

## ORIGINAL ARTICLE

# Homeopathic treatment of patients with psoriasis – a prospective observational study with 2 years follow-up

CM Witt,\*† R Lüdtkke,‡ SN Willich†

†Institute for Social Medicine, Epidemiology and Health Economics, Charité University Medical Center, Berlin, Germany

‡Karl and Veronica Carstens Foundation, Essen, Germany

\*Correspondence: CM Witt. E-mail: claudia.witt@charite.de

## Abstract

**Design** Prospective multicentre observational study.**Objective** To evaluate details and effects of homeopathic treatment in patients with psoriasis in usual medical care.**Methods** Primary care patients were evaluated over 2 years using standardized questionnaires, recording diagnoses and complaints severity, health-related quality of life (QoL), medical history, consultations, all treatments, and use of other health services.**Results** Forty-five physicians treated 82 adults, 51.2% women, aged  $41.6 \pm 12.2$  (mean  $\pm$  SD) years. Patients had psoriasis for  $14.7 \pm 11.9$  years; 96.3% had been treated before. Initial case taking took  $127 \pm 47$  min. The  $7.4 \pm 7.4$  subsequent consultations (duration:  $19.4 \pm 10.5$  min) cumulated to  $169.0 \pm 138.8$  min. Patients received  $6.0 \pm 4.9$  homeopathic prescriptions. Diagnoses and complaints severity improved markedly with large effect sizes (Cohen's  $d = 1.02$ – $2.09$ ). In addition, QoL improved (SF-36 physical component score  $d = 0.26$ , mental component score  $d = 0.49$ ), while conventional treatment and health service use were considerably reduced.**Conclusions** Under classical homeopathic treatment, patients with psoriasis improved in symptoms and QoL.

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## Keywords

homeopathy, prospective observational study, psoriasis, usual care, utilisation

## Conflicts of interest

None declared.

## Introduction

Psoriasis is currently understood as an immune system disturbance with inflammatory skin manifestation.<sup>1</sup> It affects around 1.5–2.0% of the population in industrialized countries<sup>2</sup> (Germany: 2–3%).<sup>3</sup> Chronicity and lack of causal therapies lead to permanence of physical and psycho-social suffering, increased costs, and frequent dissatisfaction with offered treatments.<sup>1,3,4</sup> Comorbidity necessitates careful selection<sup>2,5</sup> from various treatment options that include topical applications, systemic therapies (prebiological, including phototherapies), and the recently introduced immunomodifying biologicals.<sup>2</sup> Treatment must be sustained to prevent rebounds, placing a burden of side-effects, toxicity, and possible long-term risks<sup>1,5</sup> on the patient. In situations like this, patients tend to look for alternative approaches such as homeopathy.<sup>6</sup> Unfortunately, the effectiveness of homeopathy in psoriasis treatment has not been researched so far.

Homeopathy is practiced in many regions of the world,<sup>7</sup> especially in high-income countries where it ranks the most popular among traditional, complementary, or alternative medicines.<sup>7–9</sup> According to its 'rule of similarity', patients are treated with a

remedy that in a healthy proband has caused similar symptoms. A diagnosis can be treated with different remedies in different patients ('individualization'), depending on varying side symptoms. Homeopathic drugs ('remedies') are produced by alternating steps of diluting and agitating a starting substance; the resulting 'potencies' quickly reach dilutions beyond Avogadro's number. Such 'high potencies' are often prescribed; their effects constitute a subject of scientific controversy.<sup>10</sup> Meta-analyses of placebo-controlled studies have shown inconsistent results.<sup>11,12</sup>

To establish data on use and effects of homeopathy under conditions of usual care, we investigated 3981 patients in a prospective observational study.<sup>13–15</sup> This paper presents the subgroup of 82 adults consulting a homeopathic physician because of psoriasis.

## Methods

In this prospective multicentre observational study, patients were included consecutively upon their first consultation with a participating physician and followed up for 24 months using standardized questionnaires. This paper analyses the adults

( $\geq 17$  years old) suffering from psoriasis (ICD-9: 696.1, ICD-10: L40.0). Study physicians were required to have passed certified training in classical homeopathy and  $\geq 3$  years of experience in its practice (see Witt *et al.*<sup>14</sup> for details of recruitment). Written informed consent and approval by ethics review boards were obtained.

