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ORIGINAL ARTICLE

Homeopathic treatment of patients with dysmenorrhea: a prospective observational study with 2 years follow-up

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Abstract
Purpose Evaluating homeopathic treatment for dysmenorrhea.
Methods Prospective multicenter observational study in primary care, using standardized questionnaires to record for 2 years diseases, quality of life, medical history, consultations, all treatments, other health services use.
Results Fifty-seven physicians treated 128 women (age 32.4 ± 7.5 years, mean ± SD) and 11 girls (13.7 ± 4.0). Women had dysmenorrhea for 11.6 ± 9.0 (girls 3.1 ± 1.5) years. Patients received 7.5 ± 6.5 (5.9 ± 3.7) homeopathic prescriptions. Diagnoses and complaints severity improved markedly [at 24 months, dysmenorrhea relieved by > 50% of baseline rating in 46.1% (59) of the women and 45.5% (5) of the girls] with large effect sizes (24 months: Cohen's d from 1.18 to 2.93). In addition, QoL improved (24 months: SF-36 physical component score: 0.25, mental component score 0.25, KINDL sum score 0.27). Conventional medication changed little and use of other health services decreased.
Conclusions Patients with dysmenorrhea improved under homeopathic treatment. Controlled studies should investigate efficacy and effectiveness.

Keywords Dysmenorrhea · Homeopathy in usual care · Prospective observational study

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Abbreviations

WHO	World Health Organization
ICD	International Classification of Diseases
NRS	Numerical rating scale
QoL	Health-related quality-of-life
MOS SF-36	Medical outcomes trust 36-item short form survey instrument
KINDL	KINDer Lebensqualitätsfragebogen
C*n*	*n*th centesimal potency
Q*n*	*n*th quinquagintamillesimal potency
GP	General practitioner
RCT	Randomized controlled trial

Introduction

Dysmenorrhea, either primary without associated organic disease or secondary, is the most frequent gynecological problem. With a high prevalence (18–81%, depending on definition and the used survey method) [1] it causes considerable activity limitations and absenteeism from school or work [2]. The production of uterine prostaglandins that stimulate the contraction of the myometrium and cause ischemia receive increasing attention for their role in its pathogenesis in primary and secondary dysmenorrhea, but other mechanisms can also be causative for the latter [2]. Treatment options depend on causes; they include simple analgesics, NSAIDs, COX2 inhibitors (withdrawn in many countries), contraceptive hormones, levonorgestrel, and surgery. Varying degrees of therapeutic effectiveness as well as side effects cause patients to stop seeking medical help. Generally, dysmenorrhea has been seen as "underdiagnosed and undertreated." [1, 2] The available complementary therapies are often insufficiently researched [2], however, acupuncture is often successfully used in usual

care and was found to be clinically effective and cost-effective [3]. Patients also use homeopathy, but no research has focused yet on its effectiveness.

Homeopathy is practiced in many regions of the world [4], especially in high-income countries where it ranks the most popular among traditional, complementary, or alternative medicines [4–6]. In Germany, it is used in 83% of hospital-associated clinics for gynecology or obstetrics [7]. 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' may reach dilutions beyond Avogadro's number where the probability of even one molecule of the starting substance being present approaches zero. Such 'high potencies' are often used, however, their effects constitute a subject of scientific controversy [8]. Meta-analyses of placebo controlled trials (pooling a great variety of diseases and ailments) have shown inconsistent results [9, 10].

We did a first step and globally evaluated use and effects of homeopathy under the conditions of usual care. For this, we followed 3,981 patients over 2 years in a prospective observational study [11–13]. This paper presents the subgroup of 139 patients consulting a homeopathic physician because of dysmenorrhea of any etiology.

Methods

In this prospective multi-center observational study, patients were included consecutively upon their first consultation with a participating physician (almost all located in Germany and some in Switzerland, about 1% of all certified homeopathic physicians in Germany), regardless of prior homeopathic treatment elsewhere, or of any other criteria than age (>1 year) and informed consent. They were followed up for 24 months using standardized questionnaires. This paper analyses the patients suffering from dysmenorrhea (ICD-9: 625.3, ICD-10: N94.6, "painful menstruation" [14]). Study physicians were required to have passed certified training in classical homeopathy and ≥ 3 years of experience in its practice (details of recruitment [12]). 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, cured; 10, maximum severity) [15]. For girls (≤ 16 years), the parents provided medical information and severity ratings. The health-related quality-of-life (QoL) was recorded with the MOS SF-36 [16] (women, ≥17 years), and the KINDL [17, 18] (girls aged 7–16 years) questionnaires.

