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Anthroposophic vs. Conventional Therapy for Chronic Low Back Pain: A Prospective Comparative Study

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Abstract

Objective: To compare anthroposophic treatment (eurythmy, rhythmical massage or art therapy; counselling, anthroposophic medication) and conventional treatment for low back pain (LBP) under routine conditions.

Methods: 62 consecutive outpatients from 38 medical practices in Germany, consulting an anthroposophic (A-) or conventional (C-) physician with LBP of ≥ 6 weeks duration participated in a prospective non-randomised comparative study. Main outcomes were Hanover Functional Ability Questionnaire (HFAQ), LBP Rating Scale Pain Score (LBPRS), Symptom Score, and SF-36 after 6 and 12 months.

Results: At baseline, LBP duration was > 6 months in 85% (29/34) of A-patients and 54% (15/28) of C-patients ($p = 0.004$). Unadjusted analysis showed significant improvements in both groups of HFAQ, LBPRS, Symptom Score, SF-36 Physical Component Summary, and three SF-36 scales (Physical Function, Pain, Vitality), and improvements in A-patients of three further SF-36 scales (Role Physical, General Health, Mental Health). After adjustment for age, gender, LBP duration, and education, improvements were still significant in both groups for Symptom Score ($p = 0.030$), SF-36 Physical Component Summary ($p = 0.004$), and three SF-36-scales (Physical Function, $p = 0.025$; Role Physical, $p = 0.014$; Pain, $p = 0.003$), and in A-patients for SF-36-Vitality ($p = 0.032$). Compared to C-patients, A-patients had significantly more pronounced improvements of three SF-36 scales (Mental Health: $p = 0.045$; General Health: $p = 0.006$; Vitality: $p = 0.005$); other improvements did not differ significantly between the two groups.

Conclusion: Compared to conventional therapy, anthroposophic therapy for chronic LBP was associated with at least comparable improvements.

Key words: anthroposophy, comparative study, drug therapy, eurythmy therapy, intervertebral disk displacement, low back pain, physical therapy, rhythmical massage therapy

Abbreviations: A-: Anthroposophic, AM: Anthroposophic Medicine, C-: Conventional, HFAQ: Hanover Functional Ability Questionnaire, LBPRS: Low Back Pain Rating Scale Pain Score, MCS (PCS): SF-36 Mental (Physical) Component Summary Measure

Introduction

Two-thirds of adults experience low back pain (LBP) at some point in life [1]. In several studies LBP was the second most common symptom for which patients saw a physician [2]. LBP causes considerable morbidity and impairs quality of life; in a survey of German adults, 23% suffered current back pain with high pain intensity or severe functional impairment [3].

85% of LBP cases are non-specific, i. e. without a diagnosable patho-anatomical condition [2;4]. In primary care, non-specific LBP is usually treated with medication (paracetamol, non-steroid anti-inflammatory drugs (NSAID), muscle relaxants, opioid analgesics, antidepressants), physiotherapy, and spinal manipulation [5-7]. Long-term use of medication is not proven effective and poses risks for serious, sometimes fatal adverse effects (NSAID), toxicity (paracetamol), and dependency (muscle relaxants and opioids) [8-11]. In refractory LBP, intensive multidisciplinary rehabilitation programs may be helpful [12] but require high patient motivation and compliance. Under real-world conditions, primary care treatment of chronic LBP is associated with modest [13] or no improvement [5].

Anthroposophic medicine (AM) was founded in the 1920s by Rudolf Steiner and Ita Wegman [14]. AM aims to stimulate patients' salutogenetic, self-healing capacities [15] and is practiced in 67 countries worldwide [16]. AM therapy for LBP is provided by physicians (counselling, AM medication) and non-medical therapists (eurythmy therapy, rhythmical massage therapy, embrocation, and art therapy) [17-19]. Eurythmy therapy (Greek "harmonious rhythm") is an active exercise therapy, involving cognitive, emotional, and volitional elements [20]. During eurythmy therapy sessions patients are instructed to perform specific movements with the hands, the feet or the whole body. Eurythmy movements are related to the sounds of vowels and consonants, to music intervals or to soul gestures, e. g. sympathy-antipathy. Between therapy sessions patients practice eurythmy movements daily [21]. Rhythmical massage therapy was developed from Swedish massage by Ita Wegman, physician and physiotherapist [22], and is practiced by physiotherapists with 1 1/2 -3 years specialised training. In rhythmical

massage therapy, traditional massage techniques (effleurage, petrissage, friction, tapotement, vibration) are supplemented by gentle lifting and rhythmically undulating, stroking movements, where the quality of grip and emphasis of movement are altered to promote specific effects [15].