Before treatment (at baseline), patients independently from their physicians recorded the complaints that instigated homeopathic treatment, and rated their severity on a numeric rating scale (NRS; 0 = no complaints, 10 = maximum severity).<sup>16</sup> Health-related quality of life (QoL) was recorded with the MOS SF-36.<sup>17</sup>

The first questionnaires were handed out by study physicians and completed before treatment. Patients sent them in sealed envelopes directly to the study office, from where they received follow-up questionnaires at 3, 12, and 24 months, with every complaint being transferred to the follow-up questionnaires to ensure continuous assessment.

At the same times (0, 3, 12 and 24 months), the participating physicians recorded up to four diagnoses per patient and assessed their severity on identical NRSs. On a continuous basis, they recorded the homeopathic treatment, use of any conventional therapy, and all referrals.

As outcome measures, we defined the following: severity of the psoriasis diagnosis, mean severity of all baseline diagnoses (physician assessment), mean severity of all complaints (patient assessment), and QoL scores. Statistical analysis (using SAS/STAT<sup>®</sup> v8.2 software) followed the intention-to-treat approach: every included patient entered final analyses. We replaced missing values as follows: cured complaints: severity = 0 in subsequent records; deceased patients: severity = 10. The remaining missing values were multiply imputed according to Rubin:<sup>18</sup> each was given several plausible values (drawn from a multivariate normal distribution), generating a total of five distinct complete data tables, each without any missing value. These were analysed separately (see below), and the results pooled to calculate treatment effects and *P*-values.

For each imputed data set, treatment effects were estimated on the basis of a generalized multiple linear regression model: in complete analogy to the recommendations by Diggle *et al.*,<sup>19</sup> we assumed the treatment course to be mixed of a piecewise linear part (0–3 months and 3–24 months) and a quadratic term (starting at month 3). The serial correlation was assumed to be exponential with time. Effect sizes were calculated by dividing treatment effects as estimated above by baseline standard deviations (Cohen's *d*). They were classified: as  $|d| > 0.8$ , large;  $|d| > 0.5$ , medium;  $|d| > 0.2$ , small.

Usually, patients seek treatment when their health is out of average (such as severe pain, low QoL, etc.). A natural alleviation of their diseases (regression to the mean) can be mistaken for an effect of the beginning treatment.<sup>20</sup> Separating regression to the mean from treatment effects requires the mean of the target population to be known or plausibly assumed. For the QoL, we applied Mee and Chua's test<sup>21</sup> under the assumption that the patients had the same QoL as the general German population.<sup>17</sup>

## Results

We included 82 patients in the present analysis (Table 1), who were treated by 45 physicians. Almost all diagnoses made at baseline were chronic diseases that usually had been under – mostly conventional – treatment before (Tables 1 and 2) and had lasted for 2.8–28.1 years (Table 2).

The recorded consultations followed a pattern of 1 extensive initial consultation (Table 3), followed by analysis of the case. All but one patient received the first remedy on the same day. The subsequent consultations, about half of them telephone calls, were much shorter (Table 3). The last homeopathic medication was recorded after  $12.0 \pm 9.5$ , the last consultation after  $15.4 \pm 10.6$  months. About 30% of the patients continued homeopathic care at study end (Table 3).

**Table 1** Demographics and baseline status

POPULATION	
Patients	82
Female	51.2% (42)
Age (years)	41.6 $\pm$ 12.2
$\geq 10$ Years School	43.9% (36)
Patient expected: homeopathy ... (% , N)	
– Will Help	62.2% (51)
– Will Maybe Help	35.4% (29)
– Will Not Help	2.4% (2)
Baseline diagnoses	
Total, number	2.9 $\pm$ 1.1
– Severity (NRS)	5.6 $\pm$ 1.6
Chronic, number	2.8 $\pm$ 1.1
Any baseline diagnosis pretreated (% , N)	
Any Treatment	96.3% (78)
Medication*	81.5% (66)
Surgery	24.7% (20)
Other	64.2% (52)

