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 severity of back pain.

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

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**B**ack 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
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 used for constructing the GCPS. For the economic evaluation, we included samples of at least grade 1, and a completed data-set of the questions randomly selected) provided by the insurer at 39 locations in the German state of 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 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.

| 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.
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.

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 χ² 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) and the changes in direct medical costs (ΔC: post- minus pre-direct medical costs) are subtracted from this product: NMB=λ*ΔEi−ΔCi.

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 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:

Table II. Cost areas of direct and indirect medical/back disorder costs

| 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/         | ICD: all      |                     |
| Rehabilitation/outpatient        |               |                     |
| surgery                          |               |                     |
| Exercise charges                 |               |                     |
| Therapeutic aid charges          |               | 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*       |               | ICDs: M40-54 sick leave days* |
| lost productivity costs          |               | lost productivity costs per day |
| per day                          |               | 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

Table III. Back exercise program stages

| Phase                | Week | TS per week | Training intensity | 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

Results

Study participants

Of 2,444 intervention subjects contacted in writing from 2008 and 2010, 1,942 agreed to take part in the
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-: 35.6%, post-: 16.2%), while it remained approximately unchanged for ST (pre-: 37.8%, post-: 37%; Table VIII). After 2 years post-BE, the share of grades 3 and 4 also decreased for the ST group, by 25%
Effects of multimodal back exercise

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

| Criteria                          | BE (mean, SD) | ST (mean, SD) |
|-----------------------------------|---------------|---------------|
| Age, years                        | 46.6 (12.5)   | 47.6 (12.2)   |
| Females, %                        | 64.0          | 58.6          |
| Education, %                      |               |               |
| Secondary school/10th grade, no   | 18.9          | 20.9          |
| vocational training               |               |               |
| Secondary school/10th grade,      | 68.8          | 67.6          |
| vocational training               |               |               |
| Ability without vocational training| 1.1           | 1.0           |
| Ability 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)          | 4.3 (2.2)     | 4.5 (2.6)     |
| Mean back pain (0–10)             | 5.1 (2.0)     | 4.9 (2.3)     |
| Severe back pain – last half year | 6.9 (2.0)     | 6.4 (2.4)     |
| Impairment of daily activities    | 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.

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 | 3.0 (1.2)                     | 1.9 (1.6)                             | 2,391 (4,329)                          | 1,830 (3,925)                            | 20.0 (42.9)/4.6 (20.8)                        |
|                      | and pain intensity > 0 < 50 |                               |                                       |                                        |                                          |                                                |
| Grade 2 – high pain intensity | Function impairment < 3 | 5.5 (1.3)                     | 3.4 (1.8)                             | 2,868 (4,629)                          | 2,235 (4,417)                            | 24.4 (48.3)/4.6 (15.5)                       |
|                      | and pain intensity ≥ 50  |                               |                                       |                                        |                                          |                                                |
| Grad 3 – moderate functional impairment | Function impairment 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 rankings between 3 and 4 | 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.
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 VI. Mean direct and indirect medical costs per year by treatment group, in EUR

|                      | BE (Mean (SD)) | ST (Mean (SD)) | BE-ST 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) | 2,466 (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 | 1,286 (3,718) | 1,574 (6,322) | -288 -18 [-64; 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 medical costs |                |                |                          |    |
| Total costs within two years pre intervention | 895 (276) | 967 (3,798) | 72 7 [–37; 228]          | 0.639 |
| 1st year post intervention | 434 (2,303) | 787 (4,721) | -353 -45 [-1,673; -716] | < 0.001 |
| 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.

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)

| Severest back pain | BE (Mean (SD)) | ST (Mean (SD)) | BE-ST Difference % 95% CI | p  |
|--------------------|----------------|----------------|--------------------------|----|
| 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; 0.3] | 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

| GCPS Grade | Pre treatment BE | ST | 1st year post treatment BE | ST | 2nd year post treatment 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 two years (post – pre)

| Changes in direct medical costs | Changes in GCPS values |
|--------------------------------|------------------------|
| Changes in medical costs       | Changes in GCPS values |
| BE ST Difference              | BE ST Difference       |
| Mean (SD) Mean (SD) absolute % 95% CI | Mean (SD) Mean (SD) absolute % 95% CI |
| 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 | Mean 95% CI | Mean 95% CI | Mean 95% CI |
| 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 [–1,707; 1,787] 0.964 3,403 [13; 6,792] 0.049 |
| GCPS 4 4,543 [1,823; 7,262] 0.001 |

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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

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**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 \( n = 26 \).
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.