To date AM therapy for LBP has been evaluated in three observational studies, conducted in specialised settings [23-25]. Here we present a study conducted in primary care.

Material, Methods and Statistics

Design and Objective

This is a prospective one-year, non-randomised comparative study. The study was initiated by a health insurance company as part of a research program on the effectiveness and costs of complementary therapies in chronic disease (Modellvorhaben Naturheilverfahren [26-28]).

The objective was to compare clinical outcomes, therapies provided, health service use, adverse reactions, and satisfaction in outpatients seeing either AM or conventional physicians for subacute or chronic LBP and treated under routine clinical conditions.

Setting, Participants, and Therapy

Anthroposophic (A-) physicians certified by the Physicians' Association for Anthroposophical Medicine in Germany and conventional (C-) physicians not using AM or other complementary therapies were invited to participate. A-physicians were recruited from all parts of Germany, C-physicians from Berlin only. The participating physicians enrolled consecutive outpatients fulfilling eligibility criteria:

Inclusion criteria: (1) Age 17-75 years, (2) LBP at least six weeks duration, (3) starting LBP therapy for the first time with the study physician:

- A-group: AM therapy provided by A-physician or referral to AM therapist (art, eurythmy or rhythmical massage);
- C-group: any non-AM therapy provided by C-physician or referral to any non-AM therapy for LBP.

Exclusion criteria: Previous back surgery, congenital spinal malformation, spinal infectious or malignant disease, ankylosing spondylitis, Behcet's Syndrome, Reiter's Syndrome, osteoporosis with vertebral fracture, spinal stenosis, spondylolysis, spondylolisthesis, fibromyalgia.

Therapy: Treatments in A- and C-groups were tailored to individual needs and did not follow a standardised protocol. In both groups, treatments were evaluated as therapy packages, including physician-patient interactions.

Clinical Outcomes

- *Hanover Functional Ability Questionnaire (HFAQ):* The HFAQ [29] is a self-rating questionnaire of back-specific functional disability. It consists of 12 activity-related questions (e. g. "Can you bend down to pick up a paper from the floor?") which are answered on three-point Likert scales ("Can do without difficulty" / "Can do, but with some difficulty" / "Either unable to do, or only with help") [30]. The HFAQ score ranges from 0 (minimal function) to 100 (optimal function, no limitation). A score of $\leq$ 70 points indicates a clinically significant functional limitation; a difference of $\geq$ 12 points between or within groups is considered clinically relevant. The WHO lists the HFAQ among the three most relevant disease-specific instruments for spinal disorders [4].
- *Low Back Pain Rating Scale Pain Score (LBPRS):* The LBPRS [31] consists of three back pain and three leg pain items: current pain, worst pain and average pain during the last seven days (0 "no pain" to 10 "unbearable pain"). The LBPRS ranges from 0 (6 x "no pain") to 100 (6 x "unbearable pain").
- *Symptom Score:* numerical rating scale [32] from 0 („not present") to 10 („worst possible"), patients' assessment of one to six most relevant symptoms present at baseline.
- *Quality of life:* SF-36 Physical (PCS) and Mental (MCS) Component Summary Measures, eight scales [33].

Primary outcomes were HFAQ and LBPRS. Clinical outcomes were documented after 0, 6, and 12 months. LBPRS and Symptom Score were not documented in A-patients enrolled before 1 Jan 1999.