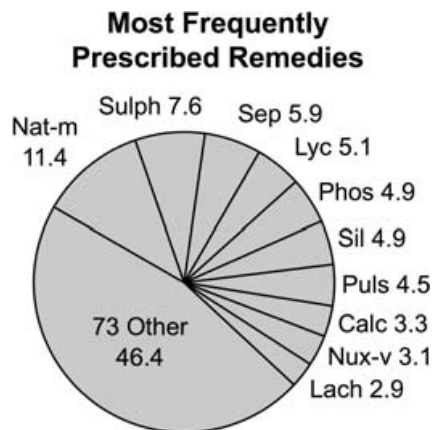
Demographics and Baseline Status: NRS: 10 = maximum, 0 = cured.

\*Excluding homeopathy.

**Table 2** Baseline diagnoses

	ICD-10 Code	Patients (% & N)	Severity (NRS)	Duration (Years)
Psoriasis	L40.9	100.0% (82)	4.9 $\pm$ 2.2	14.7 $\pm$ 11.9
Migraine	G43.9	11.0% (9)	5.9 $\pm$ 2.6	17.8 $\pm$ 11.4
Allergic rhinitis	J30.4	9.8% (8)	5.1 $\pm$ 2.4	28.1 $\pm$ 7.9
Psoriatic arthropathy	L40.5	7.3% (6)	6.7 $\pm$ 1.6	4.3 $\pm$ 2.2
Hypertension	I10.0	6.1% (5)	5.8 $\pm$ 1.3	8.4 $\pm$ 5.7
Chronic sinusitis	J32.9	6.1% (5)	5.2 $\pm$ 1.3	14.3 $\pm$ 12.6
Allergy	T78.4	4.9% (4)	6.8 $\pm$ 2.2	14.8 $\pm$ 11.3
Dermatitis	L30.9	4.9% (4)	6.8 $\pm$ 2.9	2.8 $\pm$ 1.9

Baseline Diagnoses: NRS: 10 = maximum, 0 = cured. Only diagnoses seen in  $\geq 4\%$  of the patients.



**Figure 1 Remedies.** Most Frequently Prescribed Homeopathic Remedies. Percent of prescriptions during study period, remedies identified with traditional abbreviations.

**Table 3** Consultations and continuance

Consultations (Mean ± SD)	
1st Consultation (min)	127 ± 47
Case analysis (min)	43 ± 59
Follow-ups, number, All	7.4 ± 7.4
– Telephone	3.0 ± 5.2
– Practice	3.5 ± 4.4
FUs Duration (min), All	19.4 ± 10.5
– Telephone	6.8 ± 4.9
– Practice	28.4 ± 15.7
FUs Cumulated (min), All	169.0 ± 138.8
– Telephone	38.8 ± 53.4
– Practice	141.0 ± 123.4
Last Consultation (Month)	15.4 ± 10.6
<b>Homeopathy at study end</b>	
Treatment ongoing	28.0% (23)
Changed homeopath	1.2% (1)
Currently not treated	30.5% (25)
<b>Treatment ended because of:</b>	
– Cure or amelioration	11.0% (9)
– Reason outcome-unrelated	7.3% (6)
– No effect or aggravation	14.6% (12)
– Not stated reason	0.0% (0)
No answer to treatment status	7.3% (6)

Consultations and continuance of homeopathic treatment at study end.

Over the course of the study the patients had received  $6.0 \pm 4.9$  homeopathic prescriptions. More than half of all prescriptions were covered by 10 homeopathic remedies (Fig. 1), but in total, 83 remedies were applied. The most used potencies were as follows: c200 (29.0%), c1000 (15.9%), c30 (12.7%), c10000 (6.3%), q3 (6.1%), q1 (5.5%), q6 (3.3%), and d12 (2.5%).

The strongest improvement of diagnoses and medical complaints was seen in the first 3 months; it continued during the full observation period (Tables 4 and 5). Psoriasis improved slower than the means of all diagnoses and complaints (Tables 4 and 5).