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 NRS. On a continuous basis, they recorded the homeopathic treatment (which was mostly following the 'classical' homeopathy style, see discussion), use of any conventional therapy, and all referrals.

As outcome measures, we defined: the severity of the pain due to dysmenorrhea, mean severity of all baseline diagnoses (pooled physician assessment), mean severity of all complaints (pooled patient assessment), and QoL scores. Statistical analysis (using SAS/STAT© 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 [19]. Each was given five distinct, but plausible values, based on correlations with non-missing values and reflecting the overall variability of data. This generated a total of five distinct complete data tables, each without any missing value. These were analyzed 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. [20] 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*). Their absolute values were classified: as $|d| > 0.8$, large; $0.8 \geq |d| > 0.5$, medium; $0.5 \geq |d| > 0.2$, small; $|d| \leq 0.2$ clinically not relevant. To test whether the QoL changes are regression to the mean effects, we applied Mee and Chua′s test [21] under the assumption that the patients had the same QoL as the general German population [16].

Results

We included 139 patients in the present analysis (Table 1), who were treated by 57 physicians (all in Germany except 5 patients of 3 Swiss physicians). Among them were 11 girls (7–16 years) whose QoL was evaluated with the KINDL

Table 1 Demographics and baseline status

	Women	Girls
Sample		
Patients	128	11
Age (years)[a]	32.4 ± 7.5	13.7 ± 4.0
≥10 years School	69.5% (89)	–/–
Patient expected: homeopathy (%, *n*)		
Will help	71.1% (91)	72.7% (8)
Will maybe help	28.1% (36)	27.3% (3)
Will not help	0.8% (1)	0% (0)
Baseline diagnoses		
Total, number[a]	3.3 ± 0.8	3.1 ± 0.9
Severity (NRS)[a]	6.2 ± 1.5	5.4 ± 1.3
Chronic, number[a]	3.2 ± 0.8	3.1 ± 0.9
Any baseline diagnosis pretreated (%, *n*)		
Any treatment[b]	94.5% (121)	90.9% (10)
Medication	78.9% (101)	72.7% (8)
Surgery	21.9% (28)	9.1% (1)
Other	55.5% (71)	54.5% (6)

NRS numerical rating scale: 10 maximum, 0 cured

[a] Mean ± SD

[b] Excluding homeopathy

questionnaire. All patients suffered from dysmenorrhea that had lasted for 11.6 ± 9.0 (mean ± SD) years (women) and 3.1 ± 1.5 years (girls) (Table 1). Almost all accompanying diagnoses assessed at baseline were chronic diseases that usually had been under—mostly conventional—treatment before (Tables 1, 2), the most frequently recorded had lasted for at least 4.5 years in women and 3.1 years in girls (Table 2).

The consultations consisted of an extensive initial consultation (Table 3), followed by the analysis of the case. Almost all patients received the first remedy on the same day; administration to one woman each was delayed ≤1 week and ≤1 month, to 1 girl > 1 month. The subsequent consultations (8.4 ± 8.2 by women, 6.9 ± 5.8 by girls), about half of them telephone calls (3.9 ± 5.4 and 2.9 ± 2.9), were much shorter (Table 3). The last homeopathic medication was recorded for women after on average 13.7 ± 10.5 and for girls after 14.5 ± 10.5 months. The majority of patients (54% of the women, 63.7% of the girls) continued homeopathic care at study end (Table 3) or had suspended it temporarily.

Over the course of the study, the women had received on average 7.5 ± 6.5 homeopathic prescriptions, the girls 5.9 ± 3.7.

The most frequent prescribed remedies in all patients were (identified with traditional abbreviations): sep 14.1%; nat-m 6.7%; puls 6.6%; phos 5.3%; calc 5.1%; sulph 5.1%; nux-v 4.5%; lyc3.9%; sil 2.8%; carc 2.7%. This means that more than half of all prescriptions were covered by 10 homeopathic remedies, but in total, 108 different remedies were applied in women, 26 remedies in girls, which supports the claim of individualized prescriptions in homeopathy. The most used potencies in all patients were: c200 (35.0%), c1000 (25.8%), c30 (12.4%), c10000 (8.7%), d12 (3.0%), q6 (2.5%), q1 (2.1%), and c12 (1.9%). In total, 89.4% of the used potencies implied a dilution above Avogadro's number.

