J Rehabil Med 2019; 51: Epub ahead of print

ORIGINAL REPORT

THERAPEUTIC AND ECONOMIC EFFECTS OF MULTIMODAL BACK EXERCISE: A CONTROLLED MULTICENTRE STUDY

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Objective: **To compare the cost-effectiveness of a multimodal back exercise programme for non-specific back pain with that of standard treatment. Medical costs were measured in euros (EUR) and effectiveness was measured using Graded Chronic Pain Status (GCPS).**

Design: **A controlled multicentre study (39 sites) with a 6-month intervention phase and follow-up at 6, 12 and 18 months.**

Subjects: **The study included 1,829 participants in an intervention group and 495 individuals in a control group.**

Methods: **The multimodal back exercise programme comprises 36 exercise sessions for optimizing the spine stabilizing muscles and everyday motor functions. The patients were given a home training programme at the end of the intervention programme.**

Results: **The back exercise programme resulted in a significant reduction, of 0.4, in back pain grade on the GCPS after 2 years, compared with standard treatment, and reduced medical costs by 763 EUR. The exercise programme was therapeutically effective for GCPS back pain grades 1–4 and produced cost savings in the case of grade 4 GCPS.**

Conclusion: **The multimodal back exercise programme was therapeutically effective for back pain (grades 1–2) and pain-related functional impairment (grades 3–4). It resulted in reduced costs for chronic back pain causing high pain-induced functional impairment (grade 4). The therapeutic and economic effects of the programme increase with the grade of back pain.**

Key words: cost-benefit analysis; back pain; exercise.

Accepted Sep 18, 2018; Epub ahead of print Nov 8, 2018

J Rehabil Med 2019; 51: 00–00

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LAY ABSTRACT

This study compared the cost-effectiveness of a back exercise programme for different levels of back pain with standard treatment. The back exercise programme resulted in a reduction in back pain after 2 years compared with standard treatment. Moreover, the exercise programme resulted in reduced medical costs. The back exercise programme was found to be therapeutically effective and cost-efficient. The therapeutic and economic effects of the programme increased with severity of back pain.

Back pain is the cause of more years lived with disability (YLDs) than any other disorder (1). With a monthly prevalence of 23% worldwide (2) and a lifetime prevalence in Western industrial nations exceeding 70% (3, 4), back pain incurs high direct and indirect medical costs (5–7).

In 80–90% of cases, back pain progresses favourably, and patients return to work within 6–8 weeks. Sixty percent of patients are pain free within the first 4 weeks. The 8–10% of patients who develop chronic back pain significantly increase the direct and indirect costs (8, 9). The high socioeconomic importance of back pain contrasts noticeably with a lack of knowledge about the cost-effectiveness of different interventions, and it does so against a background of tightening healthcare resources. Exercise is one of the interventions viewed as effective against chronic back pain. However, what we know about it is very general in nature: no one type of exercise is regarded as superior (10). Despite years of research, we do not yet know which exercise to favour, with how many exercise sessions, and with what intensity. Specifically, we do not know if the therapeutic and economic effects also vary with the severity of the back problem (11).

AOK Baden-Wuerttemberg, a major German statutory health insurer, since 2005 has provided insured individuals who experience back pain with a multimodal (strength/mobility and ergonomic) back exercise programme. Approximately 30,000 patients enrol in this programme annually. The goal of the present study was to determine how the benefit from this exercise

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Journal Compilation © 2019 Foundation of Rehabilitation Information. ISSN 1650-1977
doi: 10.2340/16501977-2497

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programme compared with standard care, and the effect of the programme on direct and indirect medical costs. A further aim was to examine how the health and economic effects correlate with back pain severity, as measured with the Graded Chronic Pain Status (GCPS).

METHODS

Study design

This controlled multicentre study, with follow-up at 6, 12, 18 and 24 months (t0, t1, t2, t3, t4), examined the cost-effectiveness of 6 months of multimodal back exercise (BE) compared with standard treatment (ST). Participants in the intervention group underwent BE in addition to the mandated health insurance services that collectively make up ST. The control group participants underwent only ST.

The study is categorized as a healthcare research study, since the exercise programme is a health insurance benefit offered by the insurer at 39 locations in the German state of Baden-Wuerttemberg. The control group was generated from surveys and adjusted via matching (see below). The ethics application submitted to the University of Greifswald's Ethics Commission (ID 33/08) was approved unconditionally on 3 June 2008.

Study participants

Prerequisites for participation in the back exercise programme included having a prescription or a preventive referral from the attending physician. Prescription indications include spinal syndromes with pronounced symptoms. Contraindications are acute back pain or back disorders, specifically, and conditions that preclude physical exercise.

Patients with this prescription can sign up at one of 39 back clinics in Baden-Wuerttemberg. During the period from 1 October 2007 to 31 March 2008, patients signing up for the exercise programme were invited to join the study. A total of 2,444 individuals agreed in principle to take part. For each of these participants, a statistical twin was selected from routine data (cost and demographic data) from a reduced data sample (n=348,000, randomly selected) provided by the insurer (see Table I).

Individuals interested in participating in the investigation and the selected statistical twins were invited by letter to join the pseudonymized study. Inclusion criteria were: a GCPS status (11) of at least grade 1, and a completed data-set of the questions used for constructing the GCPS. For the economic evaluation, we excluded from the study all survey subjects not covered by the insurer for the entire duration of the study (due to cancellation or death), since the study aimed to compare pre-intervention medical costs during the 2 years before the start with 2 years of post-intervention costs.