Other Outcomes

- Therapy and health service use in the pre-study year (documented at study enrolment) and follow-up year (documented after six and 12 months): inpatient hospital and rehabilitation treatment, back-related physician visits (visits to general practitioners, internists, orthopaedic surgeons, neurologists or psychiatrists), paraclinical investigations, use of back-related drugs (Anatomical Therapeutic Chemical Classification Index M01 Anti-inflammatory and antirheumatic products, M02 Topical products for joint and muscular pain, M03 Muscle relaxants, N01 Analgesics, N06A Antidepressants; additional documentation after three months), back surgery, physiotherapy, Heilpraktiker (non-medical practitioner) visits, sick leave.
- Patient rating of therapy outcome, patient satisfaction with therapy after six and 12 months.
- Adverse drug or therapy reactions reported during the 12-month follow-up: cause, intensity (mild / moderate / severe = no / some / complete impairment of normal daily activities); Serious Adverse Events.

Data Collection

All data were documented with questionnaires sent in sealed envelopes to the study office. Physicians documented eligibility criteria; all other items were documented by patients. Patient responses were not made

available to physicians. Physicians were compensated € 40 per included and fully documented patient, while patients received no compensation.

Data were entered twice by two different persons into Microsoft® Access 97. The two datasets were compared and discrepancies resolved by checking with the original data.

Quality Assurance, Adherence to Regulations

The study was approved by the Ethics Committee of the Faculty of Medicine Charité, Humboldt University Berlin, conducted according to the Helsinki Declaration and ICH-GCP guidelines, and reported according to guidelines for reporting non-randomised studies [34;35]. Written informed consent was obtained from all patients before enrolment.

Data Analysis

The study was designed to compare pre-post changes between the A- and C-groups. Previous data did not permit sample size calculation. No interim analyses were planned or performed, no specific stopping rules formulated.

Data analysis was performed on patients enrolled until 30 Sep 2000 with complete follow-up-data after six and 12 months. Clinical outcomes were compared using repeated-measures analysis of variance (ANOVA), unadjusted and after adjustment for baseline score of the outcome, for gender, age, LBP duration, and educational level (university entrance qualification).

Other outcomes were subject to bivariate analysis: For continuous data the Wilcoxon Signed-Rank test was used for paired samples and the Mann-Whitney U-test for independent samples, median group differences with 95% confidence interval (95%-CI) were estimated with the method of Hodges and Lehmann [36]. For binominal data McNemar test and Fisher's exact test were used. All tests were two-tailed. Significance criteria were $p < 0.05$ and 95%-CI not including 0.

Results

Participating Physicians and Therapists

25 A-physicians (17 male + 8 female) and 13 C-physicians (6+7) participated. Physicians' qualifications were: general practitioner (22 A-physicians + 2 C-physicians), internist (2+2), orthopaedic surgeon (0+9), and anaesthesiologist (1+0). Participating A-physicians did not differ significantly from all AM-certified physicians in Germany (n = 362) regarding gender (68.0 % vs. 62.2% males), age (mean 47.4 ± 7.3 vs. 47.5 ± 7.9 years), number of years in practice (20.7 ± 6.8 vs. 19.5 ± 8.7 years), or the proportion of primary care physicians (96.0% vs. 85.0%). A-Patients were treated by 28 A-therapists. Comparing these A-therapists to certified A-therapists without study patients (n = 730), no significant differences were found regarding gender (92.9% vs. 79.2% females) or age (mean 50.5 ± 7.1 vs. 51.2 ± 9.5 years). Median number of years since A-therapist qualification was 8.0 years (interquartile range IQR 5.0-14.0) in A-therapists with patients and 13.0 (IQR 8.0-18.0) years in A-therapists without patients (median difference 4.0 years; 95%-CI 1.0-7.0 years; $p = 0.012$).