Table 2 Baseline diagnoses

	ICD-10 code	Patients (%, *n*)	Severity (NRS)	Duration (years)
Women				
Dysmenorrhea	N94.6	100.0% (128)	6.5 ± 1.8	11.6 ± 9.0
Headache	R51	14.1% (18)	5.6 ± 1.5	7.8 ± 6.5
Frequent infections	R68.8	9.4% (12)	6.1 ± 1.7	7.6 ± 8.2
Chronic sinusitis	J32.9	7.8% (10)	7.0 ± 1.4	12.6 ± 11.5
Premenstrual tension	N94.3	7.8% (10)	7.1 ± 1.6	12.4 ± 8.1
Dermatitis	L30.9	7.8% (10)	4.9 ± 1.9	5.9 ± 7.6
Migraine	G43.9	7.8% (10)	6.7 ± 2.0	14.6 ± 9.9
Allergy	T78.4	7.0% (9)	6.9 ± 2.3	10.5 ± 9.3
Sleep disturbance	G47.9	6.3% (8)	7.0 ± 2.1	5.4 ± 5.4
Chronic rhinitis	J31.0	5.5% (7)	6.0 ± 2.2	4.5 ± 2.5
Girls				
Dysmenorrhea	N94.6	100.0% (11)	6.0 ± 1.8	3.1 ± 1.5
Headache	R51	27.3% (3)	5.0 ± 3.0	3.0 ± 1.7
Frequent infections	R68.8	18.2% (2)	4.0 ± 1.4	5.5 ± 4.9

NRS numerical rating scale: 10 maximum, 0 cured. Only diagnoses seen in ≥5% of the women or ≥2 girls

Table 3 Consultations and continuance of homeopathic treatment at study end

	Women	Girls
Consultations (mean ± SD)		
1st consultation (min)	116 ± 40	124 ± 27
Case analysis (min)	43 ± 41	31 ± 27
Follow-ups number, all	8.4 ± 8.2	6.9 ± 5.8
Telephone	3.9 ± 5.4	2.9 ± 2.9
Practice	4.1 ± 5.2	4.0 ± 3.9
FUs duration (min), all	20.1 ± 15.0	17.2 ± 6.0
Telephone	7.5 ± 4.8	6.6 ± 3.4
Practice	29.5 ± 14.7	24.8 ± 7.6
FUs cumulated (min), all	190.6 ± 176.4	121.3 ± 82.5
Telephone	45.3 ± 73.0	24.1 ± 17.3
Practice	162.9 ± 160.9	102.0 ± 81.6
Last consultation (month)	15.6 ± 9.5	17.2 ± 9.8
Homeopathy at study end		
Treatment ongoing	35.2% (45)	36.4% (4)
Changed homeopath	0.8% (1)	0% (0)
Currently not treated	18.0% (23)	27.3% (3)
Treatment ended because of		
Cure or amelioration	3.1% (4)	0.0% (0)
Reason outcome-unrelated	3.9% (5)	0.0% (0)
No effect or aggravation	21.1% (27)	18.2% (2)
Not stated reason	1.6% (2)	0.0% (0)
No answer to treatment status	16.4% (21)	18.2% (2)

The strongest improvement of the severity of diagnoses and medical complaints was seen in the first 3 months, it generally continued during the full observation period (Tables 4, 5), only dysmenorrhea in girls temporarily relapsed during months 4–12. Physicians' severity assessments tended to be more positive than patients' assessments. All severity changes since baseline were of large effect size (at 24 months 1.18–2.93), whereas improvements in health-related QoL were small or medium (at 24 months SF-36 physical component score 0.25, mental component score 0.52, KINDL 0.27). Mee–Chua tests for the SF-36 confirmed a treatment effect for physical component score after 12 and 24 months (0.0088, and 0.0017, at 3 months $P = 0.0635$), and for the mental component score after 3 months ($P = 0.0417$, after 12 and 24 months 0.5650 and 0.4061).