Physicians' severity assessments tended to be more positive than patients' assessments; still, all changes since baseline were of large effect size (1.02–2.09). The health-related QoL improved similarly, but with smaller effect sizes (physical component score: 0.26, mental component score: 0.49), and mostly in the first 3 months (Tables 4 and 5). Mee-Chua tests for the SF-36 physical component score confirmed a treatment effect after 3, 12, and 24 months ( $P = 0.0014$ ,  $P < 0.0001$ , and  $P = 0.0029$ , respectively). The results for the mental component score reached significance only after 3 months ( $P = 0.0045$ ,  $P = 0.8244$ , and  $P = 0.0899$ , respectively).

After 24 months, the psoriasis as well as the other baseline diagnoses were considerably relieved (Table 6), while large reductions in use of conventional medicines and health care services were observed (Table 7).

## Discussion

This prospective multicentre observational study was aimed to give an unbiased representation of contemporary homeopathic health care and its outcome in 82 adult psoriasis patients. Assessments of disease severity and health-related QoL consistently showed substantial improvements, although the disease was long-standing, chronic and conventionally pretreated. Similarly, all accompanying diseases (almost all chronic) were markedly ameliorated. The major improvements were seen within the first 3 months of homeopathic treatment, after 12 months ratings were less than half of baseline and continued to improve. Accordingly, QoL increased, and uses of health care services or conventional medication decreased markedly.

The methodological strengths of our study include the consecutive patient enrolment, the participation of about 1% of all certified homeopathic physicians in Germany (14% of the members of an organization for physicians practicing 'classical' homeopathy, the Hahnemann Association), and use of standardized outcome instruments. For quality assurance purposes, we avoided selecting a random sample of homeopathic physicians, choosing instead to recruit physicians schooled and certified in 'classical' homeopathy. Our results are therefore representative only for the classical type of homeopathy. In contrast to randomised trials, our study describes patients from everyday practice with multiple morbidities and a large variety of life styles. This ensures a high degree of external validity that allows extrapolation to usual medical care.

Our study was designed to evaluate homeopathic treatment in patients suffering from various diagnoses. This disallowed the use of disease-specific measurement instruments. Instead, we used a numeric rating scale that is validated, often used<sup>16</sup> and allowed for assessments of a specific complaint as well as for generalization and interpretation across various diagnoses. Using generic QoL questionnaires served the same purpose.

Table 4 Diagnoses, complaints, QoL (estimated means and 95% confidence intervals from the statistical model)

Severity, NRS	STATUS (95% CI)			CHANGE (95% CI)			
	Month 0	Month 3	Month 12	Month 24	Months 0-3	Months 0-12	Months 0-24
Psoriasis†	4.88 (4.36; 5.39)	4.16 (3.65; 4.67)	3.35 (2.84; 3.86)	2.65 (2.14; 3.16)	-0.72** (-1.15; -0.29)	-1.53 (-2.08; -0.97)	-2.23 (-2.85; -1.61)
All Diagnoses (Mean)‡	5.57 (5.18; 5.96)	4.03 (3.64; 4.41)	3.18 (2.79; 3.56)	2.25 (1.87; 2.64)	-1.54 (-1.84; -1.25)	-2.39 (-2.78; -2.01)	-3.32 (-3.75; -2.88)
All Complaints (Mean)‡	5.91 (5.44; 6.38)	4.04 (3.50; 4.57)	3.48 (3.07; 3.90)	3.01 (2.60; 3.42)	-1.87 (-2.55; -1.19)	-2.42 (-3.04; -1.81)	-2.90 (-3.52; -2.26)
QoL, SF-36†							
Physical component Score	47.38 (44.10; 50.67)	50.82 (47.47; 54.16)	52.06 (48.85; 55.28)	51.36 (48.18; 54.54)	3.43 (1.83; 5.03)	4.68 (2.13; 7.23)	3.98* (0.67; 7.28)
Mental component Score	40.67 (37.79; 43.56)	46.80 (43.74; 49.87)	44.47 (41.74; 47.21)	47.43 (44.75; 50.10)	6.13 (3.78; 8.49)	3.80* (0.58; 7.02)	6.76 (3.02; 10.50)

Diagnoses, Complaints, QoL (Estimated Means and 95% Confidence Intervals from the Statistical Model); NRS: 10 = maximum, 0 = cured. QoL: higher values = better. 95% CI, 95% confidence interval.  
 †Patients' answers, ‡physicians' answers. \* $P < 0.05$ , \*\* $P < 0.01$  – All other changes  $P < 0.001$ .