Patient Recruitment and Follow-up

From 1 July 1998 to 30 Sep 2000 a total of 86 patients (38 A-patients and 48 C-patients) were enrolled. 89% (34/38) of A-patients and 58% (28/48) of C-patients had follow-up data after six and 12 months and were included in the analysis ($p = 0.002$). C-patients with (n = 28) and without (n = 20) complete 0-6-12 month follow-up data did not differ significantly regarding age, gender, LBP duration, or baseline scores of clinical outcomes (HFAQ, LBPRS, Symptom Score). No corresponding dropout analysis was performed in the A-group, because only four A-patients were without complete 0-6-12 month follow-up data. Three-month follow-up data (used for medication analysis only) was available for 100% (34/34) of included A-patients and 68% (19/28) of C-patients.

Patients were enrolled by general practitioners (31 A-patients + 3 C-patients), internists (2+2), orthopaedic surgeons (0+23), and anaesthesiologists (1+0). Physicians' setting was office-based non-referral practice (33+28 patients) and outpatient clinic (1+0).

Screening data were available for the A-group only. 13 patients starting AM therapies for LBP with A-physicians were screened but not included. Reasons for non-inclusion: LBP duration < 6 weeks (n = 5), other exclusion criteria fulfilled (n = 4), other reason (n = 4). Included and not included A-patients did not differ significantly regarding age, gender, or baseline scores of clinical outcomes (HFAQ, LBPRS, Symptom Score). LBP duration was median 4.0 years longer (95%-CI 0.1-9.5; $p = 0.022$) in included than in not included A-patients.

Baseline Characteristics

Baseline socio-demographics and health status (Table 1): A- and C-groups did not differ significantly regarding gender, age, primary education, occupational status, living alone, income, smoking, alcohol use, sport, overweight, work disability pension, severe disability status, lumbar disc disease, health-care use in previous year (hospitalisation, back-related physician visits, physiotherapy, back-related drugs, sick leave), or depressive symptoms (Center for Epidemiological Studies Depression Scale [37]). A-patients were recruited from 10 out of 16 German federal states, C-patients from one state (Berlin). A-patients had higher occupational qualification than C-patients. LBP duration was median 4.5 years (95%-CI 0.5-8.3 years; $p = 0.004$) longer in A-patients than in C-patients.

Baseline scores of clinical outcomes: In the unadjusted analysis A- and C-groups did not differ significantly regarding HFAQ, SF-36-MCS, or five SF-36 scales. A-patients had lower (worse) scores for one SF-36 scale (Mental Health). C-patients had lower (worse) scores for SF-36-PCS and two SF-36 scales (Physical Func-

Table 1. Baseline characteristics.

Item		Anthroposophy group		Conventional group		Difference
		N	%	N	%	
Female gender		27/34	79%	18/28	64%	p = 0.254
Age (years, mean ±SD)		50.1	±12.8	53.4	±15.4	p = 0.229
Age groups	20-39 years	9/34	26%	7/28	25%	
	40-59 years	14/34	41%	8/28	29%	
	60-75 years	10/34	29%	13/28	46%	
School-leaving certificate		33/34	97%	27/28	96%	p = 1.000
"Fachhochschulreife" or university entrance qualification		17/34	50%	1/28	4%	p < 0.001
Formal vocational qualification		27/29*	93%	15/28	54%	p < 0.001
University degree		6/29*	21%	0/28	0%	p = 0.024
Occupational status						p = 0.192**
-Self-employed + salaried employee		13/29*	45%	6/28	21%	
-Wage earner		2/29*	7%	6/28	21%	
-Pensioner		9/29*	31%	9/28	32%	
-Unpaid family worker + unemployed + student		5/29*	17%	7/28	25%	
Living alone		11/34	32%	14/28	50%	p = 0.198
Net monthly household income < 900 €		4/24*	17%	10/22	45%	p = 0.054
Daily smoker		4/34	12%	8/28	29%	p = 0.117
Alcohol use daily		1/29*	3%	0/27	0%	p = 1.000
Sports activity ≥ 1 hour weekly		13/29*	45%	8/28	29%	p = 0.274
Permanent work disability pension		1/29*	3%	2/28	7%	p = 0.612
Severe disability status		5/29*	17%	4/28	14%	p = 1.000
Overweight = Body Mass Index ≥ 25		12/29*	41%	19/28	68%	p = 0.064
Previously treated by study physician		23/29*	79%	11/28	39%	p = 0.003
Low back pain duration in years	(mean ±SD)	11.02	±11.36	7.21	±14.94	
	(median + interquartile range)	8.2	1.0-20.0	1.0	0.1-4.0	p = 0.004
	6 weeks - ≤ 3 months	3/34	9%	10/28	36%	
	3 months ≤ 6 months	2/34	6%	3/28	11%	
	6 months - ≤ 12 months	4/34	12%	2/28	7%	
	≥ 12 months	25/34	74%	13/28	46%	
LBPRS back pain (0-50, mean ±SD)		27.36*	±10.70	32.56	± 7.82	p = 0.068
LBPRS leg pain (0-50, mean ±SD)		5.86*	±9.40	17.68	±15.77	p = 0.004
Lumbar disc herniation or protrusion with nerve root compression		8/26	31%	3/28	11%	p = 0.095
Hanover Functional Ability Questionnaire ≤ 70 points = clinically relevant limitation in back function		20/33	61%	18/28	64%	p = 0.797
Center for Epidemiological Studies Depression Scale, German version ≥ 24 points = depressive range		8/26	31%	7/24	29%	p = 1.000