After 24 months, the dysmenorrhea was relieved by > 50% of the baseline rating in 46.1% (59) of the women and 45.5% (5) of the girls and the other baseline diagnoses were considerably relieved (Table 6). Conventional medication changed little, and the use of health-care services decreased (Table 7).

Discussion

This prospective multicenter observational study was aimed to give an unbiased representation of contemporary homeopathic health care and its outcome in 128 dysmenorrhea patients. Assessments of disease severity and health-related quality-of-life (QoL) consistently showed substantial improvements, although the disease was long-standing, chronic, and conventionally treated. Similarly, all accompanying diseases (almost all chronic) (Table 2) were markedly ameliorated. The major improvements were seen within the first 3 months of homeopathic treatment. QoL increased with the severity improvements, conventional medication changed little, and the use of health-care services decreased.

The methodological strengths of our study include the consecutive patient enrollment and the use of standardized outcome instruments. The participation of about 1% of all certified homeopathic physicians in Germany (=14% of the members of an association for physicians practicing 'classical' homeopathy, the Hahnemann Association) in the main study makes the study and the subgroup presented in this paper a representative sample for contemporary homeopathic practice. For quality assurance purposes, we avoided selecting a random sample of homeopathic physicians, choosing instead to recruit physicians trained and certified in 'classical' homeopathy. Our results are, therefore, representative only for the classical type of homeopathy, which is the type of homeopathy that is accepted and certified by the German Medical Association. In contrast to randomized 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 a more complex disease-specific measurement instrument. We used a numeric rating scale which is validated, often used [15] and accepted to measure pain. In addition, we used generic QoL questionnaires.

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 [22]. These factors could be indicative for a health-awareness above average and an inclination to self-treatment for lesser ailments [23]. As a result, accompanying chronic diseases were strongly predominant in our study, as was seen in other observations [23–27]. 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

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

		Status (95% CI)				Change (95% CI)		
		Month 0	Month 3	Month 12	Month 24	Months 0–3	Months 0–12	Months 0–24
Disease severity (NRS)								
Dysmenorrhea[a]	Women	6.51 (6.12; 6.89)	3.64 (3.26; 4.03)	2.58 (2.20; 2.97)	1.89 (1.50; 2.27)	−2.86*** (−3.23; −2.50)	−3.92*** (−4.38; −3.47)	−4.62*** (−5.12; −4.12)
	Girls	6.00 (3.89; 8.11)	3.64 (1.70; 5.57)	4.60 (2.66; 6.53)	1.72 (−0.22; 3.65)	−2.36* (−4.55; −0.17)	−1.40 (−3.96; 1.15)	−4.28** (−6.96; −1.61)
All diagnoses (mean)[a]	Women	6.19 (5.90; 6.48)	3.74 (3.45; 4.03)	2.50 (2.21; 2.79)	1.73 (1.44; 2.02)	−2.45*** (−2.72; −2.19)	−3.69*** (−4.02; −3.35)	−4.46*** (−4.82; −4.09
	Girls	5.37 (4.47; 6.28)	3.09 (2.26; 3.92)	3.24 (2.41; 4.07)	1.34 (0.51; 2.17)	−2.28*** (−3.19; −1.37)	−2.13** (−3.20; −1.06)	−4.03*** (−5.16; −2.90)
All complaints (mean)[b]	Women	6.39 (5.98; 6.80)	3.71 (3.27; 4.16)	3.48 (3.10; 3.87)	2.99 (2.62; 3.36)	−2.67*** (−3.11; −2.24)	−2.91*** (−3.43; −2.38)	−3.40*** (−3.95; −2.85)
	Girls	6.97 (4.56; 9.37)	2.46 (−0.34; 5.25)	4.07 (2.48; 5.67)	4.88 (2.84; 6.92)	−4.51* (−8.26; −0.76)	−2.89 (−5.69; −0.09)	−2.09 (−5.04; 0.87)
Quality of life[b]								
SF-36 Physical component score	Women	47.48 (45.29; 49.68)	48.97 (46.72; 51.21)	50.29 (48.13; 52.44)	50.60 (48.48; 52.71)	1.48* (0.27; 2.69)	2.80** (0.86; 4.74)	3.11* (0.68; 5.54)
Mental component score	Women	37.41 (35.06; 39.76)	43.89 (41.39; 46.38)	43.78 (41.53; 46.04)	44.06 (41.88; 46.23)	6.48*** (4.43; 8.53)	6.37*** (3.57; 9.17)	6.64*** (3.53; 9.76)
KINDL sum score	Girls	63.14 (56.00; 70.28)	65.70 (56.67; 74.72)	65.44 (60.05; 70.83)	65.68 (58.69; 72.66)	2.56 (−7.69; 12.80)	2.30 (−5.79; 10.40)	2.54 (−7.22; 12.30)