Table I. Criteria for the first round of matching

Variable	Deviation
Age	±2 years
Sex	Match
Insured type	Match
Work status	Match
Sum of medical costs for the two years preceding the start of the intervention (baseline)	±30 %
Medical costs related to back pain for each of the four half years preceding the start of the intervention separately (baseline)	Select statistical twin with the least sum in the absolute deviation across all cost areas in each four half years preceding the start of the intervention

After gathering the survey data, a second matching, which included the GCPS (11), was performed. The second matching was required because of significant differences among the study groups relative to the success criteria (GCPS, back treatment costs, work days lost due to back problems) and the standardized differences in part also exceeded 10%. Due to the small number of control group participants, weighted propensity score matching was performed (12, 13). Matching was by age, sex, direct medical cost categories, direct back disorder cost categories, and work days lost due to back problems. No calliper was set.

Cost outcomes

The cost data are based on routine data supplied by the insurer. They were pseudonymized for the study by the insurer's in-house information technology department. Costs are net costs without co-payments by the insured.

The *direct costs* comprise all relevant cost areas, including charges for the BE. The BE charges cover the cost of leasing the exercise machines, exercise centre administrative costs (as fixed by administrative regulation cost schedules) and personnel costs. The direct back disorder medical costs are based on costs in the M40–M54 diagnostic index. Outpatient costs are not included in the direct back disorder medical costs, since pinpointing costs based on the diagnostic index codes was not feasible in this case. Direct costs also do not include costs of therapeutic appliances, since they are irrelevant for this disorder. The *individual* exercise costs were calculated based on the individual number of training sessions. The cost of a training session is the quotient of the total cost of the back exercise programme divided by the number of training sessions.

To calculate the drug and therapeutic costs, we selected drugs commonly prescribed for back pain (including, but not limited to, corticoids for systemic application, antiphlogistics and antirheumatics (M01A/B), muscle relaxants (M03), and health aids (physiotherapy, massage, among others)) (Table II).

The *lost productivity costs* were calculated by the human capital method, based solely on the number of sick leave days and using data produced by the Federal Institute for Occupational Safety and Health for the years 2006–09 (14–17).

Therapeutic outcomes

For the survey, we used the GCPS (11). It contains 7 questions on the dimensions of pain intensity and pain-induced functional impairment in daily life, leisure, and work. For each dimension, back pain is presented as divided into 5 grades (no pain, low pain intensity, high pain intensity, moderate functional impairment, and severe functional impairment).

In GCPS grades 1 (low pain intensity) and 2 (high pain intensity), the back pain intensity as graded does not yet significantly impact daily life, leisure, and work functions. The last 2 grades are differentiated by the degree of functional impairment. Although they are constructed exclusively according to the severity of the functional impairment, the pain intensity dimension also increases in both. The direct and indirect medical costs also increase concomitantly with the GCPS (18).

Back exercise programme

The multimodal BE programme consists of dynamic strength training of the trunk stabilizers and neck muscles, functional gymnastics exercises, stretching and exercises in everyday motor activity (sitting, standing, lifting loads).

Each group of 5 exercisers is supervised by a trainer. The complete exercise programme comprises 36 training sessions

Table II. Cost areas of direct and indirect medical/back disorder costs (ICD = international classification of diseases, ATC-Codes = Anatomical Therapeutic Chemical/Defined Daily Dose Classification)

Cost areas	Medical costs	Back disorder costs
Direct medical costs		
Hospital charges	ICD: all	ICD: M40–54
Rehabilitation charges	ICD: all	ICD: M40–54
Sick pay	ICD: all	ICD: M40–54
Outpatient charges	ICD: all	-
Outpatient charges Cure/ Rehabilitation/outpatient surgery	ICD: all	-
Exercise charges	Exercise costs per exercise session (2008: 14.09 EUR, 2009: 13.64 EUR)* number of training sessions	-
Therapeutic aid charges	all	Hydrotherapy/Med. baths, Traction therapy, movement exercises, electrotherapy, physiotherapy, machine-aided medical gymnastics, complex services D1-KG, non-specific massages, non-specific packs
Drug charges	ATC-Codes: all	ATC-Codes: H02, M01A, M01B, M02, M03, N01B, N02A, N02B, N03AX12, N06AA
Indirect medical costs		
Lost productivity costs	ICDs: all sick leave days* lost productivity costs per day	ICDs: M40-54 sick leave days* lost productivity costs per day

(TS) spanning 24 weeks. The core of the exercise programme consists of dynamic strength/mobility training. During the first 12 weeks, 2 exercise sessions take place per week (basic exercises in 4 stages, see Table III); in the second 12 weeks (maintenance training), this reduces to 1 session per week. Each exercise session lasts 1 h, during which the strength and mobility of the trunk stabilizers and the neck muscles are exercised on 5 machines (19): the DAVID® F110, 120, 130, 140, and 150 (DAVID® Health Solutions, Helsinki, Finland).

In the basic training stage, the exercising follows the 1-set principle, i.e. 1 exercise set is completed on each machine. During maintenance training, 2 sets are performed per exercise machine. The intensity is calculated and set on the machine to achieve maximal strength results (maximum voluntary contraction; MVC). The muscle group just trained is stretched before moving on to the next machine.

