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Yoga, Eurythmy Therapy and Standard Physiotherapy (YES-Trial) for Patients With Chronic Non-specific Low Back Pain: A Three-Armed Randomized Controlled Trial

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Introduction

Chronic back pain is a major public health problem of global relevance. According to current surveys, about 22% of the German population aged between 18 and 79 suffer from back pain, 62% were affected by episodes of back pain within the last 12 months, and 19% suffered from chronic back pain during the past 12 months. Only 50% of those suffering from back pain for longer than 6 months can be re-integrated into work; over 60% of all applications for invalidity and disability are made due to back pain.^{24, 25, 27, 36} Worldwide the prevalence of chronic low back pain in adults is between 3.9% and 25.4%.^{18, 21, 27}

Chronic back pain can seriously affect patients' quality of life and has a high co-morbidity with reduced psychological well-being and depression. Furthermore, it is the most cost-intensive disease of the working age, with medical costs amounting to 10 billion euros annually in Germany and more than 30 billion dollars in the United States (US).^{19, 20} A variety of treatments for back pain exist including analgesic and anti-inflammatory medication, exercise, acupuncture, injections, manual therapies and surgery. However, there is still limited evidence to support most of these treatments.

Besides specific pharmacotherapies, non-pharmacological interventions such as psychotherapy, physical training, and psychoeducation are recommended for patients with chronic back pain.¹⁵ The most common treatment prescribed by physicians is physical training/exercise.¹⁵ Meta-analyses reported beneficial effects of physical/physiotherapeutic exercise training, for example, on fitness and occupational status as well as on functional outcomes, pain (intensity), disability, and recurrence.^{14, 28, 31, 34} Also interventions of the Complementary and Integrative Medicine (CIM) play an important role in the care of patients with back pain.^{9, 38} Here, several methods of Mind-Body Medicine have found to be effective in back pain.

Hatha Yoga, which combines movement and muscle development with stretching, breathing and relaxation, is a promising form of exercise as an additional therapy for chronic low back pain, with promising evidence for beneficial effects. Yoga is an increasingly used self-care and health-promoting technique in the US and Europe. Yoga was the most commonly used complementary health approach among US adults in 2017 (14%).⁷ Compared to non-exercise controls, yoga showed results in small to moderate improvements in back-related function³⁷ and was found to have positive effects on pain and pain related disability.³ In 2007, yoga has already been implemented by the American College of Physicians and the American Pain Society in clinical guidelines for patients with chronic low back pain.⁶ A recent three-armed randomized controlled trial (RCT) comparing yoga with physiotherapy and education showed noninferiority of yoga to physiotherapy. Yoga was not superior to education for either outcome. Yoga and physiotherapy were similar for most secondary outcomes.²⁶

In anthroposophic medicine, eurythmy therapy, a non-pharmacological, mindfulness-oriented movement

therapy, is frequently prescribed.^{4, 17} Here, specific slow movements and gestures are combined with speech articulation (i.e. specific vowels and consonants or even poems). Eurythmy therapy focuses on the conceptual relationship and regulation of 'spirit' and 'soul' with the physical body and 'life forces'.^{4, 32, 35} However, the principle idea behind this intention is that the movements have to be first imagined in the mind in order to be converted into the physical movement of the body. Thus, it starts with a cognitive ('spirit') and emotional ('soul') approach which influences the physiological dimension and vitality ('life forces') and physical ('body') aspects of the practitioner. Therefore, the intention (imagination) of the practitioner is in the forefront, which in turn influences the emotions and body movements. With the slow and conscious movements also the breathing pattern (depending on the related sounds) is modulated, which in turn has an influence on heart rate variability and health-related quality of life (eg, emotional role, vitality or mental health).^{8, 16, 29} Eurythmy therapy is largely practised in the chronic pain management in out- and inpatients settings of anthroposophic medicine.¹¹ Two cohort studies showed an association with positive effects of a multimodal anthroposophic treatment concept including eurythmy therapy in patients with chronic back pain including a 2 year follow-up.^{12, 13} Due to the fact that the results refer to uncontrolled study designs, reliable and valid data obtained from RCTs are so far missing.

The aim of this randomized-controlled study was to evaluate the effects of yoga and eurythmy therapy in comparison to physiotherapy after 8 weeks of intervention in patients with chronic low back pain. In Germany, physiotherapy is a standard therapy according to chronic low back pain guidelines. The costs are covered by health insurance companies.

Moreover, we were interested in differential effects of these three treatments, as physiotherapy is primarily body based, while both yoga and eurythmy therapy combine body with mind-body elements (and additional vocational sounds and dance elements in eurythmy therapy). Thus, we expected different effects on patients with pain. The study had no influence on the pharmacological treatment of pain and therefore provided evidence for the additional use of yoga, eurythmy therapy or physiotherapy for clinical application in the general care of patients with chronic back pain. However, the absence of a fourth arm (ie, usual care only; or usual care with waiting) can limit the observed effects in this study.

Methods

This study was designed as a multicentre, three-armed, randomized controlled trial over 16 weeks (8 weeks intervention and 16 weeks follow-up). The study protocol has been published elsewhere.⁵ All study participants gave informed consent. The study protocol was reviewed and approved by the ethics committees of Charité – Universitätsmedizin Berlin, and Witten/

Herdecke University, Witten, Germany. Patients were enrolled between October 2012 and November 2014; the study was completed in February 2015. It was registered in the German Clinical Trials Register (DRKS00004651) in March 2013. All study procedures and data collection were carried out at the following study centers: 1) the Charité outpatient department for Integrative Medicine at Immanuel Hospital, Berlin, Germany, 2) Research Institute Havelhöhe with Gemeinschaftskrankenhaus Havelhöhe, Berlin, Germany and 3) Institute of Integrative Medicine, Witten/Herdecke University, with Gemeinschaftskrankenhaus Herdecke, Herdecke, Germany. All study centers had the same standards (according to a standard operating procedure) for interventions and data collection. There were no specific audits of the study sites.

Study Procedures

Participants were recruited by means of press releases or through (external) physicians who informed their patients of the study by offering cost-free participation in a study for chronic low back pain. Potential participants were screened for eligibility by telephone interviews, and eligible candidates were scheduled for enrolment appointments. The written study information emphasized that all three treatment options might be useful for the treatment of chronic back pain. A study physician performed physical examinations. After signing informed consent and collection of baseline data, patients were randomized to the three groups: 1) yoga, 2) eurythmy therapy or 3) physiotherapeutic exercises.