NRS numerical rating scale: 10 maximum, 0 cured. Quality of life: higher values = better; CI 95% = 95% confidence interval

[a] Physicians' answers

[b] Patients' answers

* $P < 0.05$

** $P < 0.01$

*** $P < 0.001$

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
Disease severity (NRS)			
Dysmenorrhea[a]			
Women	1.59*** (1.80; 1.39)	2.18*** (2.43; 1.93)	2.57*** (2.84; 2.29)
Girls	1.31* (2.53; 0.10)	0.78 (2.20; 0.64)	2.38** (3.87; 0.89)
All diagnoses (mean)[a]			
Women	1.61*** (1.79; 1.44)	2.43*** (2.64; 2.21)	2.93*** (3.17; 2.69)
Girls	1.50*** (2.10; 0.90)	1.40** (2.11; 0.70)	2.65*** (3.40; 1.91)
All complaints (mean)[b]			
Women	1.52*** (1.76; 1.27)	1.65*** (1.94; 1.35)	1.93*** (2.24; 1.61)
Girls	2.56* (4.68; 0.43)	1.64 (3.23; 0.05)	1.18 (2.86; 0.49)
Quality of life[b]			
SF-36 physical component score			
Women	0.12* (0.02; 0.22)	0.23** (0.07; 0.39)	0.25* (0.06; 0.45)
Mental component score			
Women	0.50*** (0.34; 0.66)	0.50*** (0.28; 0.71)	0.52*** (0.27; 0.76)
KINDL sum score			
Girls	0.27 (0.81; 1.35)	0.24 (0.61; 1.09)	0.27 (0.76; 1.29)

NRS numerical rating scale, negative change = improvement. Quality of life, positive change = improvement. Absolute effect size classes: $|d| > 0.8$, large; $0.8 \geq |d| > 0.5$, medium; $0.5 \geq |d| > 0.2$, small; $|d| \leq 0.2$ clinically not relevant. CI 95% = 95% confidence interval

[a] Physicians' answers

[b] Patients' answers

* $P < 0.05$

** $P < 0.01$

*** $P < 0.001$

Table 6 Response rates at study end

	Women	Girls
Responders, dysmenorrhea (patients, percent, *n*)		
Fully cured	24.2% (31)	27.3% (3)
Better by ≥ 50% baseline	21.9% (28)	18.2% (2)
Better by ≥ 10%… <50%	6.3% (8)	9.1% (1)
Change within ± 10%	1.6% (2)	0.0% (0)
Worse > 10%	1.6% (2)	0.0% (0)
Responders, all diagnoses (diagnoses, percent, *n*)		
Total	298	23
Fully cured	33.9% (101)	43.5% (10)
Better by ≥ 50% baseline	27.5% (82)	26.1% (6)
Better by ≥10%… <50%	8.7% (26)	4.3% (1)
Change within ±10%	4.4% (13)	0.0% (0)
Worse >10%	1.7% (5)	0.0% (0)

than a quick fix for a single issue. That other diagnoses besides dysmenorrhea were ameliorated as well in our patients supports the 'whole person' approach of the observed treatment. Besides dysmenorrhea, the patients suffered from headache/migraine, allergies, and eczema. Those diagnoses were also observed among the most frequent in other homeopathic observational studies [26, 28]. The long duration of the diseases was also observed in earlier studies [24, 28, 29].

The latter, and the high rate of previously treated 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 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 [30, 31]. The duration of homeopathic follow-up consultations is clearly longer than the 7.6 ± 4.3 min of a German GP consultation [32], but might be compensated by their low frequency. On average, conventional consultations take place about 24 times in 24 months per patient with a resulting doctor workload of about 190 min in 2 years [33].

