL PAPER

# Expectations and effectiveness of medical treatment and classical homeopathic treatment for patients with hypersensitivity illnesses—One year prospective study

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**Objective:** To describe and compare characteristics of adult patients who received treatment for hypersensitivity illnesses by general practitioners (GPs) and classical homeopaths (CHs) over a period of 1 year and examine the statistical predictors of self-reported treatment outcomes.

**Material and methods:** We conducted a survey on 151 Danish adult patients with hypersensitivity illnesses, who chose treatment from one of 13 GPs or one of 10 CHs who participated in the project. The treatments were given as individual packages in the naturalistic clinical setting. Patients completed questionnaires at start of treatment, after 6 months and a year after start of treatment. Response rates for the first, second and third questionnaire were respectively 68%, 98%, 95% for the GP patients and 82%, 98%, 94% for the CH patients.

**Results:** Patients seeking CH treatment in this study are significantly different in gender and education from patients seeking GP treatment. We did not find significant differences in terms of occupational training, occupation, sickness absence due to hypersensitivity illnesses, diseases other than hypersensitivity illnesses, symptoms severity due to hypersensitivity illnesses before treatment and expectation of the ability of the treatment to alleviate symptoms.

Eighty-eight percent of GP and 21% of CH patients were continuing treatment after 1 year. Regression analysis showed that the only significant independent variables to explain the probability of obtaining very positive effect or cure for GPs and CHs were that the patients were in 'maintenance treatment', and had high expectation before treatment of the ability of the treatment to relieve their symptoms.

**Conclusion:** In this study self-reported very positive effect of GP treatment and very positive effect and cure of CH treatment are associated with the patients' high expectation of the treatment and continuation of maintenance treatment. *Homeopathy* (2007) 96, 233–242.

**Keywords:** prospective study; user-evaluation study; outcome assessment; health care; cure

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## Introduction

Increasing numbers of patients in the Scandinavian countries and world wide use various alternative treatment modalities.<sup>1-14</sup> This tendency is also observed in relation to use of treatment for hypersensitivity illnesses (a collective term for asthma, allergic rhinoconjunctivitis, atopic eczema, contact dermatitis and food allergy). Most patients with hypersensitivity illnesses are treated by general practitioners (GPs) but homeopathic treatment is frequently used.<sup>15-19</sup> This usage raises the issue about patients' experiences with GP treatment and CH treatment in naturalistic clinical settings and predictors of self-reported effectiveness of the two treatments.

The authors of a Cochrane review<sup>20</sup> conclude that there is not enough evidence to reliably assess the possible role of homeopathy in asthma. They further conclude that there is a need for observational data as well as randomized controlled trials (RCTs) to document the different methods of homeopathic prescribing and how patients respond. Data from observational studies and patient evaluation studies will help to establish to what extent people respond to a "package of care" rather than the homeopathic remedy alone.

RCTs do not reflect the everyday clinical homeopathic treatment practice and therefore the external validity of RCT-based results is low. Most RCTs have used standardized treatment despite the fact that standardized treatment is unlikely to represent everyday homeopathic clinical practice. The results of most trials have been negative or equivocal. However, patients as well as homeopathic practitioners report that homeopathic treatment given as an individualized "package of treatment and care" in everyday clinical practice can generate positive outcomes.<sup>21-23</sup> Thus a gap is increasingly apparent between evidence-based knowledge drawn from RCTs, systematic reviews and meta-analyses on the one side and experience-based knowledge of treatment outcomes reported by patients and homeopathic practitioners on the other side.

The focus of RCTs is on the technical intervention defined as the specific input (a drug, a remedy) determining a specific effect and answering the question: Does the intervention work? When it is possible to fulfil the prerequisites for conducting a RCT this research design is a very powerful one.

An assumption behind the RCT approach to treatment and evidence-based medicine is that the technical intervention is the most 'active component' in the curative process. But is this assumption sufficient when dealing with chronic illnesses and alternative or integrative treatment? Classical homeopathic treatment involves a 'whole system care model' encompassing the interview with the patient, thereby stimulating the patient's awareness of symptoms and possible connection to daily life situations, the homeopathic medicine and the patient's own effort in prevention and care activities.<sup>24</sup>