The exercises aim to reduce muscular imbalance, improve circulation in muscle/joint structures, and increase the strength and mobility of trunk stabilizers and neck muscles. Prior to starting BE and after the basic and maintenance exercises, biomechanical function analysis of the spine is performed. Mobility and maximal strength measurements are taken from the exercise machines and related to standard values for age and sex (20). The resulting strengths/weaknesses profile is incorporated into the training plan: the weakest muscle group is exercised first and, in case of pronounced muscular imbalance, the weaker side (left/right) or the weaker antagonists (extensors/flexors) are worked more intensively.

In the ergonomic exercises, proper spinal seating posture (frequent change of position, keep moving) as well as spine-friendly work and lifting techniques are taught and practiced (approximately 5 min per exercise session, for a total of 3 h).

Starting with the 13th session, an exercise programme is taught for transferring the functional gymnastic exercises to the home for daily use. It is supported by a training manual (or DVD) designed to teach back-friendly behaviour in daily life and the workplace. The home exercises must be continued independently following the formal training in order to sustain the improvements achieved.

Table III. Back exercise program stages

Phase	Week	TS per week	Training intensity (MVC), %	Repetitions
Orientation	1–4	2	< 30	35
Adjustment	5–6	2	40–60	25
Strength	7–9	2	70–80	15
Optimization	10–12	2	80–90/40–60*	12/30
Maintenance program	13–24	1	1st set: 30–40	30
			2nd set: 80–90	12

*weekly change of training intensity

Statistical analyses

The study is based on the intention-to-treat (ITT) principle. Similar to an ITT evaluation in an RCT, the study participants remain in their initial groups and are considered in the analyses regardless of whether they actually participated in the intervention.

Disparities among the studied groups in the differences between means of the indirect and direct medical costs were checked with univariate analyses of variance (ANOVA). For the 3-fold interactions time*treatment*GCPS and time*treatment*direct medical costs, repeated measurement ANOVAs were used to determine whether the back exercise has a significant effect on the changes in back pain and the direct medical costs. Binary data (sex) were checked with the χ^2 test. The cost-effectiveness of different back pain severity grades (GCPS) was arrived at by calculating the individual net monetary benefit (NMB). For this, the maximum willingness to pay (MWTP=λ) for a reduction of 1 GCPS grade λ is multiplied by the individual effectiveness (ΔE: pre- minus post-GCPS value) and the changes in direct medical costs (ΔC: post- minus pre-direct medical costs) are subtracted from this product:

$$NMB_i = \lambda * \Delta E_i - \Delta C_i.$$

The difference between means of BE and ST for different MWTPs were then tested with ANOVA. By iteration, the MWTP values that resulted in significant differences between means were determined. The NMB represents the individual monetary benefit at a specified maximum willingness to pay λ. It exhibits all the stochastic properties of a normally distributed random variable (21–23). Unlike in the case of the incremental cost-effectiveness ratio (ICER), for the NMB the maximum willingness to pay is also considered. The statistical processing of the data is facilitated, since costs and effects are brought into linear form by a quotient (24). All analyses were performed with propensity score weights. The analyses were run using IBM SPSS release 22, including the SPSS propensity score matching extension by Thoemmes (12).

RESULTS

Study participants

Of 2,444 intervention subjects contacted in writing from 2008 and 2010, 1,942 agreed to take part in the

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study. A final total of 1,829 intervention participants were included in the study (Fig. 1). Of the 2,444 contacted insured persons, 978 agreed to join the control group. After excluding 163 study participants, and following matching, a total of 495 remained in the control group (Fig. 1).

Adjustment of the control group with propensity score matching for time t0 resulted in good comparability of the treatment groups (Table IV). Except for sex (χ^2 (1) (n=2,319)=4.66, p<0.035), no significant differences emerged and all standardized differences were <0.1. Complete cost data were available for all measurement time periods. The response rate for the individual measurement points for questionnaire data (GCPS) ranged between 64% (t6) and 51% (t4). The study participants were preponderantly female (ST 64%, BE 58.6 %). The mean age was 46.8 years (ST 47.6 years, 95% confidence interval (95% CI) [46.5; 48.7]; BE 46.6 years, 95% CI [46.1; 47.2]). The mean GCPS at t0 for ST and BE was 2.2 (ST: 2.18, 95% CI [2.090; 2.274]; (BE: 2.201, 95% CI [2.153; 2.249]) (Table IV).

