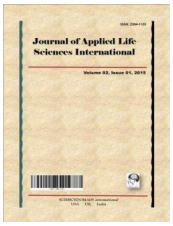

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The Influence of an Eight Week, Structured Strength-endurance Training on Pain Perception and Health-related Quality of Life in Patients with Non-specific Low Back Pain: Who Profits?

K. Baum[1*], U. Hofmann[1] and F. Bock[2]

[1]Institute of Physiology and Anatomy, German Sport University Cologne, Germany.
[2]Medical Center, Am grünen Turm, Ravensburg, Germany.

Authors' contributions

This work was carried out in collaboration between all authors. Author KB designed the study, wrote the protocol and wrote the first draft of the manuscript. Author UH performed the statistical analysis. Author FB managed the questionaire searches. All authors read and approved the final manuscript.

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ABSTRACT

Purpose: Non-specific low back pain is one of the leading public health problems worldwide. With respect to the duration of pain, it is generally divided into acute, subacute, and chronic. While physical exercises are promoted as a non-pharmacologic treatment in the chronic state, the actual literature refuses specific exercises in the acute phase. However, there is a lack of data concerning the effect of structured training programs in these patients. The present study investigated the influence of a structured and supervised strength-endurance program on pain intensity and quality of life in non-specific, acute, subacute, and chronic low back pain patients.
Methods: 1147 adult patients of both sexes entered the multi-centered, controlled, and randomized training intervention. The control group was advised to maintain a physically active lifestyle. The eight-week, two-times per week training intervention consisted of a circle with eight strength-endurance and two endurance exercises for back-pain relevant muscle groups. In each session, the

**Corresponding author: E-mail: baum@professor-baum.de;*

circle was performed two-times with 60 seconds and 240 seconds durations for the strength-endurance and endurance exercises, respectively. The break between each exercise lasted 30 seconds. Anthropometric data, comorbidities, regular physical activities, actual physiotherapeutic and medical treatment, probability of pain-chronification, pain quality and quantity, and health related physical and mental quality of life was evaluated at the beginning, after four weeks, and finally after eight weeks by means of online-questionnaires.

Results: The drop-out rate at the end of intervention amounted to 14.4% in the control group and 30% in the training group. None of the obtained parameters had a prognostic meaning for adherence of patients. Finishers: In both the acute, subacute, and chronic stages of the training group a significant and clinically important reduction in pain intensity could be obtained while a smaller, clinically not important but still statistically significant reduction occurred in the acute and subacute control group. No improvement occurred in the chronic control group. Simultaneously, a significant increase in health related physical quality of life was observed in all stages of the training group.

Discussion: In contrast to the main part of the existing literature, training was in all stages of non-specific low back pain superior to an exclusively active lifestyle. Especially for acute low back pain the actual guidelines does not promote exercise as a treatment. The discrepancy may at least in part be explained by the kind and quality of exercise interventions used in previous studies.

Conclusion: Structured medical training therapies should be recommended as an essential treatment in all stages of non-specific low back pain.

Keywords: Low back pain; exercise; training; medical training therapy; VR-12; health; quality of life; pain intensity.

1. INTRODUCTION

Low back pain is a worldwide common disease which burdens both patients and the national health systems to a serious extent [1,2]. Patients suffering from low back pain often have to cope with mental, physical, and social problems leading to a considerably reduced quality of life [3,4,5,6]. The one-year prevalence of low back pain in adults is very high at about 70% [7]. Beside the classification concerning the pathogenesis (specific versus non-specific low back pain with a relation of about 15% to 85% [8,9]), a duration-dependent differentiation divides into acute, subacute and chronic stages with periods of up to 6 weeks (acute), 7-12 weeks (subacute) and more than 12 weeks (chronic) [10].

The importance of physical exercises as a non-surgical, non-pharmacological treatment appears to depend on the duration of the actual pain episode. A considerable number of reviews reported evidence that in the acute stage exercises are not superior to maintaining everyday activities or other conservative treatments [11,12,13,14,15,16]. In contrast, the same papers strongly recommended exercise as an important tool to treat low back pain in the chronic stage. Similar advices were given in a recent guideline for noninvasive treatments for acute, subacute, and chronic low back pain [17].

However, a major difficulty in assessing the effectiveness of physical training in the treatment of low back pain is the wide range of measures summarized under the term "exercise". They range from Tai Chi [18,19,20], Pilates [21,22,23], vibration training [24,25], nordic walking [26,27], aquatic exercises [28,29,30], stretching [31,32], and strength training [33,34,35] to mixed types [36,37]. Such heterogeneous and in part unspecific treatments will hardly lead to comparable effects.