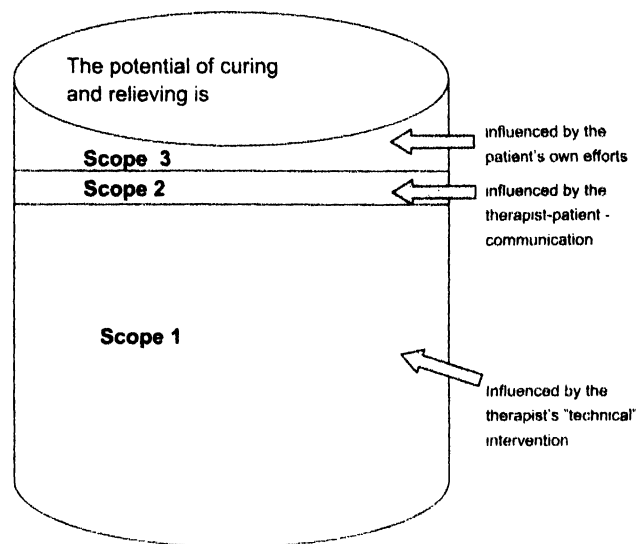


Fig. 1 Assumption behind evidence-based medicine.

Figs. 1 and 2 illustrate two very different assumptions of what are the 'active components' in a relieving or curative process. RCTs are based on the assumption that the technical intervention (Scope 1) has the dominant role and cancel out other elements such as patient-practitioner communication and the patient's own efforts.<sup>25,26</sup> From studies on patients' and alternative practitioners' perceptions of what are the "active components" in a relieving, curative or healing process we know that the patient's own efforts are important in dealing with chronic illnesses. The potential of patient-practitioner communication and the patient's own efforts are embedded in their capability to promote (and not inhibit) healing processes. The assumption presented in Fig. 2 is in line with the concept "Whole System Research (WSR)". WSR evaluates systems of care, in a way that respects the integrity and complexity of the practice.<sup>27</sup> When asking for the patients' assessment of the effectiveness of treatment such assessment encompasses the whole system of care. Studies focusing on patient self-reported effectiveness of 'package of care' or 'whole system care' are few.<sup>28,29</sup>

The study presented here is based on research on 'packages of treatment and care' offered by GPs and CHs, in everyday clinical practice, to patients with hypersensitivity illnesses, including patient-practitioner communication and the patient's own efforts. Both the GP and the CH practitioners wanted the research design to include their 'package of care' and patients' reported effectiveness of this 'package of care', not just their input of a single drug or remedy.

Researching the GPs' and CHs' treatment models in a previous study<sup>24</sup> we found a difference in the two groups of practitioners in their perception of 'cure' as an outcome of treatment. GPs' did not perceive 'cure' as an attainable outcome whereas according to the CHs' understanding of their treatment 'cure' was a

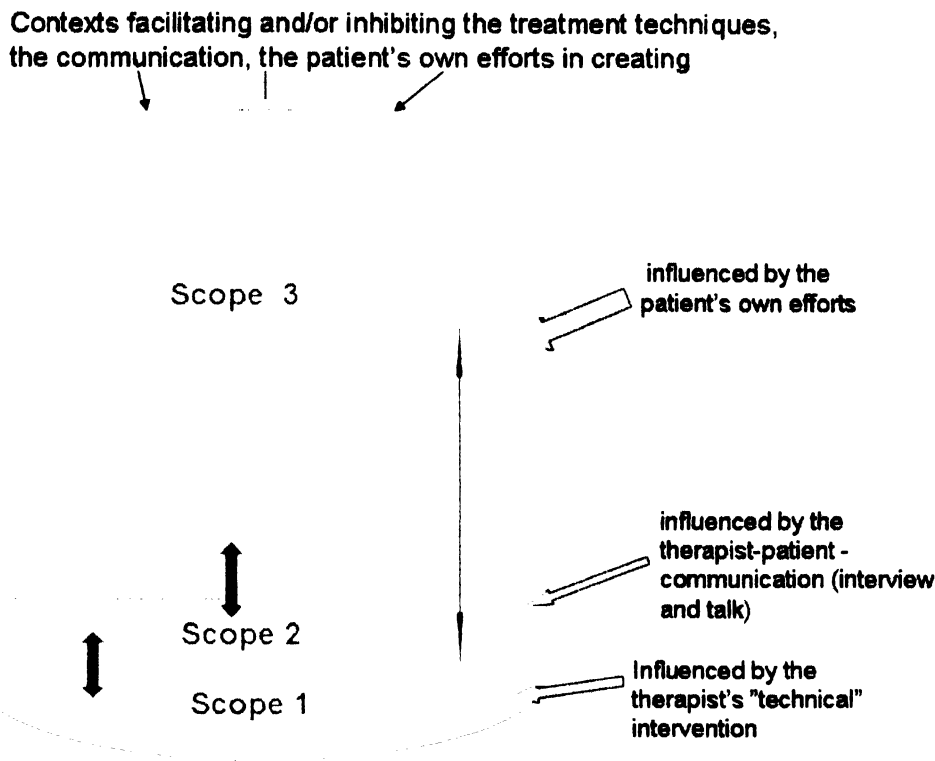


Fig. 2 Therapeutic components of treatment.

possible outcome. Therefore we included 'cured' in the outcome categories in the study.