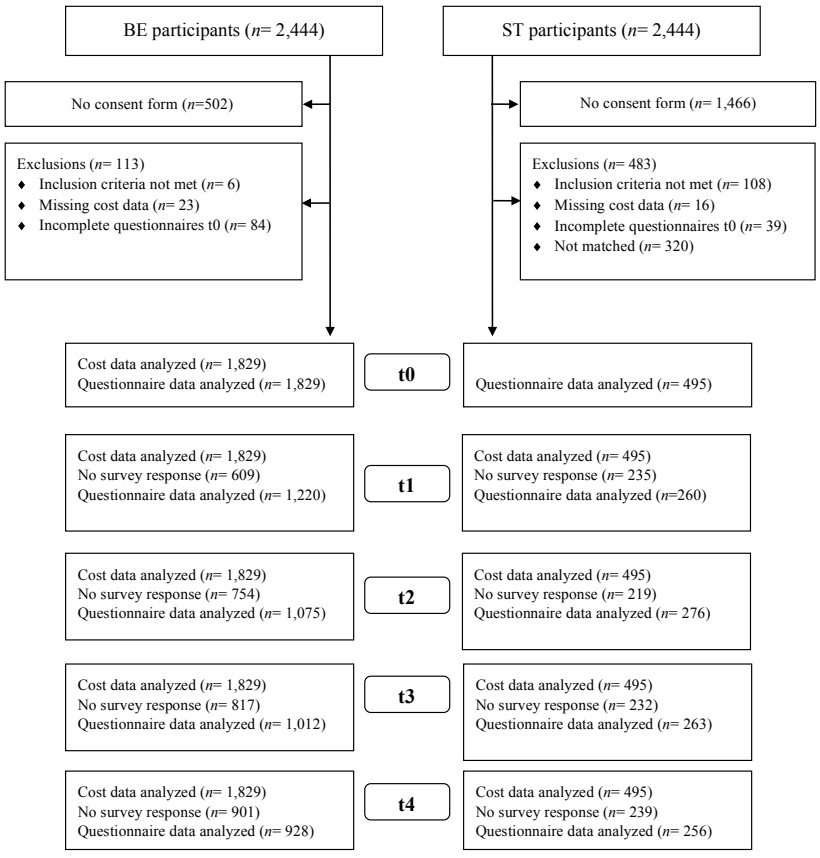


Fig. 1. Recruitment of study participants: exclusions, and questionnaire responses at each measurement point (BE: intervention group "multimodal back exercise", ST: control group "standard treatment").

Although the 2 last grades of the GCPS exclusively reflect the severity of the functional impairment, the pain intensity dimension, of course, nevertheless also increases in both grades. The direct and indirect medical costs also increase with increasing GCPS (Table V).

Costs

The direct medical costs for BE and ST did not differ significantly during the intervention period (Table VI). This reflects the higher exercise costs, amounting to 467 EUR, that each BE participant incurred in addition to the medical costs. During the second post-intervention year and for the entire period of the intervention, the BE costs were significantly lower than the ST costs (Fig. 2).

The higher direct medical costs for ST are due specifically to the cost areas for hospital charges and sick pay (Table VII). Relevant for the cost picture are the costs during the 2 years after intervention start: for direct medical costs, direct back pain medical costs (without exercise costs), and indirect medical costs, the BE costs are significantly less than the ST costs. The indirect back pain medical costs from BE are not significantly different to ST, even with the indirect costs of ST within the 2 years after intervention being 30% higher than for BE (Table VI).

Therapeutic effects

BE significantly reduced the 2 back pain parameters (most severe back pain, mean back pain) and the function parameters (impairment of daily work, days with pain) (Table VIII). This resulted in a significant reduction in the mean value GCPS grade of 0.4 BE compared with ST (2 years post-intervention) (Table VIII). The group with moderate and severe functional impairments (grades 3 and 4) reduced in number by more than half during the first year post-BE (pre-: 37.8%, post-: 16.2%), while it remained approximately unchanged for ST (pre-: 35.6%, post-: 37%; Table VIII). After 2 years post-BE, the share of grades 3 and 4 also decreased for the ST group, by 25%

Table IV. BE and ST compared before study start (pre)

Criteria	BE	ST
Age, years, mean (SD)	46.6 (12.5)	47.6 (12.2)
Females, %	64.0	58.6
Education, %		
Secondary school/compl. 10th grade, no vocational training	18.9	20.9
Secondary school/compl. 10th grade, vocational training	68.8	67.6
Abitur without vocational training	1.1	1.0
Abitur with vocational training	4.7	3.7
Technical college degree	2.4	3.4
University degree	4.1	3.4
Back pain		
Current back pain (0–10), mean (SD)	4.3 (2.2)	4.5 (2.6)
Mean back pain (0–10), mean (SD)	5.1 (2.0)	4.9 (2.3)
Severest back pain – last half year (0–10), mean (SD)	6.9 (2.0)	6.4 (2.4)
Impairment of daily activities (0–10), mean (SD)	3.8 (2.3)	3.7 (2.6)
Days with pain, mean (SD) – last half year	86.7 (62.6)	87.6 (67.5)
GCPS 1, %	31.3	35.6
GCPS 2, %	30.9	28.9
GCPS 3, %	24.3	17.4
GCPS 4, %	13.5	18.2
GCPS, mean (SD)	2.2 (1.0)	2.2 (1.1)
Medical costs, EUR, mean (SD)		
Direct hospital costs	3,215 (5,998)	3,343 (4,329)
Direct back medical costs	571 (1,686)	564 (1,424)
Indirect medical costs	2,711 (5,362)	2,845 (5,323)
Indirect back medical costs	895 (2,760)	967 (3,798)

SD: standard deviation.

(pre- 35.6%, post- 26.6%), while for BE the reduction remained approximately unchanged at 56% (Table IX).

Overall, therapeutic effects run ahead of cost-effects, because the exercise costs are frontloaded during the intervention year (Fig. 2).

The therapeutic and economic efficacy of back exercise increases with the starting level of the back problem (GCPS). The interaction time*treatment*GCPS (pre-) for both the direct medical costs (F 7, 2,316 = 5.096; p < 0.001) and for GCPS (F 7, 1,176 = 94.27; p < 0.001) is significant (Fig. 3).