*Item documented in Anthroposophy patients enrolled after 1 Jan 1999 (n = 29) **Fisher-Freeman-Halton test. LBPRS: Low Back Pain Rating Scale Pain Score

tion, Bodily Pain), and higher (worse) LBPRS and Symptom Score. In the adjusted analysis these differences remained significant, except for the worse SF-36 Mental Health scores in the A-group, which could largely be explained by the longer LBP duration in A-patients.

Therapies and Health Service Use

AM therapies (in the A-group): At study enrolment, A-patients started therapy provided by their A-physician (n = 1) or were referred to AM therapies (n = 33, thereof eurythmy: n = 23, rhythmical massage: n = 8, art therapy: n = 2). AM therapies were administered to all 33 patients and started median 9 (IQR 0-35) days after enrolment. Median therapy duration was 88 (IQR 59-123) days, median number of therapy sessions was 12 (IQR 10-12). In addition to AM therapies, 79% (27/34) of A-patients used AM medication.

Back-related drugs were used in the pre-study year and in the year after study enrolment by 34% (10/29) and 21% (6/29) of A-patients, respectively (p = 0.219), and by 53% (10/19) and 74% (14/19) of C-patients, respectively (p = 0.219). In the year after enrolment the odds ratio (A- vs. C-group) for use of back-related drugs was 0.09; 95%-CI 0.02-0.43; p < 0.001). Back-related drugs used in the year after enrolment were N02 Analgesics (used by 3/29 A-patients and

Table 2. Clinical outcomes: Anthroposophy group (A-group, n = 34) vs. Conventional group (C-group, n = 28).