Homeopathic treatment is defined as an alternative treatment in Denmark and is not reimbursed by public agencies. Research-based knowledge about patients' self-reported effectiveness of treatment by GPs compared to treatment by CHs is limited. The GPs and CHs participating in this study emphasized the need for the patients' assessment of treatment outcome. GPs and the CHs agreed that objective improvement was not sufficient to say whether or not a treatment is effective for a patient.<sup>24</sup> We assume that the patients' self-reported outcomes reflect their "lived experiences"<sup>30</sup> and thus give a realistic picture of how the treatments are working for patients in their different everyday life situations.

The research questions of this study are: (1) What characterizes patients who attended treatment for hypersensitivity illnesses by GPs and CHs? (2) What is the patients' self-reported effectiveness of the treatment for hypersensitivity illnesses given by GPs or CHs over a period of 1 year. (3) What are the predictors of self-reported very positive outcome of treatment?

This was a prospective study, data was collected between October 2001 and December 2003 in Denmark. The Committee for Research Ethics considered the project outside their area of competence. An smaller, explorative and retrospective study was conducted before the prospective study.<sup>23</sup> The findings from this study indicated a need for a larger, prospective study.

## Material and methods

### Recruitment of GPs and CHs

One hundred and four GPs were contacted by mail about the previous retrospective study.<sup>23</sup> Six GPs agreed to participate in the retrospective study and also to participate in the prospective study. A further 500 GPs were contacted by a telemarketing agency and asked to participate in the prospective study; in total thirteen agreed to participate. All GPs were 46–58 years old, six male and seven female. Twelve are specialists in general medicine, one is a specialist in orthopaedic surgery. The recruitment of homeopaths took place through The School of Classical Homeopathy in Denmark. The school manager selected the CHs on the basis of the following inclusion criteria:

- completed training in classical homeopathy
- minimum of 2 years clinical practice,
- experience with treating people with hypersensitivity illnesses.

Ten CHs fulfilled the inclusion criteria and all agreed to participate in the study. The CHs were aged between 35 and 64; five male and five female.

### The recruitment of patients

The first questionnaire was handed out by the 13 GPs and the 10 CHs to 200 of their patients with hypersensitivity illnesses, age 0–10 or 18 or over. Hypersensitivity illnesses had to be the primary or secondary reason for seeking treatment. The exclusion criterion was: not Danish-speaking. The questionnaires were returned by the patients to the researchers

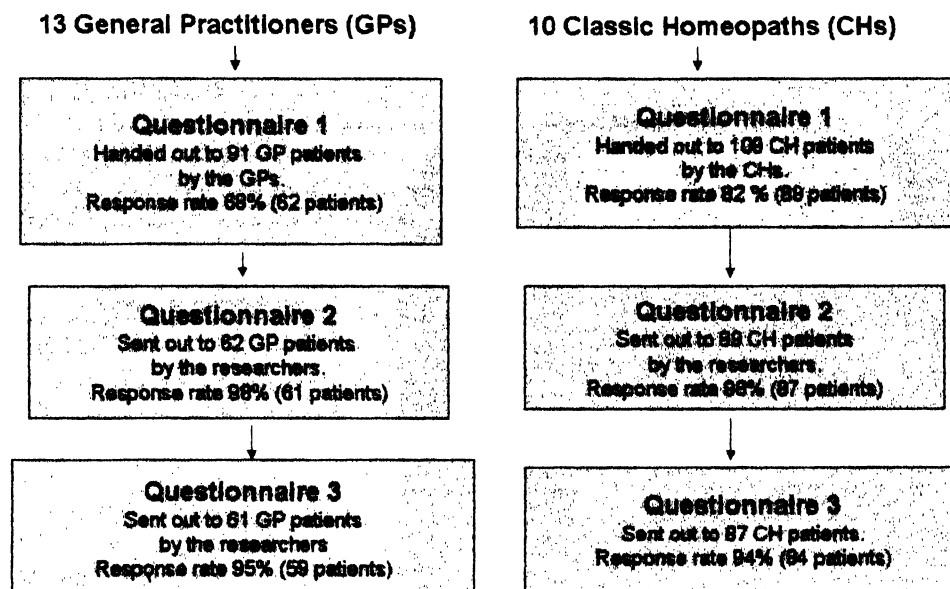


Fig. 3 Summary of the distribution of questionnaires and response rates.