Only for grade 4 GCPS do direct medical cost savings occur and are the exercise programme costs more than compensated for (Table X). Conversely, for none of the grades do the BE costs significantly exceed the ST costs and therapeutic effects of exercising are achieved across all back pain grades. For the indirect medical costs (including exercise costs) also, the cost difference between BE and ST is significant only with grade 4 (mean –5,076 EUR, 95% CI –8,394 EUR to –1,757 EUR, p = 0.003). Exercising represents a do-

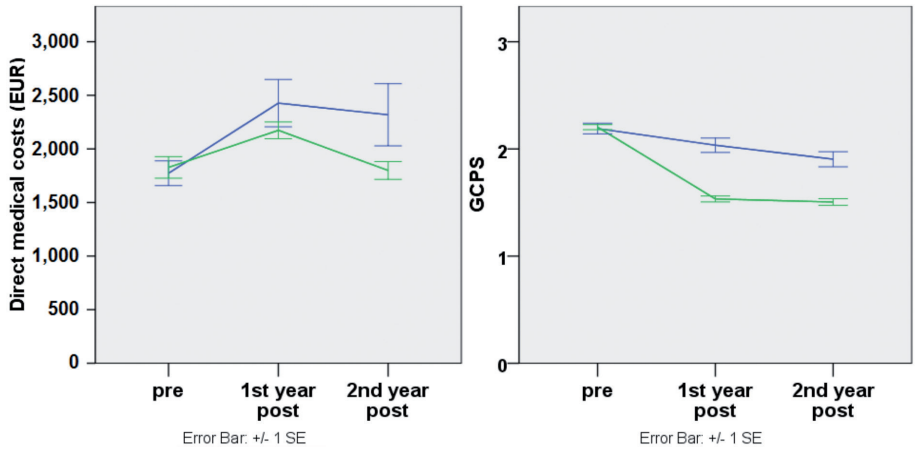


Fig. 2. Therapeutic effects (right: Graded Chronic Pain Status scale (GCPS), pre: before intervention (t0), 1st year post-: after 1 year (t2), 2nd year post- after 2 years (t4)) and economic impacts (left: direct medical cost per insured in EUR/year) of multimodal back exercise (BE) (treatment groups BE: green; standard treatment (ST): blue). Direct medical costs for all measurement points: BE n = 1,829, ST n = 495; GCPS pre-: BE n = 1,829; ST n = 495, 1st year post-: BE n = 1,075, ST n = 276, 2nd year post-: BE n = 928, ST n = 256.

Table V. Calculating the Graded Chronic Pain Status (GCPS) and exemplary study results (mean values) from the pre-measurement

Grade	Calculation from scores	Back pain severity * Mean (SD)	Impairment of daily activity* Mean (SD)	Direct medical costs (EUR)** Mean (SD)	Indirect medical costs (EUR)** Mean (SD)	Total sick days/days with back pain** Mean (SD)
Grade 0 – no pain***	Pain intensity = 0 and function impairment = 0	–	–	–	–	–
Grade 1 – low pain intensity	Function impairment < 3 and pain intensity > 0 < 50	3.0 (1.2)	1.9 (1.6)	2,391 (4,329)	1,830 (3,925)	20.0 (42.9)/4.6 (20.8)
Grade 2 – high pain intensity	Function impairment < 3 and pain intensity ≥ 50	5.5 (1.3)	3.4 (1.8)	2,868 (4,629)	2,235 (4,417)	24.4 (48.3)/4.6 (15.5)
Grad 3 – moderate functional impairment	Function impairment ranks between 3 and 4	5.9 (1.7)	5.0 (1.7)	3,629 (7,677)	2,959 (5,055)	32.3 (55.2)/11.7 (27.7)
Grade 4 – severe functional impairment	Function impairment ranks between 5 and 6	7.1 (1.7)	6.8 (1.6)	5,310 (6,093)	5,471 (8,520)	59.7 (92.9)/29.9 (58.4)

*in the past 6 months, 0 to 10 max. pain/impairment. **costs/days within two years pre. ***Not available pre-study. SD: standard deviation.

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Table VI. Mean direct and indirect medical costs per year by treatment group, in EUR

	BE	ST	BE-ST			
	Mean (SD)	Mean (SD)	Difference	%	95% CI	p
Direct medical costs						
Total costs within two years pre intervention	3,215 (5,998)	3,343 (4,329)	−128	−4	[−692; 437]	0.658
1st year post intervention	2,173 (3,355)	2,446 (4,906)	−272	−11	[−644; 99]	0.151
2nd year post intervention	1,799 (3,554)	2,289 (6,322)	−491	−21	[−917; −64]	0.024
Total costs within two years post intervention	3,972 (6,155)	4,735 (9,783)	−763	−16	[−1,467; −59]	0.034
Direct back pain medical costs						
Total costs within two years pre intervention	571 (1,686)	564 (1,424)	7	1	[−156; 169]	0.935
1st year post intervention	242 (1,056)	471 (252)	−228	−49	[−377; −80]	0.003
2nd year post intervention	242 (1,233)	253 (1,839)	−10	−4	[−148; 127]	0.883
Total costs within two years post intervention	485 (1,709)	723 (3,248)	−239	−33	[−451; −27]	0.027
Indirect medical costs						
Total costs within two years pre intervention	2,711 (5,362)	2,845 (5,323)	−134	−5	[−666; 398]	0.620
1st year post intervention	1,368 (3,634)	2,563 (7,767)	−119	−47	[−1,673; −716]	< 0.001
2nd year post intervention	1,286 (3,718)	1,574 (4,009)	−288	−18	[−664; 87]	0.132
Total costs within two years post intervention	2,654 (5,637)	4,137 (9,032)	−148	−36	[−2,129; −836]	< 0.001
Indirect back pain medical costs						
Total costs within two years pre intervention	895 (276)	967 (3,798)	72	7	[−371; 228]	0.639
1st year post intervention	434 (2,303)	787 (4,721)	−353	−45	[−650; −56]	0.020
2nd year post intervention	378 (2,788)	365 (2,516)	13	4	[−259; 284]	0.926
Total costs within two years post intervention	812 (3,737)	1,152 (5,455)	−340	−30	[−754; 73]	0.107

SD: standard deviation; CI: confidence interval; BE: back exercise; ST: standard treatment.