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**REFERENCES**

1. Vos T, Barber RM, Bell B, Bertozzi-Villa A, Biryukov S, Bolliger I, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 2015; 386: 743–800.
2. Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, et al. A systematic review of the global prevalence of low back pain. Arthritis Rheum 2012; 64: 2028–2037.
3. Andersson GB. Epidemiological features of chronic low-back pain. Lancet 1999; 354: 581–585.
4. Biering-Sørensen F. A prospective study of low back pain in a general population. I. Occurrence, recurrence and aetiology. Scand J Rehab Med 1982; 15: 71–79.
5. Maetzel A, Li L. The economic burden of low back pain: a review of studies published between 1996 and 2001. Best Pract Res Clin Rheumat 2002; 16: 23–30.
6. Kohlmann T, Schmidt CO. Epidemiologie des Rückenschmerzes. Lendenwirbelsäule: Ursachen, Diagnostik und Therapie von Rückenschmerzen. Munich: Urban und Fischer; 2005: 3–13.
7. van Tulder, Maurits W, Koes BW, Bouter LM. A cost-of-illness study of back pain in The Netherlands. Pain 1995; 62: 233–240.
8. Torstensen TA, Ljunggren AE, Meen HD, Odland E, Mo-winkel P, Geijerstam S. Efficiency and costs of medical exercise therapy, conventional physiotherapy, and self-exercise in patients with chronic low back pain. A pragmatic, randomized, single-blinded, controlled trial with 1-year follow-up. Spine 1998; 23: 2616–2624.
9. Kohlmann T. Die Chronifizierung von Rückenschmerzen. Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz 2003; 46: 327–335.
10. Hayden J, van Tulder MW, Malimvaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. Cochrane Database of Systematic Reviews 2005; 3.
11. Korff M von, Omeljancic J, Keefe FJ, Dworkin SF. Grading of the severity of chronic pain. Pain 1992; 50: 133–149.
12. Thoemmes F. Propensity score matching in SPSS. arXiv preprint arXiv:1201.6385 2012.
13. Guo S, Fraser MW, editors. Propensity score analysis: Statistical methods and applications. 2nd ed. Thousand Oaks, CA: Sage Publications; 2015.
14. Arbeitsmedizin (BAuA) Sicherheit und Gesundheit bei der Arbeit 2006–Unfallverhütungsbericht Arbeit. Dortmund: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin; 2008.
15. Arbeitsmedizin (BAuA). Sicherheit und Gesundheit bei der Arbeit 2007–Unfallverhütungsbericht Arbeit. Dortmund: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin; 2009.
16. Arbeitsmedizin (BAuA). Sicherheit und Gesundheit bei der Arbeit 2008–Unfallverhütungsbericht Arbeit. Dortmund: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin; 2010.
17. Arbeitsmedizin (BAuA). Sicherheit und Gesundheit bei der Arbeit 2009–Unfallverhütungsbericht Arbeit. Dortmund: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin; 2011.
18. Wenig Christina M., Schmidt Carsten O., Kohlmann T, Schweikert Bernd. Costs of back pain in Germany. Eur J Pain 2009; 13: 280–286.
19. Kienbacher T, Paul B, Habenicht R, Starek C, Wolf M, Kollmitzer J, et al. Reliability of isometric trunk moment measurements in healthy persons over 50 years of age. J Rehabil Med 2014; 46: 241–249.
20. Denner A. Muskuläre Profile der Wirbelsäule: Springer-Verlag; 2013.
21. Killian PRD. Gesundheitsökonomische Evaluation in der psychiatischen Versorgungsforschung. Prävention und Gesundheitsförderung 2008; 3: 135–144.
22. Hoch JS, Smith MW. A guide to economic evaluation: methods for cost-effectiveness analysis of person-level data. J Trauma Stress 2006; 19: 787–797.
23. Hoch JS, Briggs AH, Willan AR. Something old, something new, something borrowed, something blue: A framework for the marriage of health economics and cost-effectiveness analysis. Health Econ 2002; 11: 415–430.
24. Stinnett AA, Mullahy J. Net health benefits: a new framework for the analysis of uncertainty in cost-effectiveness analysis. Med Decis Making 1998; 18: 80.
25. Lühmann D, Stoll S, Burkhardt-Hammer T, Raspe H. Prävention rezidivierender Rückenschmerzen – Präventions- maßnahmen in der Arbeitsplatzumgebung. GMS Health Technology Assessment 2006; 2: 12.
26. Damm O., Greiner W. Gesundheitsökonomischer Kurz- HTA-Bericht “Rückenschmerzen”. Bielefeld: Universität Bielefeld und Berteismann Stiftung; 2007.
27. van der Roer N, Goossens ME, Evers SM, van Tulder MW.
What is the most cost-effective treatment for patients with low back pain? A systematic review. Best Pract Res Clin Rheumatol 2005; 19: 671–684.

28. Linton SJ, van Tulder MW. Preventive interventions for back and neck pain problems: what is the evidence? Spine 2001; 26: 778–787.

29. Löllgen H. Bedeutung und Evidenz der körperlichen Aktivität zur Prävention und Therapie von Erkrankungen. DMW-Deutsche Medizinische Wochenschrift 2013; 138: 2253–2259.

30. Lee I-M. Dose-response relation between physical activity and fitness: even a little is good; more is better. JAMA 2007; 297: 2137–2139.

31. Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary rehabilitation for chronic low back pain: systematic review. BMJ 2001; 322: 1511–1516.

32. Heymans MW, van Tulder MW, Esmail R, Bombardier C, Koes BW. Back schools for nonspecific low back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. Spine 2005; 30: 2153–2163.

33. Müller G, Burton AK, Balagué F, Cardon G, Eriksen HR, Henrotin Y, et al. Evidenz für die Wirksamkeit von Maßnahmen zur Prävention von Rückenschmerzen-Europäische Leitlinien. Physioscience 2005; 1: 100–112.

34. Steffens D, Maher CG, Pereira LS, Stevens ML, Oliveira VC, Chapple M, et al. Prevention of low back pain: a systematic review and meta-analysis. JAMA Int Med 2016: 176: 199–208.