Study Participants

Patients had to meet the following criteria to be included in this study: 1) age between 18 and 70 years, 2) non-specific back pain for at least 3 months including a medical specialist's written diagnostic confirmation, and 3) back pain intensity at least 40 mm on the 100 mm visual analog scale (VAS) on at least 4 of 7 weekdays. They were excluded with 1) acute herniated disc (<3 months) or herniated disc with indication for surgery, 2) other severe comorbidities like cancer or bone metastases, 3) other active, non-pharmacological treatments (at least 3 months prior to enrolment), with the exception of participation in standard back school training and psychotherapy, 4) participation in another clinical trial within the last 4 weeks prior to enrolment, 5) acute somatic or psychiatric disorders, 6) pregnancy and lactation, 7) ankylosing spondylitis, rheumatoid arthritis, or other rheumatic diseases, 8) somatoform pain disorders, 9) spinal malformations, 10) symptomatic spinal canal stenosis, 11) spinal surgery in the past 6 weeks prior to enrolment or planned surgery in the next 2 months, and 12) ongoing recognition procedure for early retirement. In the process of finalizing the protocol and ethics the criteria #6-12 were added and unfortunately this amendment was not transferred into the clinical trials registration.

Randomization

Patients were randomly allocated to a treatment group by a non-stratified block-randomization with a fixed block length of 6 blocks and by preparing sealed, sequentially numbered opaque envelopes containing the treatment assignments. Randomization was based on the "ranuni" pseudo-random number generator of the Statistical Analysis System (SAS) Base statistical software (SAS Inc., Cary NC), and the sealed opaque envelopes were prepared by the study biostatistician. Each local study center got consecutively numbered envelopes with randomization numbers and study arms. When a patient fulfilled all enrolment criteria, the study physician opened the lowest numbered envelope to reveal that patient's assignment. The randomization form was then send by fax to the head study center to be recorded by an independent person.

Outcomes and Measurements

Outcomes

All patients were asked to complete standardized questionnaires (baseline, visit 0 [V0]), after 8 weeks at the end of the intervention (visit 1 [V1]) and at a 16 week follow up (visit 2 [V2]).

Primary outcome was the change of the mean score of the Roland Morris Disability Questionnaire (RMDQ) after 8 weeks.¹ Secondary outcome variables were pain intensity and pain-related bothersomeness (100 mm VAS), health-related quality of life Short Form 12 (SF-12)¹⁰, and Brief Multidimensional Life Satisfaction Scale (BMLSS).² Further secondary outcome variables, which will be published separately, were: anxiety and depression (Center for Epidemiologic Studies Depression Scale, CES), stress (Perceived Stress Scale, PSS), self-regulation (SR), mood (subscale of Profile Of Mood States, POMS), coherence (Internal Coherence Scale, ICS), inner congruence and harmony with the exercises (ICPH), mindfulness (Freiburg Mindfulness Inventory, FMI), expectation of self-efficacy (Selbstwirksamkeitserwartung, SWE).

To control non-specific treatment effects, patients' outcome expectation of the assumed effects of the intervention was assessed by a 100 mm VAS.

Adverse effects were assessed by pre-specified forms to be filled in by the study physician during the study visits. Additionally, patients were asked to keep a diary to record the duration of their practice, well-being, pain intensity as well as any use of oral rescue medication. Blinded research assistants collected patient-reported data, and research personnel blinded to group allocation entered and continuously monitored the data.

The conventional pain therapy treatment by treating physicians was not influenced by the study, but needed be documented by the participants in their pain diary. Ongoing additional therapies that were not excluded by inclusion/exclusion-criteria were allowed. All participants were asked to maintain their routine activities and not to begin any other new exercise or active pain management program during the study period.

Interventions

Patients were asked to participate once a week over a period of 8 weeks according to their allocated treatment in a 75-minute 1) yoga class, 2) eurythmy therapy group or 3) physiotherapeutic exercises. Each session was structured as follows: 5 minutes social welcome and accommodation phase, 60 minutes for intervention practices, 5 minutes for relaxation and resting, 5 minutes for farewell. The groups consisted of max. 13 participants per group. The interventions have been described in detail in the study protocol and in the supplemental files.⁵ All therapists were highly qualified in their respective fields and had longstanding professional experience. Each study center provided two to three teachers for each intervention.

Participating therapists consented on a set of 'standard exercises', which were compiled in a treatment manual for each intervention (Supplement 1/2). Additionally, there was an option to implement specific individual exercises for a patient, if necessary, in each group. The basic exercises for the three interventions were defined by a consensus process. Throughout the program, participants were encouraged to continue their practice at home for at least 15 minutes per day according to an instruction handbook (Supplement 2).

Yoga

Patients were taught by certified BDY (Berufsverband der Yogalehrenden in Deutschland e.V. – Professional Association of Yoga Teachers in Germany) yoga instructors. The classes focused on postures that, according to yoga tradition, are supposed to alleviate back pain, particularly standing poses, back/forward-bends and inversions. Examples of physical postures/exercises are: raising/lowering arms, actively sitting down/standing up, asymmetric bending down/up; half crouch; back-greeting sequence; stretching the back leg muscles using the stool, standing scale, tiger breathing variation 1/2, hover quadrupeds, circling hands, grasshopper, deep push-up, side plank, shoulder bridge, 'Apanasana', abdominal breathing, relaxing body journey, the stretching dog, cow/horse and leaning forward, rose tree/reed, buddy breathing & cooling breath (Sitali/Sitkali). Each yoga class ended with 5 minutes of meditation in Savasana.