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 dysmenorrhea treatment and the overall observational study [11] support this impression. The predominant use of high potencies is also typical for this line of homeopathy.

According to the predominant opinion in the homeopathic community, a longer period until a clear effect would become noticeable was to be expected. The 3-months improvements might include several aspects and could be influenced by changed life style, reduced conventional medications, or reflect context effects induced by expectations from the waiting list time, or the long and detailed

Table 7 Use of other treatment and health care services

	Baseline (%, *n*)	3 months (%, *n*)	12 months (%, *n*)	24 months (%, *n*)
Patients using conventional drugs[b]				
ATC-class G (genito-urinary system and sex hormones)				
Women	11.7 (15)	5.5 (7)	10.2 (13)	5.5% (7)
Girls	9.1 (1)	9.1 (1)	0.0 (0)	18.2% (2)
ATC-class H (systemic hormones)				
Women	12.5 (16)	12.5 (16)	14.1 (18)	11.7% (15)
Girls	0.0 (0)	0.0 (0)	0.0 (0)	0.0% (0)
Analgetics				
Women	8.6 (11)	7.0 (9)	7.8 (10)	8.6 (11)
Girls	9.1 (1)	9.1 (1)	9.1 (1)	9.1 (1)
	Baseline	0–3 months	>3–12 months	>12–24 months
Patients consulting other health-care providers[b]				
Any physician[a]				
Women	97.7% (125)	39.8% (51)	71.9% (92)	79.7% (102)
Girls	100.0% (11)	54.5% (6)	72.7% (8)	81.8% (9)
Gynecologist				
Women	62.5% (80)	19.5% (25)	43.8% (56)	51.6% (66)
Girls	36.4% (4)	9.1% (1)	27.3% (3)	45.5% (5)
CAM treatments[a]				
Women	21.1% (27)	3.1% (4)	6.3% (8)	10.2% (13)
Girls	45.5% (5)	0.0% (0)	9.1% (1)	18.2% (2)

Data related to dysmenorrhea only

[a] Data related to treatments for all diagnoses as well as routine checks (e.g., dentist, gynecologist)

[b] Patients' answers

Multiple answers possible

initial case taking. Future research should look into these (and other) contexts of the treatment, e.g., searching for correlations between time spent in consultations and the subsequently observable improvement, or vary consultation patterns systematically.

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 und social scales of other instruments such as the Duke Health Profile. [24] The version of KINDL that was available at study time has been updated by its authors since to correct its insensitivity to change [34]. We can only speculate that the new version would have reported much greater effects, as would a diagnosis-specific tool to measure the psycho-social part in dysmenorrhea suffering.

Usually, patients seek treatment when their health is out of average (such as severe pain, low QoL, and so on). A natural alleviation of their diseases (regression to the mean) can be mistaken for an effect of the beginning treatment [35]. Separating regression to the mean from treatment effects requires the mean of the target population to be known or plausibly assumed. The observed QoL improvements are unlikely to have been caused by regression toward 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. The reduction in conventional or alternative medication and treatments also may not be due to the homeopathic remedies alone. Homeopathic physicians are known to use conventional means with a certain hesitation, thus functioning as a kind of 'gatekeeper'.

Primary dysmenorrhea under homeopathy has not been researched so far. Studies on endometriosis mention its alleviation [36–38], but this area presents special challenges [39, 40]. A study on premenstrual tension syndrome [41] with 54.5% of the patients being permanently relieved by >70% of baseline severity and 36.4% by 30–70% (placebo 12.5 and 25%) does not mention dysmenorrhea explicitly.

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. Further research is clearly warranted to explore the effects of homeopathic care on dysmenorrhea of specific etiologies. It should include objective data, diagnosis-specific instruments, and specialized physicians should be involved. The aim of our study was to provide for the first time systematic and detailed information about status and effects of homeopathic medical care in routine medical practice. These data should build a good basis for the planning of further research projects on homeopathy, which could include specific instruments and control groups.

Conclusions

The patients in our study suffered from long-standing dysmenorrhea and other chronic diseases. Under homeopathic treatment the severity of the diseases and the QoL improved substantially, which supports the 'whole person' approach prevailing in contemporary homeopathy, and mostly in the first 3 months. The data represent a good basis for the planning of further research projects on homeopathy.

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