(Fig. 3). The number of questionnaires was based on what the GPs and the CHs considered realistic in terms of their intake of patients with hypersensitivity illnesses over a period of a year.

The patients had made their own choice of treatment by one of the GPs or CHs participating in the research project and the treatments were paid for by the patients themselves. Consecutive patients were recruited between October 2001 and October 2002. Each patient was followed for a year with a total of three questionnaires, one at the start of treatment, one 6 months after start of treatment and one a year after start of treatment. Questionnaires 2 and 3 were sent out to the patients by the researchers. We were able to follow-up patients for only 1 year due to financial restraints.

We present data based on questionnaires 1 (initial) and 3 (1 year) and limited to the adult respondents ( $n = 151$ ). The patients were asked to report their assessment of the response of their health conditions to the treatment given by the GP or the CH from whom the patient received the first questionnaire.

### Questionnaires

The questionnaires were developed in collaboration with the GPs and CHs participating in the project. The questions reflected the information the practitioners considered important, the practitioners' treatment models<sup>24</sup> and the researchers' experience drawn from the use of a questionnaire in the previous retrospective study.<sup>23</sup> The first questionnaire included the following socio-demographic, life style, treatment, and health-related variables: gender, age, school education, occupational education, occupation, self-assessed hypersensitivity illnesses, everyday life activities to reduce symptoms, smoking, intake of fruit and vegetables, attitude to ecological goods, daily exercise, use of

nutritional supplements, use of supplementary treatment, duration of hypersensitivity symptoms, expectations to relief from treatment, compliance, understanding of GPs and CHs treatment models. Questionnaires 2 and 3 contained questions related to changes in life situation, use of treatment, description of symptoms, self-assessed effectiveness of the treatments and assessment of symptoms and quality of life on 0-10 scales.

### Pilot studies

The respondents' understanding of the different questions and response categories in the first, second and third questionnaire was examined by carrying out qualitative interviews with a pilot sample of, respectively, 8, 6 and 6 patients after they had filled in the three questionnaires. This was done to ensure that the respondents and the researchers had the same understanding of the questions and the reply categories. The questions and reply categories in the questionnaires were revised before the main data collection was conducted for each of the questionnaires.

### Explorative sub-study on cost-effectiveness

As an explorative sub-study one of the authors (Anne Hvenegaard), conducted an economic evaluation to assess if homeopathic treatment was cost-effective compared to conventional treatment. Few economic evaluations have been conducted to compare costs of GP and CH treatment.<sup>31,32</sup> All patients included in the main study were invited to participate in the economic study. The inclusion of patients happened 1-3 months after the inclusion in the main study. The economic study was carried out as a 2 year follow-up study. Data on resource utilization (direct medical costs) and quality of life (assessed by EuroQol 5D) were collected via questionnaires and telephone

interviews. Direct medical costs included health care contacts to the primary health care sector, to medical specialists, physiotherapists and to the hospital sector. Data on the use of other types of alternative treatment were also collected. The EuroQoL 5D measures quality of life created from 5 questions of physical as well as mental wellbeing. The EuroQoL 5D measures the patient's own assessment of their health on a scale from 0 to 100 with 100 indicating full health. Only 52 patients wanted to participate over the period of 2 years. Thus the number of patients was too small to be able to draw any conclusion about resource utilization and quality of life.<sup>33</sup>

### Statistical methods

The questionnaire responses were coded and the data entered in the SPSS statistical program. The analyses were performed in SAS (version 9.1) using the CATMOD-procedure for the Chi-square tests, the TTEST-procedure for the *t*-tests and the LOGISTIC-procedure for the logistic regression. When appropriate, separate Chi-tests were supplemented by composite tests to control for multiple tests of significance.

## Results

### Baseline data

Socio-demographic variables are summarized in Table 1. The adult patients seeking CHs in this study are significantly different in gender ( $p = 0.013$ ) (a higher proportion of women) and school education ( $p = 0.003$ ) (a higher proportion with high school diplomas) from patients seeking GPs. CH and GP patients had almost the same mean age (37.8 and 38.7 years respectively) but the GP patients tended to be younger or older than the patients seeking CH treatment. We did not find significant differences regarding occupational training, occupation, absence of sickness due to hypersensitivity illnesses and other diseases than hypersensitivity. These conclusions are not changed if allowance is made for multiple comparisons. Table 2 does not show significant differences in GP and CH patients' rating of discomfort of symptoms due to hypersensitivity illnesses before start of treatment ( $p = 0.99$ ) or in the two groups of patients' expectations of the capability of the treatment to alleviate their symptoms ( $p = 0.65$ ).