As a general observation, especially for industrialized countries, homeopathic patients tend to be younger and better educated than conventional patients, of higher socioeconomic status, and more often female.<sup>22</sup> These factors could be indicative for a health-awareness above average and an inclination to self-treatment for lesser ailments.<sup>23</sup> As a result, chronic diseases were strongly predominant in our study, as was seen in other observations.<sup>23-27</sup> Additionally, waiting lists of sometimes several months would preclude the shorter periods of acute illnesses, and the reputation of homeopathy as a 'medicine for the whole person' (reflected in the extensive initial case taking) may cause a self-selection of patients seeking more than a quick fix for a single issue.

Besides psoriasis, the baseline diagnoses migraine, hayfever, hypertension, and arthritis were also observed among the most frequent in other homeopathic observation studies.<sup>26,28</sup> So was the long duration of the diseases.<sup>24,28,29</sup> The latter and the high rate of pretreated patients might indicate that patients turn to homeopathy after finding conventional care not satisfactory for their conditions. In comparison to (hypothetical) conventional practices, the patients in our study are likely to suffer from more severe cases of their diseases and see the homeopath in later stages of them; possibly, they may have a more critical or demanding attitude towards health care providers.

The cost-effectiveness of an early-referral strategy has not been thoroughly investigated so far.<sup>30,31</sup> The duration of homeopathic follow-up consultations is clearly longer than the  $7.6 \pm 4.3$  min of a German GP consultation,<sup>32</sup> but might be compensated by their low frequency; conventional consultations take place about 24 times in 24 months with a resulting doctor workload of about 190 min in 2 years<sup>33</sup> (all: per patient).

Our study focused on the widespread individualizing ('classical') homeopathy and did not evaluate other types of homeopathy. In a broader interpretation of the rule of similars, remedies were selected for symptoms both typical of the diagnoses and outside the predominating pathologies ('constitutional'). The broad variety of chosen remedies and the similar frequencies of the leading remedies in psoriasis treatment (Fig. 1) and the overall observational study<sup>13</sup> support this impression. The frequent use of high potencies is also typical for this line of homeopathy.

The effect size of the severity ratings after 12 and 24 months was large. This may be partly explained by placebo and/or regression to the mean effects that our study was not designed to control (effect sizes in between-group comparisons are usually smaller). We also cannot rule out overestimation of the treatment effect. The QoL improvements, on the other hand, may have been greater than recorded: The SF-36 is unlikely to overestimate changes; its mental scales have even been found to be less sensitive than the mental and social scales of other instruments such as the Duke Health Profile.<sup>24</sup> We assume that diagnosis-specific tools that also measure the large psycho-social part in psoriasis suffering would report much greater effects. The already observed QoL improvements are almost impossibly caused by regression toward

**Table 5** Effect size of changes in diagnoses, complaints, and quality of life

	EFFECT SIZE (95% CI)		
	Months 0–3	Months 0–12	Months 0–24
<b>Severity, NRS</b>			
<b>Psoriasis‡</b>	0.33** (0.53; 0.13)	0.70 (0.95; 0.44)	1.02 (1.30; 0.74)
<b>All Diagnoses (Mean)‡</b>	0.97 (1.16; 0.79)	1.51 (1.75; 1.27)	2.09 (2.37; 1.82)
<b>All Complaints (Mean)†</b>	1.00 (1.37; 0.64)	1.30 (1.63; 0.97)	1.56 (1.89; 1.22)
<b>QoL, SF-36†</b>			
<b>Physical component Score</b>	0.23 (0.12; 0.33)	0.31 (0.14; 0.48)	0.26* (0.04; 0.48)
<b>Mental component Score</b>	0.45 (0.28; 0.62)	0.28* (0.04; 0.51)	0.49 (0.22; 0.77)

Effect Size of Changes in Diagnoses, Complaints, and QoL. NRS, negative change = improvement. Quality of life: positive change = improvement. Absolute effect size > 0.8 large, > 0.5 medium, > 0.2 small. 95% CI, 95% confidence interval. †Patients' answers, ‡physicians' answers. \* $P < 0.05$ , \*\* $P < 0.01$  – All other  $P < 0.001$ .