Eurythmy Therapy

Eurythmy therapy is a treatment of anthroposophical medicine based on the observations of physiological, neurological, psycho-motoric and mental processes that can be made while expressing sounds. The resulting whole body movements amplify these processes and thus lead to specific effects so that they can be used in order to treat diseases, thereby addressing somatic, mental and emotional aspects. In eurythmy therapy, the participants are taught to move and inwardly feel specific movements and gestures (in terms of an 'inner picture' which might be associated with emotions and memories) which are intended as an expression of sounds (ie, accompanying vowels and consonants).^{4, 32}

It is said that 'the exercises direct the patient's attention to their own mentally experienced intentionality when performing the exercises'.⁴

The following exercises were practised: contraction/expansion, bending and stretching, 'M' movement with the back, cradle, 'M' with the shoulders, arms, and legs, 'L' movement in the vertical, and horizontal, the spine – L, 'L' with the whole body, 'R', 'S', 'C', 'D', 'I'.⁵ The M for example is a calming movement with different variations. It starts with standing upright, the arms move in opposite directions, one arm forward, the other towards the body (the arms could be moved also with the palms up to shoulder height, than turning the palms and lower the arms again). To practice the undulating movement L, one spreads the arms up in one swing (with a feeling of easiness) and moves them sideward down in an arc, with a feeling of gravity (palms down); then the arms wave from bottom to top; at that time, one stands on the toes with knees together (x-legs); when loosening the arms, loosen the leg posture again, etc. The R is a lively rotating movement that starts with standing upright with one foot in front, while the angled arms rotate dynamically from back to front downwards; at that time the knees are bent and stretched. The D is a movement forward in three steps: Hands are stretched over the head and then lowered with tonus to the breast level then slightly relaxed followed by further lowering with tonus to diaphragm level (forearms forward) then slightly relaxed and finally lowered with tonus to hip height with final relaxing. Every relaxation is linked with a slight upward movement of the hands. During the boldly calming and controlled S movement the hands are at head level (palms in front), legs from an O. Then one performs an S movement with both arms (mirror image) from top to bottom; at that time, one jumps with O-shaped legs. The end of this movement is a position with angled elbows that is finally dissolved. The outstretched gesture I is intended to strengthen the back and starts with stretching the right arm up and the left arm down then short relaxing; then stretching the right arm diagonally up and the left arm down, and back to the starting position and short relaxing; then stretching the right arm diagonally down and the left arm up, and back to the starting position and short relaxing; finally stretching the right arm down and the left arm up. These movements are followed by a swing of straight arms sideways up and down (one arm up, the other down). The number of movements with the arms is followed by a movement of the legs which are alternately stretched forward, back to baseline position, stretched sideways, back to baseline position and backwards each followed by centered relaxing (with an intermediate step or in place). Sequences of the respective movements are shown in detail in Tapfer and Weißkircher.³³

Physiotherapy

The physiotherapy exercises in particular aimed at strengthening the pelvic muscles, the gluteal muscles, the proximal leg muscles as well as the dorsal, ventral

and lateral trunk muscles, and at stretching the hip flexor muscles in order to improve body tension, body awareness, and spinal stabilization. Thereby it was intended to treat the most common muscular imbalances (stretching of shortened muscles and training of weak muscles) in humans. The physiotherapy exercise program could be performed with the individual body weight and without having to use any additional tools with the exception of a chair and a gym mat.

In all three groups, the participants were encouraged to perform a daily 20 minute home training. A booklet showing the exercises for home training was handed out together with a daily logbook to note their home exercise, the average intensity of pain (on a numerical rating scale), pain medication, and on a five graded smiley scale to indicate wellbeing.

Sample Size and Statistical Analysis

Our primary goal was to determine whether or not eurythmy therapy and yoga, when added to standard care, would be more effective than standard physiotherapy. As we did not have any data at the time to estimate what difference to expect between the treatment conditions, we elected to power the study to be able to detect at least a 0.6 effect size difference between the groups, based on the findings from a pilot study comparing eurythmy therapy to conventional therapy.¹² Using the standard parameters of $\alpha = 0.05$ for a one-sided test (superiority) and a power of 80% ($\beta = 0.20$), the optimal sample size for an individually randomized study is $n = 75$ per group. However, as participants were planned to receive the yoga / eurythmy lessons in groups of up to six participants, an additional design effect (DE) for intra-class correlations (ICC) found in "individually randomized group treatments" must be taken into account.²³ Following Morone et al.,²² the empirically derived ICC four the endpoint used also here is 0.01 to 0.02, why we (conservatively) used 0.02, resulting in a $DE = 1.1$ and thus an increased sample size of $n = 75 \times 1.1 = 83$. With a presumed drop-out rate of 10%, a total of 274 patients were recruited.

Outcomes were analysed on an intention-to-treat (ITT) base. In order to check whether outcome and demographic baseline measures were balanced among intervention groups, comparisons were conducted with analyses of variance (ANOVA) or chi-square tests. General linear models (GLM) were applied separately for visit 1 and visit 2 and the factor 'intervention group' was binary coded to evaluate the effect of yoga and eurythmy therapy compared to physiotherapy on primary and secondary outcome variables. Treatment effects were adjusted by including baseline outcome values as covariates in the model. The 95% confidence intervals (CI) of treatment effects with corresponding P -values and Cohen's d effect size estimates were calculated. All statistical analyses were performed using SAS software (Version 9.4, SAS Institute) and P -values < 0.05 were considered significant. Missing values were replaced by multiple imputation with correlation models according to the Markov-Chain-Monte-Carlo

method. No restrictions were imposed on the value range of the imputed results.

Results

715 patients responded to the study advertisement (Fig 1, flow chart). 384 individuals declined participation, citing unavailability because of scheduling problems, time demands, travel requirements or unspecified reasons. 331 patients were assessed for eligibility at the study centres, of which 33 patients were excluded. 298 patients fulfilled all entry criteria and were enrolled into the study. 24 patients were early dropouts (physiotherapy $n = 17$ and eurythmy therapy $n = 7$) and did not fill out the baseline questionnaires and were excluded. Participants were recruited between October 2012 and November 2014 and were randomly allocated to yoga ($n = 100$), eurythmy therapy ($n = 92$) or physiotherapy ($n = 82$) and included in the ITT analysis ($n = 274$). Overall, 205 patients (75%) completed V1, 179 (65%) completed V2. There were no significant differences between the interventions concerning the dropout rate.

Baseline Characteristics

Participants' ages ranged from 20 to 70 years (mean age 54.6 ± 11.3 years) (Table 1), about two third of the participants were female. Baseline characteristics were balanced between groups. Patients had approximately on average 14 years back pain and reported approximately 50 mm on the 100 mm VAS low back pain and pain-related bothersomeness. Approximately half of the participants in the yoga and eurythmy groups used pain medication in the last four weeks for their pain, in the physiotherapy group 35%.