**Table 1** Baseline characteristics of CH patients and GP patients

Baseline characteristic	Patient group		Chi <sup>2</sup> -value (p-value) degrees of freedom <sup>1</sup>
	CH	GP	
Total number of patients <sup>2</sup>	89	62	
Gender (%)			
Male	20	39	$\chi^2 = 6.16$ ( $p = 0.013$ ) $f = 1$
Female	80	61	
Age (%)			
< 30	23	31	$\chi^2 = 8.33$ ( $p = 0.040$ ) $f = 3$
30–39	45	23	
40–49	16	24	
50 and >	16	23	
School education			
12 years (High School Diploma)	72	48	$\chi^2 = 8.60$ ( $p = 0.003$ ) $f = 1$
< 12 years	28	52	
Occupational training			
≤ 3 years	31	47	$\chi^2 = 5.46$ ( $p = 0.065$ ) $f = 2$
> 3 years	51	45	
None/missing	19	08	
Occupation			
Private sector	35	42	$\chi^2 = 1.77$ ( $p = 0.622$ ) $f = 3$
Teaching, research, health care and social sector	11	06	
Other kinds of public services and administration	43	44	
None/missing	11	08	
Absence of sickness due to hypersensitivity illnesses within the last 12 months			
Yes	83	79	$\chi^2 = 0.37$ ( $p = 0.542$ ) $f = 1$
No	17	21	
Other illnesses or diseases than hypersensitivity			
Yes	43	47	$\chi^2 = 0.26$ ( $p = 0.607$ ) $f = 1$
No	57	53	

<sup>1</sup>Chi<sup>2</sup>-tests for equal distribution of baseline characteristics for CH- and GP-patients were performed separately for each characteristic. Test-statistic used is 'Likelihood Ratio Chi-Square'.

<sup>2</sup>The following group had missing values not included in the analysis: absence of sickness due to hypersensitivity illnesses within the last 12 months" (CH 5, GP 4), "Other illnesses or diseases than hypersensitivity" (CH 2, GP 0).

**Table 2a** CH and GP patients' self-reported discomfort of symptoms due to hypersensitivity illnesses and expectations to the capability of the treatment to alleviate their symptoms before start of treatment (Questionnaire 1)

	<i>N</i>	<i>Mean</i>	<i>Std error of mean</i>	<i>Confidence interval of mean</i>
Patient's discomfort of symptoms due to hypersensitivity illnesses before start of treatment <sup>1</sup>				
Homeopath-patients <sup>2</sup>	88	6.69	0.34	[6.12; 7.26]
GP-patients <sup>3</sup>	60	6.70	0.29	[6.01; 7.39]
Difference (CH - GP)		0.01	0.45	[ - 0.89; 0.88]
Patient's expectations to the capability of the treatment to alleviate their symptoms <sup>1</sup>				
Homeopath-patients	89	7.37	0.26	[6.85; 7.89]
GP-patients	62	7.56	0.35	[6.86; 8.27]
Difference (CH - GP)		- 0.19	0.43	[ - 1.05; 0.66]

For each part of the table a two-sample *t*-test was performed to compare CH- and GP-patients (Table 2b).

<sup>1</sup>Self-reported symptoms measured on scale from 0 to 10.

<sup>2</sup>One patient missing.

<sup>3</sup>Two patients missing.

**Table 2b** Comparison of CH patients' and GP patients' self-reported discomfort of symptoms due to hypersensitivity illnesses and expectations to the capability of the treatment to alleviate their symptoms before start of treatment (Questionnaire 1)

	<i>Value of t-statistic</i>	<i>p-value</i>	<i>Degrees of freedom for test</i>
Patient's discomfort of symptoms due to hypersensitivity illnesses before start of treatment <sup>1</sup>	0.02	0.99	146
Patient's expectations to the capability of the treatment to alleviate their symptoms <sup>1</sup>	0.45	0.65	149

<sup>1</sup>Self-reported symptoms measured on a scale from 0 to 10.