Table VII. Difference in direct medical costs (total costs within two years post intervention) of back exercise and standard treatment

Cost areas	Difference	%	95% CI	p
Drugs	−207	−22	[−480; 66]	0.318
Therapeutics	−36	−16	[−75; 3]	0.069
Outpatient	−66	−5	[−177; 57]	0.248
Hospital	−463	−36	[−855; −71]	0.021
Sick pay	−431	−53	[−693; −169]	0.001
Rehabilitation	−28	−29	[−74; 18]	0.235
Back exercise	467	97	[443; 492]	< 0.001
Total	−763	−16	[−1,467; −59]	0.034

CI: confidence interval.

minant strategy for grade 4 GCPS, since therapeutic effects are realized simultaneously with cost savings. Exercising is cost-effective ($p < 0.05$) at a maximum willingness to pay of 4,370 EUR at grade 3 GCPS, 7,500 EUR at grade 2, and 19,300 EUR at grade 1 (Table XI). MWTP values for the individual GCPS grades were determined by iterations.

Table VIII. Back pain and functional impairments during the last 6 months (pre intervention = t0, 1st year post intervention = t2, 2nd year post intervention = t4)

	BE	ST	BE-ST			
	Mean (SD)	Mean (SD)	Difference	%	95% CI	p
Severest back pain						
Within six months pre intervention	6.9 (2.0)	6.4 (2.4)	0.5	8.6	[0.3; 0.8]	< 0.001
1st year post intervention	4.8 (2.4)	5.7 (2.6)	−0.9	−15.9	[−1.2; −0.6]	< 0.001
2nd year post intervention	4.5 (2.4)	5.5 (2.6)	−1.0	−17.8	[−1.3; −0.6]	< 0.001
Mean back pain						
Within six months pre	5.1 (2.0)	4.9 (2.3)	0.1	2.7	[−0.10.3]	0.197
1st year post intervention	3.4 (2.0)	4.4 (2.4)	−1.0	−23.3	[−1.3; −0.8]	< 0.001
2nd year post intervention	3.2 (2.1)	4.1 (2.3)	−0.9	−21.8	[−1.2; −0.6]	< 0.001
Impairment of daily activities						
Within six months pre intervention	3.8 (2.3)	3.7 (2.6)	0.1	3.0	[−0.1; 0.3]	0.358
1st year post intervention	2.3 (2.2)	3.3 (2.6)	−1.0	−30.5	[−1.3; −0.7]	< 0.001
2nd year post intervention	2.2 (2.2)	3.0 (2.5)	−0.8	−27.1	[−1.1; −0.5]	< 0.001
Days with pain						
Within six months pre intervention	86.7 (62.6)	87.6 (67.5)	−0.9	−1.1	[−7.3; 5.4]	0.775
1st year post intervention	52.5 (60.7)	75.0 (67.3)	−22.5	−30.0	[−30.7; −14.3]	< 0.001
2nd year post intervention	48.9 (57.7)	68.3 (64.7)	−19.4	−28.4	[−27.5; −11.3]	< 0.001
Graded Chronic Pain Status						
Within six months pre intervention	2.2 (1.0)	2.2 (1.1)	0.0	0.9	[−0.1; 0.1]	0.722
1st year post intervention	1.5 (0.9)	2.1 (1.2)	−0.5	−26.0	[−0.7; −0.4]	< 0.001
2nd year post intervention	1.5 (0.9)	1.9 (1.1)	−0.4	−20.0	[−0.5; −0.2]	< 0.001

SD: standard deviation; BE: back exercise; ST: standard treatment.

Table IX. Percent changes in Graded Chronic Pain Status grade shares

	Pre treatment		1st year post treatment		2nd year post treatment	
	BE	ST	BE	ST	BE	ST
GCPS 0, %	0.0	0.0	1.7	3.6	2.9	3.5
GCPS 1, %	31.3	35.6	67.0	39.5	68.1	46.1
GCPS 2, %	30.9	28.9	15.1	19.9	12.4	23.8
GCPS 3, %	24.3	17.4	10.0	21.4	10.2	13.7
GCPS 4, %	13.5	18.2	6.2	15.6	6.4	12.9

BE: back exercise; ST: standard treatment

DISCUSSION

To our knowledge, this study is the first to investigate the therapeutic and economic effects of a multimodal back exercise programme in relationship to back pain severity (measured with the GCPS). This information is useful to patients with back pain and to health insurers.

A key finding of this study is that the therapeutic effect is more pronounced the higher the level of back pain (GCPS) before the start of the exercise programme. Hence, the results point in the same direction as current research: physical exercise achieves low to moderate therapeutic effects for chronic back pain. These effects could not be demonstrated for subacute and acute back pain (10). However, the chronic, subacute, and acute classification is made over the course of the back pain, while the GCPS ranks the back problems in a more complex fashion, over the course of the back pain plus the pain intensity and pain-induced functional impairment in daily life, leisure and work (11). Thus, the results of the present study bring the connection between the severity of the problem and the effectiveness of the exercise programme into sharper focus.