Outcomes

In all groups, the primary outcome RMDQ showed no significant between-group differences in the general linear models at visit 1 and 2 (Table 2, Fig 2). However, RMDQ at V1 showed within group reductions of -1.24 CI 95%: $[-2.13, -0.36]$, $P = .006$, $d = -0.28$ with yoga, -0.45 $[-1.22, 0.33]$, $P = 0.256$, $d = -0.12$ with eurythmy therapy and -1.33 $[-2.27, -0.39]$, $P = .006$, $d = -0.31$ with physiotherapy (Table 2). At V2 the RMDQ decreased further and again comparable (yoga: -1.63 $[-2.66, -0.60]$, $P = .002$, $d = -0.31$, eurythmy therapy: -1.79 $[-2.79, -0.78]$, $P = .001$, $d = 0.36$ and physiotherapy: -1.57 $[-2.62, -0.52]$, $P = .004$, $d = -0.32$). In the three study centers there were no significant between-group differences regarding the primary outcome RMDQ. The distribution of the participants in the centers are shown in Table 3.

Overall, also the secondary outcomes showed no significant between-group differences, but comparable improvements of symptoms, function and quality of life in all three intervention groups (Table 2, Fig 1). Within the groups there were more pronounced improvements of pain severity and pain bothersomeness by yoga and physiotherapy, of physical quality of life (SF-12 physical score) by physiotherapy and eurythmy therapy, and of

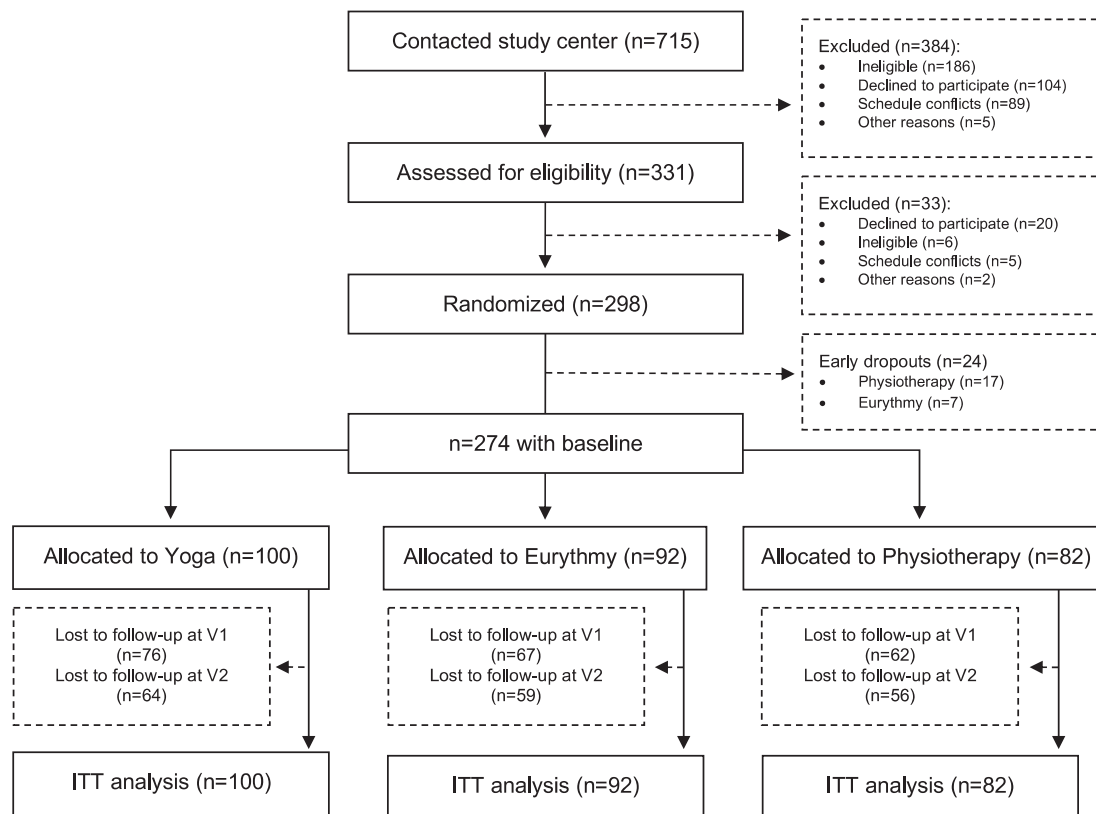


Figure 1. Trial flowchart

life satisfaction by eurythmy therapy (Table 2). Furthermore, significant within-group improvements of SF-12 mental score were found for yoga and eurythmy therapy only, but not for physiotherapy.

Further explorative analysis by general linear models with physiotherapy as reference pointed to a possible therapeutic advantage of eurythmy therapy in the SF-12 mental score at V1 and V2 (Table 4). For all other parameters, there were no significant differences at V1 and V2 regarding the interventions.

Adherence

Adherence to yoga classes was moderate, with participants of yoga visiting 5.7 ± 2.7 (Median (M): 7; interquartile range (IQR): [4; 8]), participants of eurythmy therapy visiting 6 ± 2.7 (M: 7; IQR: [4; 8]) and participants of physiotherapy visiting 6.1 ± 2.5 (M: 7; IQR: [5; 8]) of eight offered classes. There were no significant differences between the interventions concerning adherence.

Safety

Adverse events were mostly mild and self-limited exacerbating back pain ($n = 25$ in physiotherapy, $n = 7$ in yoga and $n = 3$ in eurythmy therapy), general pain ($n = 15$ in physiotherapy, $n = 4$ in yoga and $n = 4$ in eurythmy therapy) and muscle pain ($n = 8$ in physiotherapy, and none in yoga group and eurythmy therapy). There were in total significantly more adverse events in the physiotherapy group compared to both other

interventions ($P < 0.001$). Causal connection of above mentioned adverse events with physiotherapy: $n = 5$ none, $n = 1$ unlikely, $n = 17$ possible, $n = 12$ probable, $n = 4$ secured, $n = 9$ unclear. Causal connection of above mentioned adverse events with yoga: $n = 1$ none, $n = 1$ unlikely, $n = 7$ possible, $n = 1$ probable, $n = 0$ secured, $n = 1$ unclear. Causal connection of above mentioned adverse events with eurythmy: $n = 4$ none, $n = 0$ unlikely, $n = 2$ possible, $n = 0$ probable, $n = 0$ secured, $n = 1$ unclear.