**Table 3** CH and GP patients' self-reported outcomes of treatment of hypersensitivity illnesses assessed a year after start of treatment. Comparison of outcomes<sup>1</sup>

<i>The treatment had</i>	<i>CH patients</i>		<i>GP patients</i>		<i>Total</i>	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
Cured	8	10	0	0	8	6
Very positive effect	19	23	22	38	41	29
Positive effect	11	13	21	37	32	23
No effect	20	24	6	11	26	18
Negative reactions	1	1	0	0	1	1
Don't know	18	21	5	9	23	16
Only effect in the beginning	7	8	3	5	10	7
Total	84	100	57	100	141 <sup>2</sup>	100

<sup>1</sup>Comparison of distribution of outcomes for CH- and GP-patients: 'Likelihood Ratio Chi-Square' = 23.77, *p*-value = 0.0002, degrees of freedom = 5 (no effect and negative reactions were grouped in the test).

<sup>2</sup>Frequency missing: 10.

### The patients' self-reported effectiveness of treatment?

The percentage of GP patients and CH patients continuing the treatment 1 year after the start of the treatment was 88% for GP patients and 21% for CH patients.

Table 3 shows that a total of 75% of the GP patients reported very positive or positive effects of the treatment compared to 46% of the CH patients (including also the self-reported 'cured' ones). Twenty-four percent of the CH patients reported no effect compared to eleven percent of the GP patients. Of the CH patients 21% did not know whether the treatment had any effect compared to 9% of the GP patients. Eight percent of the CH patients reported an effect only in the beginning of the treatment compared

to 5% of the GP patients. No patient reported being 'cured' by the GP treatment, but 10% of the CH patients reported being 'cured'.

We conducted a separate analysis based on what patients understood by 'cured'. This showed that the self-reported 'cured' patients are all women, had allergies diagnosed by a medical doctor, and had high expectations of the ability of the CH treatment to relieve their hypersensitivity symptoms. They continued 'maintenance treatment', have a healthy lifestyle, have been very active themselves in preventing their allergy, have had a stable life situation or a life situation which has change in a self-assessed positive direction, and they have been very compliant with treatment. They differ in age, duration of their allergy,

**Table 4** Univariate analyses of dependence between "patients' self-reported outcomes of treatment" and supplementary explanatory variables

<i>Explanatory variable</i>	<i>Likelihood ratio Chi-square'</i>	<i>Degrees of freedom</i>	<i>p-Value</i>
Occupational training	1.05	2	0.59
Occupation	2.36	3	0.50
Absence of sickness due to hypersensitivity illnesses within the last 12 months	1.77	1	0.18
Other illnesses or diseases than hypersensitivity	0.42	1	0.52
Importance of eating ecological food	2.54	2	0.28
Smoking	0.48	2	0.78
Intake of vegetables	3.10	3	0.39
Exercise	2.31	4	0.68
Larger changes in life during the last 9 months	1.41	1	0.23
Number of consultations by the GPs or the CH	3.34	5	0.64
Feeling of being understood by the practitioner	4.09	3	0.25
Nuisances of symptoms before start of treatment	4.53	6	0.61

use of other alternative practitioners than the CH, and in relation to self-assessed quality of life. The patients were asked to describe what they actually meant by 'cured'. 'Cured' was perceived as a healing and a learning process where a connection between hypersensitivity symptoms and stress factors was recognized as important. This recognition made the patient able to control her symptoms so that the hypersensitivity symptoms had disappeared or had been imperceptible for a long time.

#### **Explanation of variation in the patients' self-reported effectiveness**

We conducted a logistic regression analysis to explore the statistical probability of very positive outcome and 'cure' against the independent variables (socio-demographic, life style, treatment, and health-related variables). The dependent variable was "patients' self-reported outcomes of treatment for hypersensitivity illnesses assessed a year after the start of treatment" (see Table 3) and dichotomized into the patients self-reporting "cured" or "very positive effect" (coded 1) and all other outcomes ("positive effect", "no effect", "negative reaction", "don't know", "only effect in the beginning after treatment") (coded 0). The explanatory variables of main interest were "age", "gender", "school education", "practitioner (CH or GP)", "still in maintenance treatment", and "expectations of treatment". These were supplemented with the following variables: "occupation", "occupational training", "absence of sickness due to hypersensitivity illnesses within the last 12 months", "other illnesses or diseases than hypersensitivity", "smoking", "intake of vegetables", "importance of eating ecological food", "exercise", "number of consultations with the GP or CH", "feeling of being understood by the practitioner", "the patients' rated nuisance of symptoms before start of treatment", and "large changes in every day life during the last 9 months".