Item	Baseline scores (unadjusted) A-Group		C-Group		Do A- and C-groups differ at baseline?		Do A- and C-groups improve over time (0-6-12 months)?		Do improvements C- differ between A- and C-groups?	
	Mean	**±SD**	**Mean**	**±SD**	**Unadjusted**	**Adjusted***	**Unadjusted**	**Adjusted†**	**Unadjusted**	**Adjusted†**
HFAQ (0-100)	59.0	±22.5	56.2	±20.4	p = 0.126	p =0.055	p < 0.001	p = 0.151	p = 0.055	p = 0.079
LBPRS (0-100)	33.2	±15.8	50.2	±20.8	p = 0.004	p = 0.001	p < 0.001	p = 0.751	p = 0.499	p = 0.080
Symptom Score (0-10)	5.8	±2.2	6.2	±1.4	p = 0.024	p = 0.003	p < 0.001	p = 0.030	p = 0.100	p = 0.425
SF-36 Physical Component	35.2	±9.4	32.5	±8.2	p = 0.009	p = 0.001	p < 0.001	p = 0.004	p = 0.162	p = 0.192
SF-36 Mental Component	41.9	±10.4	50.5	±11.1	p = 0.084	p = 0.905	p = 0.961	p = 0.729	p = 0.061	p = 0.093
SF-36 Scales (0-100)										
Physical Function	59.2	±23.9	52.6	±24.1	p = 0.039	p = 0.004	p = 0.029	p = 0.025	p = 0.415	p =0.579
Role Physical	29.7	±37.8	41.1	±39.8	p = 0.241	p = 0.141	A-group: p = 0.003 C-group: p = 0.912	p = 0.014	p = 0.036	p = 0.068
Role-Emotional	48.9	±43.5	72.0	±38.8	p = 0.356	p = 0.941	p = 0.670	p = 0.977	p = 0.056	p = 0.076
Social Functioning	65.2	±25.2	75.9	±25.0	p = 0.555	p = 0.208	p = 0.473	p = 0.109	p = 0.185	p = 0.512
Mental Health	55.9	±19.0	66.6	±20.8	p = 0.036	p = 0.519	A-group: p = 0.015 C-group: p = 0.400	A-group: p = 0.128 C-group: p = 0.069	p = 0.012	p = 0.045
Bodily Pain	34.5	±20.5	31.7	±16.0	p = 0.058	p < 0.001	p < 0.001	p = 0.003	p = 0.232	p = 0.099
Vitality	38.3	±16.5	45.4	±14.1	p = 0.711	p = 0.407	p = 0.004	A-group: p = 0.032 C-group: p = 0.102	p = 0.080	p = 0.005
General Health	49.8	±20.3	48.7	±17.1	p = 0.172	p = 0.260	A-group: p = 0.043 C-group: p = 0.310	A-group: p = 0.280 C-group: p = 0.576	p = 0.019	p = 0.006

*Adjusted for gender, age, low back pain duration, and educational level. †Adjusted for gender, age, low back pain duration, educational level, and for baseline score of the outcome. HFAQ: Hanover Functional Ability Questionnaire. LBPRS: Low Back Pain Rating Scale Pain Score.

Fig. 1. Hanover Functional Ability Questionnaire (HFAQ, 0 "minimal function", 100 "optimal function"), Low Back Pain Rating Scale Pain Score (0 "no pain", 100 "unbearable pain"), Symptom Score (0 "not present", 10 "worst possible").

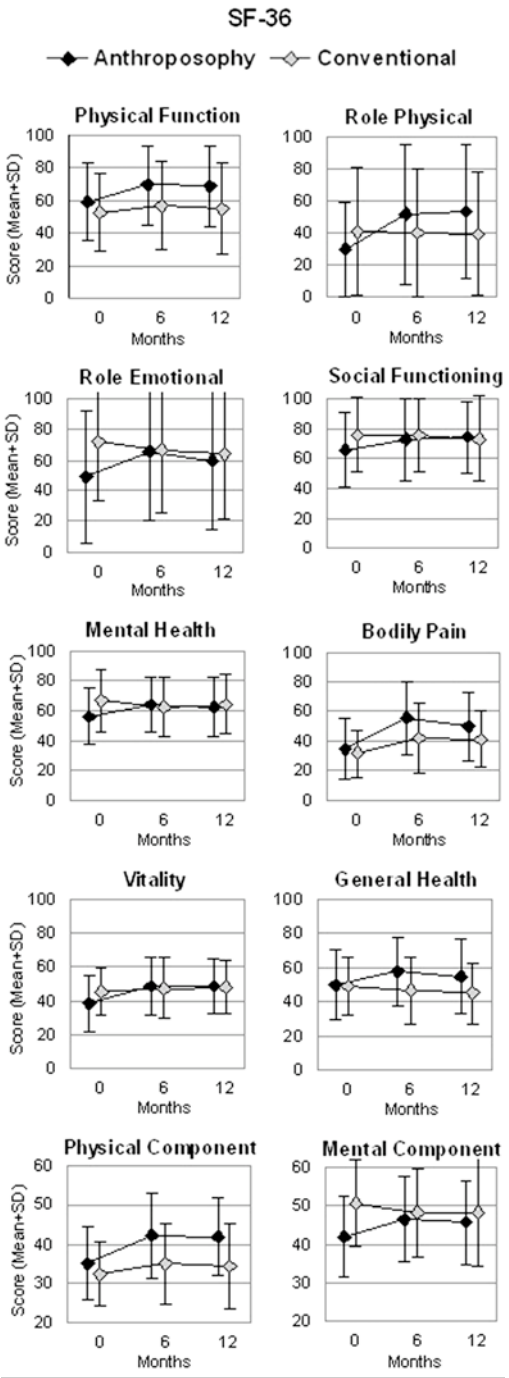

Fig. 2. SF-36 scales, SF-36 Physical and Mental Component Summary Measures (higher scores indicate better health).