Discussion

In this study no superiority of yoga or eurythmy therapy over physiotherapeutic exercises could be demonstrated. The primary outcome, patients' physical disability (RMDQ) showed no significant between-group differences. Also the secondary outcomes showed no significant between-group differences, but comparable improvements of symptoms, function and quality of life in all three intervention groups. The within group effect sizes were small to moderate, but did not reach clinical meaningfulness on RMDQ (reduction under 30% from baseline). Furthermore, there appeared to be a benefit for eurythmy therapy to improve the SF-12's mental health component in the general linear model when compared to physiotherapy. Results showed significant within-group improvements in the SF-12 mental score and were observed for yoga and eurythmy therapy only, but not for physiotherapy. Thus, yoga and

Table 1. Baseline characteristics

CHARACTERISTIC	YOGA(N = 100)		EURYTHMY(N = 92)		PHYSIOTHERAPY(N = 82)		P-VALUE
	MEAN	(SD)	MEAN	(SD)	MEAN	(SD)	
Age (years)	53.9	(10.7)	56	(9.8)	53.9	(13.4)	.35
Pain duration (years)	14.9	(12.6)	14.3	(13.2)	14.3	(12.7)	.94
BMI	26.8	(5.1)	26.1	(6.0)	26.0	(4.7)	.51
Systolic blood pressure	130.0	(17.6)	127.5	(15.6)	124.5	(13.9)	.08
Diastolic blood pressure	81.5	(8.4)	81.4	(8.5)	80.6	(8.0)	.77
Questionnaires							
RMDQ	9.1	(4.5)	9.6	(4.8)	8.7	(4.3)	.45
VAS Pain severity	50.6	(12)	50.1	(14.9)	51.0	(13.6)	.90
VAS Pain bothersomeness	50.2	(15.5)	45.9	(16.7)	48.2	(12.5)	.15
SF-12 Physical score	38.4	(8.6)	37.3	(8.7)	39.0	(8.1)	.49
SF-12 Mental score	42.9	(11.1)	43.9	(11.9)	44.4	(11.4)	.74
BMLSS	58.7	(17.7)	64.7	(17.2)	62.9	(17.7)	.06
Treatment expectation	56.6	(16.8)	59.5	(16.6)	53.6	(17.5)	.66
	n	(%)	n	(%)	n	(%)	
Gender							
Female	64	(64.0)	69	(75.0)	54	(65.9)	.23
Male	36	(36.0)	23	(25.0)	28	(34.2)	
Education							
Secondary school	18	(18.0)	21	(22.8)	23	(28.1)	.61
Comprehensive school	25	(25.0)	24	(26.1)	19	(23.2)	
Grammar school	39	(39.0)	35	(38.0)	25	(30.5)	
Other	14	(14.0)	11	(12.0)	14	(17.1)	
Missing	4	(4.0)	1	(1.1)	1	(1.2)	
Marital status							
Married	48	(48.0)	52	(56.5)	48	(58.5)	.72
With partner	14	(14.0)	8	(8.7)	7	(8.5)	
Divorced	16	(16.0)	16	(17.4)	14	(17.1)	
Single	18	(18.0)	13	(14.1)	12	(14.6)	
Widowed	3	(3.0)	3	(3.3)	0	(0.0)	
Missing	1	(1.0)	0	(0.0)	1	(1.2)	
Comorbidities							
Any comorbidity	76	(76.0)	67	(72.8)	62	(75.6)	.86
Cardiovascular disease	3	(3.0)	2	(2.2)	1	(1.2)	—
Chronic pulmonary disease	5	(5.0)	5	(5.4)	3	(3.7)	—
Diabetes mellitus II	5	(5.0)	3	(3.3)	1	(1.2)	—
Hypertension	25	(25.0)	20	(21.7)	17	(20.7)	.77
Nucleus pulposus prolapse	12	(12.0)	10	(10.9)	9	(11.0)	.96
Depression	5	(5.0)	2	(2.2)	2	(2.4)	—
Thyroid disease	18	(18.0)	13	(14.1)	19	(23.2)	.30
Arrhythmia	2	(2.0)	4	(4.3)	2	(2.4)	—
Sleep disorder	3	(3.0)	1	(1.1)	1	(1.2)	—
Osteoarthritis	6	(6.0)	6	(6.5)	4	(4.9)	—
Other diseases	31	(31.0)	32	(34.7)	22	(26.8)	.86
Medication							
Any pain medication last 4 weeks	53	(53.0)	44	(47.8)	35	(42.7)	.72
NSAID	45	(45.0)	34	(37.0)	27	(32.9)	.23
Paracetamol	3	(3.0)	4	(4.3)	2	(2.4)	—
Myotonolytics	2	(2.0)	0	(0.0)	0	(0.0)	—
Mild opioids	1	(1.0)	2	(2.2)	1	(1.2)	—
Moderate opioids	5	(5.0)	10	(10.9)	3	(3.7)	—
Antidepressants	1	(1.0)	2	(2.2)	1	(1.2)	—
Anticonvulsants	2	(2.0)	3	(3.3)	0	(0.0)	—
Metamizole	7	(7.0)	4	(4.3)	6	(7.3)	—

(continued on next page)

Table 1. Continued

CHARACTERISTIC	YOGA(N = 100)		EURYTHMY(N = 92)		PHYSIOTHERAPY(N = 82)		P-VALUE
	MEAN	(SD)	MEAN	(SD)	MEAN	(SD)	
Others	6	(6.0)	4	(8.7)	3	(3.7)	–
Methods of pain treatment in the past							
Any pain treatment	92	(92.0)	84	(91.3)	71	(86.6)	.48
Medications	62	(62.0)	60	(65.2)	45	(54.9)	.36
Surgery	12	(12.0)	8	(8.7)	8	(9.8)	.74
Injections in area of pain	45	(45.0)	43	(46.7)	39	(47.6)	.94
Injections in spinal cord	17	(17.0)	19	(20.7)	16	(19.5)	.80
Neuraxial probes or pumping systems	5	(5.0)	4	(4.3)	1	(1.2)	–
Physiotherapy	78	(78.0)	68	(73.9)	59	(72.0)	.63
Massages	53	(53.0)	43	(46.7)	35	(42.7)	.37
Baths, heat and cold therapy	31	(31.0)	32	(34.8)	23	(28.0)	.63
Electrical nerve stimulation (ENS)	28	(28.0)	27	(29.3)	20	(24.4)	.75
Acupuncture	46	(46.0)	35	(38.0)	25	(30.5)	.10
Chiropractic	34	(34.0)	32	(34.8)	14	(17.1)	.02
Psychotherapy	13	(13.0)	11	(12.0)	8	(9.8)	.79
Relaxation techniques, hypnosis, biofeedback	31	(31.0)	23	(25.0)	19	(23.2)	.45
Rehabilitation	28	(28.0)	29	(31.5)	19	(23.2)	.47