We first conducted univariate analyses of dependence between "patients' self-reported outcomes of treatment" and each of the supplementary variables,

primarily to reduce the dimensionality of the problem but missing values were also taken into consideration.<sup>34</sup> All supplementary explanatory variables were categorical hence we performed separate Chi-square tests for independence both for CH and GP patients separately (not shown) and CH and GP patients combined. Results for CH and GP patients combined are given in Table 4. None of the test gave significant results at a 5% level. The same was true when CH and GP patients were treated separately. Hence the supplementary explanatory variables were omitted from the first round of the logistic regression. They were reintroduced one by one in the final logistic regression model but did not give rise to any qualitative changes.

A multivariate logistic regression with "outcome of treatment" (two levels) as dependent variable and "age", "gender", "school education", "practitioner (CH or GP)", "still in maintenance treatment", and "expectations of treatment" (numerical scale from 0 to 10) as explanatory variables was performed (Table 5).

The two significant variables 'still in maintenance treatment', and 'expectations of treatment' (Table 5) were retained after stepwise backward elimination of insignificant effects (see Table 6).

The logistic regression analysis further showed that significant statistical correlation is found between being in 'maintenance treatment' one year after the start of treatment and the dependent variable "cure" or "very positive effect" ( $p = 0.0123$ ), and between the patient's expectation of the ability of the treatment to relieve the hypersensitivity symptoms reported before start of treatment and the dependent variable "report of cure" or "very positive effect" ( $p = 0.0154$ ). No significant difference was found between GP and CH patients.

## **Discussion**

The two groups of patients are significantly different in gender and age. Regarding absence of sickness due to hypersensitivity illnesses and other illnesses or diseases, discomfort of hypersensitivity symptoms

**Table 5** Multivariate logistic regression analysis with "outcome of treatment" as dependent variable

<i>Explanatory variable</i>	<i>Estimate of regression coefficient</i>	<i>Std error</i>	<i>Wald Chi-square</i>	<i>Pr &gt; Chi-square</i>
Intercept	3.33954	1.35	6.15	0.013
Gender				
Male (baseline)				
Female	-0.0078	0.45	0.0003	0.986
Age				
years	0.0005	0.017	0.0012	0.972
Practitioner				
GP (baseline)				
CH	0.786	0.55	2.11	0.147
Still in maintenance treatment				
No (baseline)				
Yes	1.458	0.53	7.67	0.0056
School education				
< 12 years (baseline)				
12 years	0.400	0.44	0.82	0.366
Expectation of treatment (numerical) 0-10	0.222	0.10	5.35	0.021

**Table 6** Final model for multivariate logistic regression analysis with "outcome of treatment" as dependent variable

<i>Explanatory variable</i>	<i>Estimate of regression coefficient</i>	<i>Std error</i>	<i>Wald Chi-square</i>	<i>Pr &gt; Chi-square</i>
Intercept	3.289	0.79	13.43	0.0002
Still in maintenance treatment				
No (baseline)				
Yes	0.943	0.38	6.26	0.0123
Expectations of treatment (numerical) 0 to 10	0.223	0.09	5.87	0.0154

before start of treatment, and the patients' expectations to the capability of the treatment to alleviate their symptoms reported before start of treatment, we did not find any significant differences.

Of the GP patients 75% reported positive effects of the treatment compared to 46% of the CH patients. These results have to be considered in relation to the fact that only 21% of the CH patients, compared to 88% of the GP patients, decided to continue their CH treatment throughout the year.

Regression analysis showed that being in 'maintenance treatment' a year after the start of treatment was one of the two variables explaining the probability of obtaining cure or very positive effect of the GP treatment and the CH treatment. This finding is supported by the findings from our retrospective study.<sup>23</sup> The other significant independent variable to explain the probability of cure or very positive effect of treatment was the patient's high degree of expectation to the ability of the treatment to relieve the hypersensitivity symptoms reported before treatment start. For both variables the same pattern was found for GP and CH patients.

No patients reported being cured by the GP treatment compared to 10% of the CH patients. All these patients were women who had a diagnosed allergy, had high expectations of the capability of the CH treatment to relieve their hypersensitivity symptoms, were in 'maintenance treatment', had a healthy lifestyle, were very active themselves in preventing their

allergy, had a stable life situation or a life situation which had changed in a self-assessed positive direction, and they were very compliant. The 'cured' patients differed in age, duration of allergy, use of other alternative practitioners than the CH and in relation to self-assessed quality of life. 'Cured' was described as the situation where the hypersensitivity symptoms had disappeared or had been imperceptible for a long time. The women perceived 'cure' as a healing and learning process and recognized a connection between the hypersensitivity symptoms and stress factors. This recognition made the 'cured' patients able to take preventive actions to control their symptoms. These findings can be explained by the patient practitioner communication for the patient's own efforts, the homeopathic remedy and by a positive interaction between these. One hypothesis could be that the potential cure is embedded in the patient's learning processes and thereby in the empowerment of the patient in developing her competences in the role as her own disease-manager.