A novel finding is that the economic impact also becomes more pronounced the more severe the back pain experienced before the start of the exercise programme. As Lühmann et al. (25) surmised, the largest therapeutic and economic effects arise due to the high initial probability in the high-risk groups. The direct medical costs, and therefore also the potential for economic impact, at GCPS grade 4 (severe functional impairment) were more than double those at GCPS grade 1 (Table V and Fig. 3). Indeed, for grade 4, the multimodal back exercise represented a dominant strategy, considering that therapeutic effects were realized in tandem with cost savings. For GCPS grade 1, by contrast, the MWTP of 19,300 EUR seems too high.

This study helps to clarify the inconsistency in the literature about the cost-effectiveness of back training programmes (26, 27), since previous studies fell short in determining the effects differentiated by the degree of back pain. Furthermore, as shown in the present study, the economic impacts occur with a delay, while the therapeutic exercise effects appeared during the year of the intervention, the cost-effects only impact the second year following the start of the intervention (Fig. 2). Consequently, studies with shorter follow-ups are not set up to demonstrate the cost-effects.

The multimodal exercise concept rested on the basis of discussed mechanisms of action, since the state of the research did not reflect the extent to which the positive effects of back training depend on the type, intensity, and volume of exercise (25, 10). Adaptive muscles and improved circulation in the muscle/joint structures are adduced as possible causes for the efficacy of exercise for back pain (28). These adaptive reactions depend on the frequency of exercising, the exercise duration, and the loading. This speaks for a dose-effect relationship, such as we also encounter, for example, with cardio exercises (29, 30). The training volume, and thus the dosing of the multimodal exercise programme, therefore was conceived as correspondingly high, with a half year of exercising (36 training sessions, increasing intensity) and a consecutive home exercise programme (42% regular participation rate).

Table X. Changes in direct medical costs (EUR) and Graded Chronic Pain Status within in two years (post – pre)

	Changes in direct medical costs						Changes in GCPS values					
	BE	ST	Difference				BE	ST	Difference			
	Mean (SD)	Mean (SD)	absolute	%	95% CI	*p*	Mean (SD)	Mean (SD)	absolute	%	95% CI	*p*
GCPS 1	897 (4,339)	491 (5,246)	406	83	[−367; 1,179]	0.303	0.1 (0.6)	0.3 (0.9)	−0.2	−64	[−0.4 ; 0.1]	0.006
GCPS 2	617 (4,750)	517 (5,458)	100	19	[−801; 1,001]	0.827	−0.6 (0.7)	−0.3 (0.7)	−0.3	123	[−0.5 ; −0.1]	0.001
GCPS 3	971 (7,666)	1,011 (6,909)	−40	−4	[−1,787; 1,707]	0.964	−1.3 (1.0)	−0.2 (0.9)	−1.0	442	[−1.4 ; −0.7]	< 0.001
GCPS 4	367 (7,215)	4,909 (18,189)	−4,543	−93	[−7,262; −1,823]	0.001	−1.7 (1.3)	−0.7 (1.1)	−1.0	158	[−1.6 ; −0.5]	< 0.001

BE: back exercise; ST: standard treatment; SD: standard deviation; CI: confidence interval.

Table XI. Net monetary benefit (NMB) depending on differing maximum willingness to pay (MWTP) and Graded Chronic Pain Status

	λ = 0 EUR			λ = 4,370 EUR			λ = 7,500 EUR			λ = 19,300 EUR		
	Mean	95% CI	*p*	Mean	95% CI	*p*	Mean	95% CI	*p*	Mean	95% CI	*p*
GCPS 1	−406	[−1,179; 367]	0.303	−16	[−1254; 1,222]	0.980	627	[−912; 2,167]	0.424	3,052	[10; 6,093]	0.049
GCPS 2	−100	[−1,001; 801]	0.827	842	[−552; 2,235]	0.236	1,834	[10; 3,659]	0.049			
GCPS 3	40	[−1707; 1,787]	0.964	3,403	[13; 6,792]	0.049						
GCPS 4	4,543	[1,823; 7,262]	0.001									

The combination of strength and movement exercise with back-friendly daily motor activity training was selected, since physical exercise and back schools with a high physical training component witness the therapeutic effects on chronic back pain (10, 31–34). Further studies should examine in more differentiated fashion the question posed in this study of to what extent the effectiveness of back exercise depends on the grade of back pain, and should examine the degree to which the exercise type and volume determine efficacy.

Study limitations

Participant randomization was not feasible in this study, since the back exercise programme represents a service offering by the insurer to which the insured