Means and standard deviations (SD) or numbers (n) and percentages (%) of baseline characteristics. *P*-values of *F*-tests for therapy group mean comparisons or *p*-values of chi-square tests for therapy comparisons of categorical variables. The chi-square test was not calculated (-) if the cell count was less than 5 in at least one of the therapy groups

BMI = body mass index; NSAID = non-steroidal anti-inflammatory drugs; RMDQ = Roland Morris Disability Questionnaire; VAS = visual analog scale; SF-12 = health-related quality of life Short Form 12; BMLSS = Brief Multidimensional Life Satisfaction Scale

eurythmy therapy may have more impact on psychological parameters. However, this was only analysed exploratively with a relatively high probability of false-positive results. Baseline scores of RMDQ and SF-12 were in a range that commonly regarded to indicate reduced health-related quality of life due to low back pain.

Current evidence for yoga for chronic low back pain is better than for any other complaint.³⁷ The effects of yoga on chronic low back pain have been studied in a recent published multicentre trial, comparing yoga, physiotherapy, and education.²⁶ A 12-week standardized yoga program was found to be non-inferior to individualized physiotherapy with respect to improvements in back-related function and pain after intention-to-treat analysis.²⁶ The yoga course showed a slightly more pronounced reduction of -3.8 (95%CI: -4.6 – -2.9) on the RMDQ (physical therapy -3.5 (95%CI: -4.5 – -2.6)). Compared to this study the magnitude of the effect in our study was smaller, although the program was delivered by trained yoga teachers. One possible explanation for the modest effect of yoga and physiotherapy in our trial is the shorter intervention (8 vs 12 weeks) and lower adherence.

In one of the most important landmark yoga studies, Sherman et al. showed that a 12-week Vini-Yoga course was more effective than a passive intervention (self-care book) for improving function and reducing low back pain.³⁰ A recent Cochrane review including more than 1000 patients concluded 'low- to moderate-certainty

evidence that yoga leads to small to moderate improvements in back-related function at 3 and 6 months compared to non-exercise (passive) controls'.³⁷ According to those studies, the effect was not dependent on the chosen yoga style. Similar results have also been found for 'Iyengar yoga', and for 'Hatha yoga', that is yoga styles that include especially physical yoga postures (asana). However, the effect sizes not reached predefined levels of minimum clinical importance. It remains unclear, whether there is any difference between yoga and other exercise for back-pain or -function, or whether yoga, added to exercise, is more effective than exercise alone.³⁷ Our results are thus in line with these findings. Further research is warranted examining the meditative components of yoga and eurythmy therapy, which may have an additional benefit particularly on mental health indicators of patients' with chronic pain syndromes.

This is the first RCT examining the effects of eurythmy therapy in patients with low back pain. A previous uncontrolled study showed positive sustainable effects of a multimodal anthroposophical treatment concept including eurythmy therapy in patients with chronic back pain even in a 2 year follow-up.^{12, 13} Eurythmy therapy as part of anthroposophical medicine, in which speech sounds and language are translated into movements, seems to have in our study similar effects as yoga and physiotherapy and showed first explorative evidence of a possible superiority in terms of mental health-related quality of life compared to physiotherapy. This is of particular interest in the context of the

Table 2. Outcome parameters

Estimated means and corresponding 95% confidence intervals (CI) of physical and mental variables differences between visit V0, V1 and V2. RMDQ = Roland Morris Disability Questionnaire; VAS = visual analog scale; SF-12 = health-related quality of life Short Form 12; BMLSS = Brief Multidimensional Life Satisfaction Scale

	YOGA (N = 100)				EURYTHMY (N = 92)				PHYSIOTHERAPY (N = 82)			
	MEAN	95% CI	P	EFFECT SIZE	MEAN	95% CI	P	EFFECT SIZE	MEAN	95% CI	P	EFFECT SIZE
RMDQ												
V1-V0	-1.24	[-2.13, -0.36]	.006	-0.28	-0.45	[-1.22, 0.33]	.256	-0.12	-1.33	[-2.27, -0.39]	.006	-0.31
V2-V0	-1.63	[-2.66, -0.60]	.002	-0.31	-1.79	[-2.79, -0.78]	.001	-0.36	-1.57	[-2.62, -0.52]	.004	-0.32
V2-V1	-0.39	[-1.11, 0.33]	.288	-0.11	-1.34	[-2.16, -0.51]	.002	-0.33	-0.24	[-1.08, 0.61]	.582	-0.06
VAS Pain severity												
V1-V0	-10.89	[-14.59, -7.2]	<.0001	-0.58	-8.05	[-11.76, -4.34]	<.0001	-0.44	-7.98	[-11.39, -4.58]	<.0001	-0.51
V2-V0	-13.29	[-16.91, -9.66]	<.0001	-0.72	-13.68	[-18.06, -9.3]	<.0001	-0.64	-13.70	[-17.71, -9.68]	<.0001	-0.74
V2-V1	-2.39	[-5.31, 0.52]	.107	-0.16	-5.63	[-9.1, -2.16]	.002	-0.34	-5.71	[-8.77, -2.65]	<.001	-0.41
VAS Pain bothersomeness												
V1-V0	-11.15	[-15.42, -6.88]	<.0001	-0.52	-5.94	[-10.21, -1.67]	.007	-0.29	-8.50	[-12.03, -4.98]	<.0001	-0.53
V2-V0	-14.23	[-18.15, -10.31]	<.0001	-0.71	-11.20	[-15.67, -6.74]	<.0001	-0.51	-15.89	[-20.18, -11.6]	<.0001	-0.81
V2-V1	-3.08	[-6.66, 0.5]	.091	-0.17	-5.26	[-8.78, -1.74]	.004	-0.31	-7.39	[-11.19, -3.59]	<.001	-0.43
SF-12 Physical score												
V1-V0	1.81	[-0.05, 3.68]	.057	0.19	2.62	[0.46, 4.77]	.018	0.25	3.39	[1.48, 5.3]	.001	0.38
V2-V0	2.31	[0.33, 4.28]	.022	0.23	4.75	[2.42, 7.07]	<.0001	0.42	4.59	[2.66, 6.53]	<.0001	0.51
V2-V1	0.50	[-1.32, 2.31]	.589	0.05	2.13	[0.17, 4.09]	.033	0.22	1.21	[-0.88, 3.29]	.255	0.13
SF-12 Mental score												
V1-V0	3.29	[0.74, 5.85]	.012	0.25	4.95	[2.17, 7.73]	.001	0.36	0.65	[-2.52, 3.83]	.684	0.05
V2-V0	3.90	[1.13, 6.68]	.006	0.28	5.13	[2.24, 8.02]	.001	0.36	1.58	[-1.26, 4.42]	.274	0.12
V2-V1	0.61	[-2.29, 3.51]	.677	0.04	0.18	[-2.6, 2.95]	.900	0.01	0.93	[-1.92, 3.77]	.521	0.07
BMLSS												
V1-V0	3.93	[0.9, 6.95]	.011	0.26	5.47	[2.66, 8.27]	<.001	0.40	4.12	[0.4, 7.85]	.030	0.24
V2-V0	4.72	[1.55, 7.88]	.004	0.29	5.66	[2.3, 9.02]	.001	0.35	2.18	[-1.6, 5.96]	.257	0.13
V2-V1	0.79	[-1.72, 3.29]	.533	0.06	0.20	[-2.37, 2.76]	.880	0.02	-1.94	[-4.97, 1.09]	.207	-0.14