It is interesting that the concept 'cured' is used only by the CH patients. We might observe a reflection of the CHs' and the GPs' understanding of their treatment options<sup>24</sup> and of how they involve their patients in treatment.

If cure and very positive outcomes depend on a longer duration of a treatment for many CH patients, the economic issue might be a barrier. As far as 'cure' is an outcome of CH treatment in relation to patients

with hypersensitivity illnesses this is a public health care issue which should be taken into account in health policy.

To explain the findings one way is further to explore the concept 'expectations'. Do the patients' expectations reflect their knowledge and intuition about the options of the treatment and thereby their options as a responder or a non-responder of the treatment? Are self-healing processes triggered and activated by the patients' expectations? We cannot answer these questions on the basis of this study or existing research-based knowledge but the questions are of interest to future research.

### Generalizability

The study has limitations for generalization. The recruitment of GPs to the study was based on self-selection. The GPs' motivation for taking part in the project was a desire to have the weaknesses and strengths of their treatment evaluated compared to homeopathic treatments. We do not have information about the participating GPs compared to non-participating GPs, so we have no data on how GPs' patients in general assess the effectiveness of treatment of patients with hypersensitivity illnesses. There are no systematic evaluation studies on the treatment results received by GP patients. In this situation we cannot conclude anything about possible differences between the GPs participating in this study and other GPs. We assume that the most important factor in participating in a study like this is the GPs' motivation for learning from differences in treatment models.<sup>24</sup>

All the invited CHs agreed to participate. Here, again we lack systematic studies on the treatment results of CH patients in general.

The response rate for the patients for the first questionnaire was 68% for the GP patients and 82% for the CH patients. For questionnaires 2 and 3 the response rate for the GP patients was 98% and 95% and for the CH patients 98% and 94%.

The researchers interviewed the GPs and CHs about any conscious selection of their patients. The GPs told the researchers that the following patient groups were underrepresented: nickel allergy, infantile eczema, eczema caused by allergies, urticaria, food intolerance and allergy, allergic gastrointestinal symptoms, bronchial asthma, mild allergic and asthmatic reactions, patients with asthma and allergy as secondary reason for referral, patients to whom the doctor has difficulties relating, patients without a profession, and socially strained patients. No underrepresentation was assessed in relation to gender.

The CHs told the researchers that the following patient groups were underrepresented compared to the total group of their patients: mild and severe allergic and asthmatic reactions, and patients without a profession. No underrepresentation was assessed in

relation to diagnosis, age, or serious diseases other than hypersensitivity illnesses.

In order to compare the respondents in our study with a representative population-based study we also received data from SUSY2000, a population study on persons in the Danish population with hypersensitivity illnesses.\* Compared to the Danish population with hypersensitivity illnesses we found significantly more females in our study, more younger persons (especially in the age group 25-40 years) and significant less persons of above 60 years old. In our study there are significantly more persons with higher school education and less with lower school education compared to SUSY2000. These differences are especially marked in relation to the CH patients.

Thus we can conclude that older persons, persons with less education and males are underrepresented in our study compared to the whole Danish population with hypersensitivity illnesses. This conclusion concerns the CH patients more than the GP patients who more closely reflect typical persons having hypersensitivity illnesses. These differences in the patient selection procedures undertaken by the GPs and the CHs make it impossible to generalize the findings of the study to the whole adult population.

## Conclusion and implications

Patients' high degree of expectation that the treatment will alleviate their symptoms and the patients' continuation in a 'maintenance treatment' a year after start of treatment are important factors in obtaining a very positive effect for GP treatment and a very positive effect and cure of CH treatment.

The study has theoretical and clinical implications. At the theoretical level the different scopes illustrated in Figs. 1 and 2 and the interactions between these scopes in improving outcomes for people with chronic diseases should be further developed and operationalized. For clinical practice the study stresses the fact that in obtaining positive treatment outcomes more treatment options should be presented to the patients, as also indicated by other studies.<sup>23,31,32</sup>

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\*Senior Researcher Mette Kjoller, The National Institute of Public Health (Statens Institut for Folkesundhed), Copenhagen delivered the data material from SUSY2000 (a representative population study on illness and health in the Danish adult population).

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