8/19 C-patients), M01 Anti-inflammatory and antirheumatic products (5+12), M02 Topical products for joint and muscular pain (0+5), M03 Muscle relaxants (0+1), and N06A Antidepressants (2+1). Average number of daily doses of all back-related drugs used during the year after enrolment was 0.12 ± 0.32 doses in A-patients and 0.37 ± 0.57 doses in C-patients (p = 0.003).

Physiotherapy was used in the pre-study year and in the year after study enrolment by 71% (24/34) and 59% (20/34) of A-patients, respectively (p = 0.607), and by 54% (15/28) and 65% (18/28) of C-patients, respectively (p = 0.344). In the year after enrolment the odds ratio (A- vs. C-group) for use of physiotherapy was 0.79; 95%-CI 0.28-2.23; p = 0.661). Average number of physiotherapy sessions during the year after enrolment was 21.4 ± 45.7 (median 6, IQR 0-18) sessions in A-patients and 15.5 ± 20.5 (median 8, IQR 0-21) sessions in C-patients (p < 0.677).

Other items (hospital and rehabilitation treatment, Heilpraktiker visits, sick-leave, back-related physician visits) did not change significantly and did not differ significantly between the groups. No patient had back surgery.

Clinical Outcomes

The unadjusted 0-6-12 month analysis showed significant improvements in both groups of HFAQ, LBPRS, Symptom Score, SF-36-PCS, and three SF-36 scales (Physical Function, Pain, and Vitality) and significant improvements in the A-group of three further SF-36 scales (Role Physical, General Health, Mental Health) (Table 2, Fig. 1-2). After adjustment, improvements were still significant in both groups for Symptom Score, SF-36-PCS, and three SF-36-scales (Physical Function, Role Physical, Bodily Pain), and in the A-group for SF-36-Vitality.

Improvements were compared between A- and C-groups: Three SF-36 scales were significantly more improved in A-patients (unadjusted: Role Physical, Mental Health, and General Health; adjusted: Mental Health, General Health, and Vitality); other improvements did not differ significantly between the two groups.

Other Outcomes

Therapy ratings: At six-month follow-up, patients' average therapy outcome rating (numeric scale: 0 "no

help at all", 10 "helped very well") was 7.28 ± 2.31 in A-patients and 5.58 ± 2.55 in C-patients (median difference 2.00 points; 95%-CI 0.00-3.00; p = 0.009); patient satisfaction with therapy (0 "very dissatisfied", 10 "very satisfied") was 7.62 ± 2.30 and 6.50 ± 2.39 (median difference 1.00 points; 95%-CI 0.00-3.00; p = 0.051). Therapy ratings did not differ significantly between six- and 12-month follow-ups.

Adverse reactions to medication or therapies occurred in 15% (5/34) of A-patients (mild: n = 1, moderate: n = 1, severe: n = 3) and 11% (3/28) of C-patients (moderate: n = 2, severe: n = 1); odds ratio A- vs. C-group for adverse reaction: 1.44; 95%-CI 0.25-10.13; p = 0.940. Causative agents in A-patients: 1) flecainid, 2) propicillin, 3) amoxicillin, 4) tamoxifen, 5) unidentified injection; in C-patients: 6) nebivolol, 7) tacalcitol, 8) stretching exercises. Agents 1, 3, 5, 6 and 8 were stopped because of adverse reactions. No Serious Adverse Events occurred.