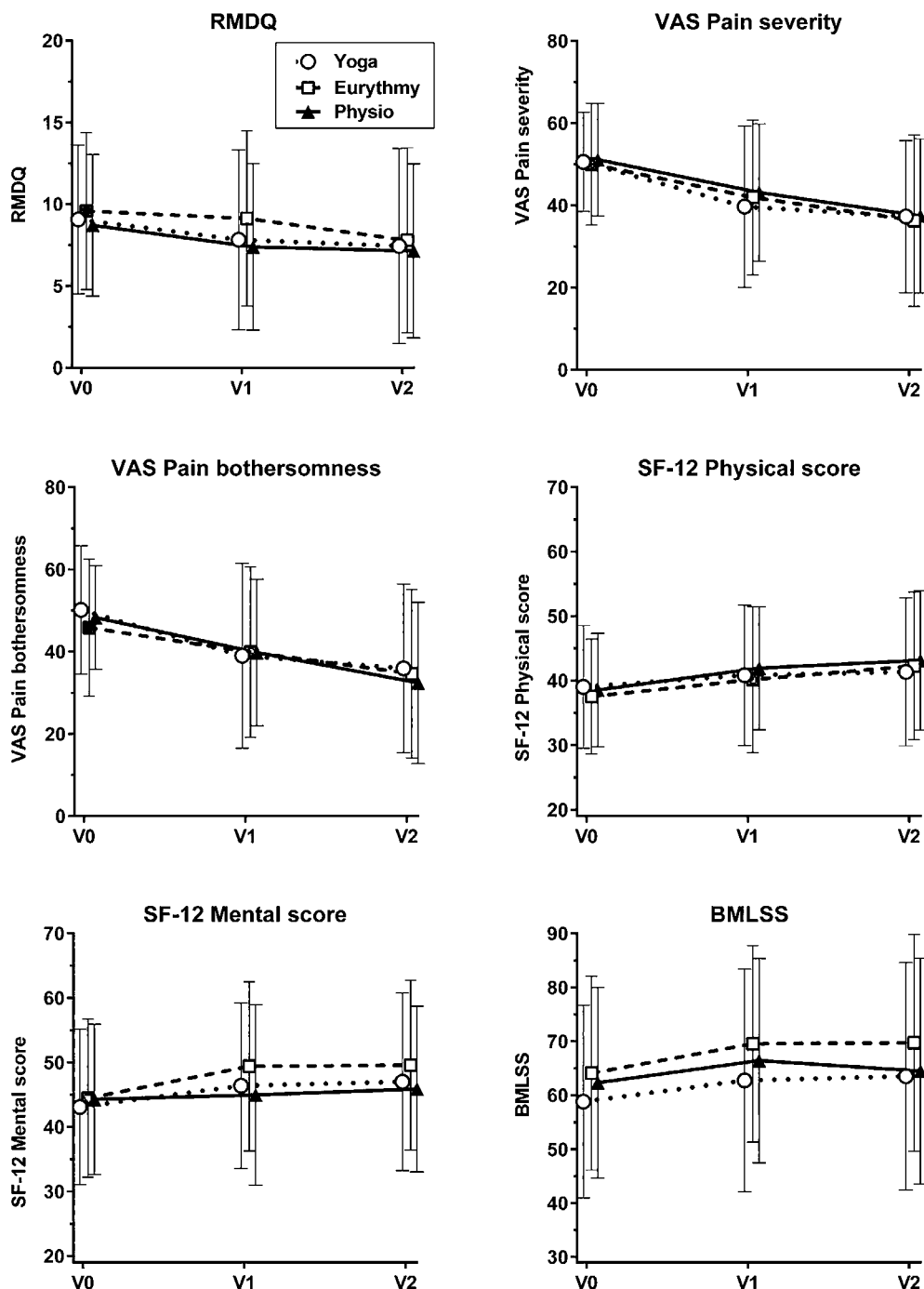


Figure 2. Means and standard deviations of outcome parameters at visit V0, V1 (after 8 weeks) and V2 (after 16 weeks)
 RMDQ = Roland Morris Disability Questionnaire; VAS = visual analog scale; SF-12 = health-related quality of life Short Form 12; BMLSS = Brief Multidimensional Life Satisfaction Scale

complexity of chronic pain disorder. More studies assessing bodily oriented exercises and underlying mechanisms of action are warranted. These studies should also consider individual characteristics and treatment moderators in obvious responders.