**Table 6** Response rates at study end

<b>Responders, psoriasis (patients, %, and N)</b>	
<b>Fully cured</b>	12.2% (10)
<b>Better by ≥ 50% Baseline</b>	12.2% (10)
<b>Better by ≥ 10% ... &lt; 50%</b>	11.0% (9)
<b>Change within ±10%</b>	7.3% (6)
<b>Worse &gt; 10%</b>	2.4% (2)
<b>Responders, all baseline diagnoses (diagnoses, %, and N)</b>	
<b>Total number of diagnoses</b>	153
<b>Fully Cured</b>	32.0% (49)
<b>Better by ≥ 50% Baseline</b>	23.5% (36)
<b>Better by ≥ 10% ... &lt; 50%</b>	9.2% (14)
<b>Change within ±10%</b>	8.5% (13)
<b>Worse &gt; 10%</b>	2.6% (4)

Response rates at study end.

the mean. They were significantly greater than could be expected, and assuming chronically ill patients with often several severe diseases to have the same QoL as the general German population was itself an extremely conservative approach. Moreover, patients received homeopathic treatment after years of other treatment and a waiting period – regression toward the mean would long have faded out by then. Our QoL improvements were much greater

than in an observational study on 933 homeopathy patients,<sup>34</sup> where about three fourths of diagnoses existed for > 6 months and 30% were severe. SF-36 effect sizes (stable after 6 months) were small and medium; Cohen's *d* ranged from 0.24 to 0.79. The reason for this difference is unclear. Diagnosis-specific results were not published, but overall health improved while lost workdays receded.

Our study does not support conclusions as to the effectiveness of the homeopathic remedies because no methodology for this purpose (control group, randomization, blinding) was built into its design and patients could use additional conventional therapies. The aim of the investigation – to provide systematic and detailed information about status and effects of homeopathic medical care in routine medical practice – was fully met. These data may also be helpful in the planning of further research projects on homeopathy. It would require specific instruments [Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), Dermatology Quality of Life Scales (DQOLS)] for more detailed assessment and effect size comparability, and a longer observation period than the quasi-standard of 12 weeks for PASI, as a slow but sustained improvement is to be expected (a 7-year follow-up of our study is in preparation).

The reduction in conventional or alternative medication and treatments also may not be due to the homeopathic remedies alone.

**Table 7** Use of other treatment and health care services

	Baseline % (n)	3 Months % (n)	12 Months % (n)	24 Months % (n)
<b>Patients using conventional drugs†</b>				
<b>ATC-Class D – Dermatologicals</b>	7.3% (6)	4.9% (4)	1.2% (1)	2.4% (2)
	Baseline	0–3 months	> 3–12 months	> 12–24 months
<b>Patients consulting other health care providers†</b>				
<b>Any Physician*</b>	96.3% (79)	35.4% (29)	65.9% (54)	80.5% (66)
<b>Dermatologist</b>	74.4% (61)	4.9% (4)	14.6% (12)	28.0% (23)
<b>CAM Treatments*</b>	15.9% (13)	3.7% (3)	7.3% (6)	8.5% (7)

Use of Other Treatment and Health Care Services. Data related to psoriasis only; \*including all diagnoses and routine checks (e.g., dentist, gynecologist). Multiple Answers possible. †Patients' answers.

Homeopathic physicians are known to use conventional means with a certain hesitation, thus functioning as a kind of 'gatekeeper'.

Research on homeopathic treatment of psoriasis is scarce. One publication describes two cases suffering from psoriasis since 10 and 20 years improving after homeopathic treatment;<sup>35</sup> two other anecdotal reports used unpotentized applications and claim good results.<sup>36,37</sup>

## Conclusions

The patients with psoriasis in our study suffered additionally from other pretreated complaints of long duration. Under homeopathic treatment, the severity of psoriasis and accompanying diseases, as well as QoL improved substantially and the uses of conventional medication and health services decreased markedly.

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