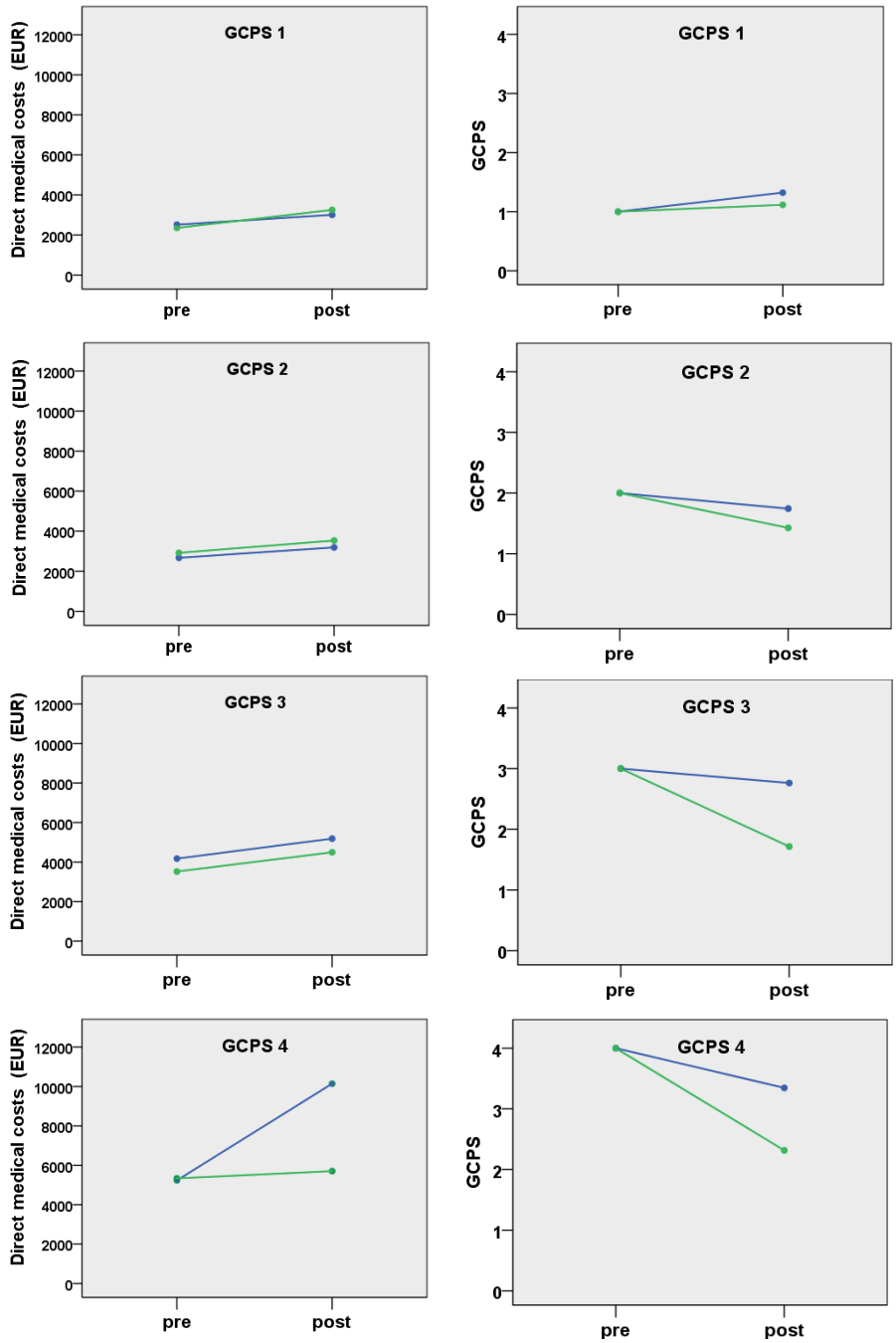


Fig. 3. Economic impacts (left: direct medical cost per insured, total costs within 2 years pre-, total costs within 2 years post-) and therapeutic effects of back exercise (right: Graded Chronic Pain Status scale (GCPS), pre-: before intervention (t0), post-: after 2 years (t4)) by back pain severity grade (GCPS 1–4) during pre-measurement (treatment groups back exercise (BE) = green, standard treatment (ST) = blue). Direct medical costs: GCPS 1 BE $n = 572$, ST $n = 176$; GCPS 2 BE $n = 565$, ST $n = 143$; GCPS 3 BE $n = 445$, ST $n = 86$; GCPS 4 BE $n = 247$, ST $n = 90$. GCPS: GCPS 1 BE $n = 326$, ST $n = 118$; GCPS 2 BE $n = 284$, ST $n = 74$; GCPS 3 BE $n = 204$, ST $n = 38$; GCPS 4 BE $n = 114$, ST $n = 26$.

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are entitled. On the other hand, a very large data-set was at our disposal (n=348,000), from which, as a first step, potential statistical twins were chosen based on cost and demographic data. The actual adjustment and selection of the control group participants was accomplished in a second step using propensity score matching, a proven procedure in healthcare research for generating comparable groups. While, due to the lack of randomization, the internal validity of this study is less than that of an RCT, the external validity of this field study designed for comparative effectiveness research should be higher.

The GCPS data variable cannot properly be regarded as metrical and normally distributed as required in parametric procedures. Nevertheless, there are indications that the intervals between the gradations can be regarded as approximately equal (Table V). For this reason, we used parametric procedures for GCPS, as is common practice for Likert scale items.

The analytical inference methods applied here, however, can be used, since appropriately large samples were available.

These results might be biased by physical and psychological comorbidities, as matching refers to age, sex, costs (direct medical and direct back disorder) and work days lost, but not to other physical or psychological comorbidities. The basic willingness to engage in sports (as operationalization of motivation) was similar in both groups at baseline (sports to baseline: BE 64.6%, ST 62.9%), but physical and psychological comorbidities were considered only via global health costs. The strength and direction of the potential bias is unclear and needs to be addressed in further research.

ACKNOWLEDGEMENTS

Funding: The study was commissioned and funded by AOK Baden-Wuerttemberg.

Conflicts of interest: Gerhard Müller, Manuela Pfinder, Michael Clement, Andreas Kaiserauer, Guido Deis, Timm Waber are employed by the sponsor, AOK Baden-Wuerttemberg; Stefanie Rieger and Dana Schwarz work for ITSCare (financed by the AOK Baden-Wuerttemberg public health insurance company), Michael Straif and Klaus Bös received consulting fees.

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