Our study has some important limitations. First, the drop-out rate was higher than anticipated. The high attrition rate may introduce a bias into the results, as we cannot rule out that patients dropped out due to dissatisfaction with or perceived ineffectiveness of the

study intervention. Further reasons for drop-out may be related to the randomized allocation to three clearly different study interventions. Especially in the eurythmy therapy and physiotherapy group participants reported disappointments due to their group allocation. Also, eurythmy therapy could have been recognized as a rather unknown form of therapy. Furthermore, a number of patients may have expected a faster pain relief through the interventions and experienced loss of motivation, when a pain relief did not emerge within the first weeks.

Table 3. Distribution of participants in the centers

CENTER NO.	YOGA	EURYTHMY	PHYSIOTHERAPY	TOTAL
	N	n	n	n
1	48	40	35	123
2	6	7	5	18
3	46	45	42	133

Center no. 1: Charité outpatient department for Integrative Medicine at Immanuel Hospital, Berlin, Germany; center no. 2: Research Institute Havelhöhe with Gemeinschaftskrankenhaus Havelhöhe, Berlin, Germany; center no. 3: Institute of Integrative Medicine, Witten/Herdecke University, with Gemeinschaftskrankenhaus Herdecke, Herdecke, Germany.

Moreover, patients did not receive any reward for filling out the questionnaires and this may have decreased their motivation to participate in an 8-week study and 16 weeks of follow up. In summary, we cannot fully explain the high dropout rate in our study and the results have to be interpreted prudently. Second, it is unclear what effect the individual pain medication may have had on the study results. We assessed pain medication and duration of practice in a diary, but most patients (>80%) were incompliant to complete the diary; thus, we decided to not perform the analysis due to lack of data. In the baseline assessment patients of the physiotherapy group had non-significant fewer pain medication in the last 4 weeks in comparison to yoga and eurythmy therapy. Third, we do not collect any data regarding the socio-economic background. Fourth, the study did not have a minimal treatment or waiting list control group, thus we cannot estimate the absolute effects of any of the three active interventions. The effects might be the natural course of the disease and/or patients might have variable pain.

Fifth, the physiotherapy approach used to represent physiotherapy exercises is one of many different approaches used to treat back pain, and the evidence supporting the approach used in this trial is weak or unknown. Sixth, no procedures were used to ensure treatment compliance. Seventh, this trial was not adequately powered to directly test non-inferiority or equivalence of yoga or eurythmy to standard physiotherapy. In hindsight, we have to admit that our original decision to design the study as a superiority study (without waiting list control group) was not appropriate for a number of reasons. First, in examining the data available at the time, including those presented by Hamre et al. (2007)¹², the evidence for even a medium effect of eurythmy therapy over other pain treatments was very limited. Second, the absence of a fourth arm (ie, usual care only; or usual care with waiting) and the lack of diary data on usual care means that some or all of the observed improvement could be due to usual care, the natural history of chronic low back pain, or the Hawthorne effect.

Table 4. General linear models

DEPENDENT VARIABLE	PARAMETER (REFERENCE= PHYSIOTHERAPY)	VISIT V1				VISIT V2			
		β	95% CI	P-VALUE	EFFECT SIZE	β	95% CI	P-VALUE	EFFECT SIZE
RMDQ	Eurythmy	1.09	[-0.14, 2.32]	.081	0.13	0.06	[-1.34, 1.47]	.928	0.01
	Yoga	0.18	[-1.05, 1.4]	.778	0.02	0.05	[-1.28, 1.39]	.937	0.01
VAS Pain severity	Eurythmy	-0.53	[-5.24, 4.18]	.826	-0.02	-0.55	[-6.18, 5.07]	.847	-0.01
VAS Pain bothersomeness	Yoga	-3.13	[-7.97, 1.71]	.204	-0.09	0.14	[-5.27, 5.54]	.960	0.00
	Eurythmy	1.49	[-3.98, 6.95]	.593	0.04	3.40	[-2.37, 9.17]	.247	0.09
SF-12 Physical score	Yoga	-1.84	[-7.37, 3.69]	.512	-0.05	2.63	[-3.08, 8.33]	.366	0.07
	Eurythmy	-1.07	[-3.85, 1.72]	.450	-0.06	-0.17	[-3.09, 2.75]	.910	-0.01
SF-12 Mental score	Yoga	-1.44	[-3.85, 0.97]	.241	-0.09	-2.13	[-4.81, 0.54]	.118	-0.12
	Eurythmy	4.38	[0.71, 8.04]	.020	0.18	3.64	[0.22, 7.06]	.037	0.16
BMLSS	Yoga	2.07	[-1.61, 5.74]	.268	0.08	1.67	[-1.98, 5.32]	.367	0.07
	Eurythmy	1.84	[-2.24, 5.91]	.376	0.07	3.92	[-1, 8.85]	.118	0.12
	Yoga	-1.16	[-5.55, 3.22]	.601	-0.04	1.66	[-3.05, 6.37]	.488	0.05

General linear models (SAS Proc GLM) with Roland Morris Disability Questionnaire Questionnaire (RMDQ), pain severity scale, day life impairments scale, SF-12 mental and physical score, and Brief Multidimensional Life Satisfaction Scale (BMLSS) as dependent variables. Therapy (reference=physiotherapy) as factor variable. Analyses adjusted with the baseline value of the corresponding dependent variable. Model coefficient (β) with 95% confidence interval (CI) and P-value of F-Test.

RMDQ = Roland Morris Disability Questionnaire; VAS = visual analog scale; SF-12 = health-related quality of life Short Form 12; BMLSS = Brief Multidimensional Life Satisfaction Scale

Strengths of our study include the use of recommended and validated assessment tools and outcome measures, well-defined inclusion/exclusion criteria, and consented exercises in all three interventions arms.

Only minor adverse events possibly associated with the interventions were described. The interventions can be regarded as safe.

Conclusion

In conclusion, we found that neither yoga nor eurythmy was superior to standard physiotherapy. Although all therapies improved chronic low back pain, it is unclear whether any of the three interventions provided clinical benefits in addition to the usual care that was being obtained. Modest improvements in all groups were found and these improvements were maintained up to the 16 weeks follow-up. All interventions were safe. Exploratory analysis showed advantages of yoga and eurythmy therapy on mental health indicators

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which may serve as a rationale to further explore the clinical potentials and limitations of both interventions.

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Supplementary data

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