Discussion

This is the first study of comprehensive AM therapy for LBP in primary care. We aimed to provide information on AM use under routine conditions in Germany and compared patients self-selected to treatment provided by AM or conventional physicians for discogenic or non-specific LBP of at least six weeks duration. A-patients were treated mainly with eurythmy or rhythmical massage therapy and AM medication, C-patients with conventional drugs (analgesics, NSAID); furthermore, two-thirds of patients in both groups had conventional physiotherapy. During the 12-month follow-up, symptoms and some quality of life dimensions (SF-36) improved in both groups. In the adjusted analysis three SF-36 scales were significantly more improved in A-patients (Mental Health, General Health, and Vitality); other improvements did not differ significantly between the two groups.

Strengths and Limitations

Strengths of this study include a long follow-up period, a high follow-up rate in the A-group, and the participation of 5% of all AM-certified physicians and AM therapists in Germany. AM participants resembled all eligible AM physicians/therapists regarding demographic characteristics, and included A-patients resembled not included, screened patients regarding baseline characteristics. These features suggest that the study to a high degree mirrors contemporary AM practice. A limitation of the study is the low follow-rate in the C-group. Also, the small sample size may have rendered true differences within or between groups insignificant. No adjustment for multiple comparisons was performed [38]; it should be noted, however, that two of the three comparisons showing more outspoken improvements in A-patients than in C-patients had highly significant differences (SF-36 Vitality: p = 0.005, SF-36 General Health: p = 0.006).

Since our comparison groups were not randomised, baseline differences might have affected outcomes. Therefore clinical outcomes were adjusted for their baseline scores, for LBP duration, education, age, and gender. Because of restricted sample size, several other known prognostic factors (disc disease, depression, low income, living alone, previous sick-leave, previous physician visits, and smoking [39-41]) could not be included in the adjustment model. However, none of these factors differed significantly between A- and C-groups at baseline. Also, no differences were found regarding gender, age, occupation, alcohol, sport, overweight, work disability pension, severe disability status, or baseline back function. Nonetheless, we cannot exclude residual confounding, e. g. from setting differences: A-patients were recruited from 10 German federal states, C-patients from Berlin; A-patients were largely enrolled by general practitioners, C-patients by orthopaedic surgeons. Moreover, factors related to patients' self-selection (e. g. lifestyle or motivation, independent of or due to the AM approach; therapy expectations) may have affected clinical outcomes.

Other outcomes, e. g. medication use were not adjusted for baseline differences. During follow-up C-patients used average three times more conventional back-related medication than A-patients. At least some of this difference may be explained by differences in baseline pain intensity (LBPRS 50% higher/worse in C-patients; SF-36 Bodily Pain 8% lower/worse in C-patients).

Generalisability of Study Results

Study eligibility criteria excluded specific causes of LBP except disc disease, which was present in one-third of A-patients. 86% of A-patients had suffered pain for at least six months, two-third were aged 40 and above. Thus the outcomes observed after AM therapy apply to middle-aged patients with chronic non-specific or discogenic LBP.

Study Implications

This study provides the first data on AM therapy for LBP in primary care. Notably, the female-to-male ratio was much higher in A-patients (3.9/1.0) than in LBP sufferers from German primary care (1.0/1.0) [42] or from the German population (1.2/1.0) [3]. A high proportion of women and of patients with higher educational levels, as observed here, has been observed in other studies of AM users [15; 43; 44].

Previous studies of AM therapies found improvement of non-specific LBP (AM rhythmic embrocation therapy [24]) and of discogenic LBP (subcutaneous injections of AM medications [23], comprehensive inpatient AM therapy [25]). One study also found reduced NSAID and muscle relaxant use and earlier return to work after AM therapy, compared to conventional inpatient treatment [25].

In accordance with these findings from specialised settings, our primary-care LBP study demonstrated improvement in symptoms and quality of life following AM therapies, with a low use of back-related drugs (analgesics, NSAID, muscle relaxants, antidepressants). Improvements were comparable to or more extensive than in patients receiving conventional care. Since standard therapy of LBP remains unsatisfactory for many patients [45], AM seems a promising treatment

option for chronic LBP.

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