Moreover, even within a given training form, the normatives such as intensity, rest to activity ratio, or weekly exercise frequency differ from study to study. These diversities result in a limited number of comparable treatments and, therefore, a limited number of similarly treated patients. That may be the reason why a recent Cochrane Review regarded the quality of evidence for exercise as a treatment for chronic pain patients as low [38].

The rationale of the present study was to investigate the effects of a medical training therapy in non-specific low back pain patients on pain intensity and health related quality of life. To this end, a multicenter, randomized controlled

trial with a fixed and structured strength-endurance training intervention was performed. Adult patients with non-specific low back pain of acute, subacute, and chronic stages were recruited.

2. METHODS

The present study followed all the relevant national regulations and the tenets of the Declaration of Helsinki and was approved by the ethical committee of the local university.

2.1 General Overview

The empirical part of the study took place from the 15th of August to the 15th of December 2017. 67 facilities of the German Physio Aktiv ltd. group were involved as centers. Initially, all participating staffs were thoroughly instructed about procedures, contents, and endpoints of the investigation. Each center had to include patients for both the training and the control group. Since we expected a higher dropout within subjects of the training group, a 2:1 relation between training and control participants was intended. A quasi-randomisation was achieved via the chronological order of which patients entered the individual centers: The initial two patients were assigned to the training group, the third patient to the control group and so on. The individual study period lasted 8 weeks with online-questionnaires (see chap. 2.4) before, after 4, and after 8 weeks. Training was identical in all facilities and consisted of a strength-endurance circle (see chap. 2.3) with two sessions per week. At the end of the intervention, a total number of at least 13 sessions was accepted for further evaluation of data. Participants of the control group were advised and encouraged to maintain daily activities of life. After the 8 week control period, these patients started with training which was identical to that of the initial training group. Data of the second phase were not considered in the present paper. Subjects of the training and control group had to pay a one-time amount of 99 € and 79 € for participation, respectively. Patients were allowed to quit the study without mentioning any reason.

2.2 Patients

Subjects were recruited by local announcements. The inclusion and exclusion criteria were as follows:

Inclusion criteria:

age $\geq$ 18 years
non-specific low back pain (defined as the area from the gluteal folds to the lower rib [36])
low back pain with and without radiation to the legs
mastery of German language (due to the questionnaires)

Exclusion criteria:

former back surgery
specific back pain such as disc herniation, fracture, vertebrostenosis, metastasis
neurologic disorders
stroke
heart attack
heart failure
pregnancy
more than one week absence during the study period

Patients who met the criteria and agreed to participate were included after verbal and written informed consent. Initially 1147 patients entered the study. Their characteristics are presented in Tables 1 and 2. At the end of the study, 864

Table 1. Anthropometrics and educational characteristics of patients

	Control-group		Training-group	
	absolute	**%**	**absolute**	**%**
number of patients	420	37	727	63
women	235	56	430	59
men	185	44	297	41
age (years)	53 $\pm$ 13.6		54 $\pm$ 12.9	
height (cm)	172 $\pm$ 8.9		172 $\pm$ 11.4	
mass (kg)	82 $\pm$ 16.8		83 $\pm$ 25.5	
educational qualification:				
secondary school	248	59	443	61
high school	76	18	138	19
university	95	23	146	20

Table 2. Disease-related characteristics of patients

	Control-group		Training-group	
	absolute	**%**	**absolute**	**%**
mean pain intensity (0-100)	48 ± 20.6		50 ± 21.0	
back pain duration: acute	52	12	110	15
subacute	41	10	64	9
chronic	327	78	553	76
physiotherapy	98	23	170	23
physician visits (pain)	270	64	529	73
Regular drug consumption:				
painkillers	140	33	248	34
diabetes type II	19	5	33	5
fat metabolism disorder	31	7	46	6
thyroid disease	66	16	103	14
others	62	15	131	18
no drugs	135	32	264	36

Physiotherapy = actual physiotherapeutic treatments, mean pain intensity = pain intensity during the last week with a numeric scale from 0 = no pain to 100 = extreme painful

patients could be finally evaluated corresponding to 84.6% of subjects in the control group and 70% in the training group. A flowchart of finishers and dropouts is given in Fig. 1.

2.3 Training

2.3.1 Training devices and duration

The strength-endurance circle consisted of ten stations with six devices in the adaptive mode (back extension, abdominal crunch, seated rowing, leg extension, leg curl, chest press), two cable machines (trunk rotation, trunk lateral flexion), and two endurance devices (crosstrainer, stationary bike). For the first eight devices, exercise time was set to one minute and for the endurance devices to four minutes. Subjects rested for 30 seconds between all stations. The circle was performed twice per session leading to a total training time of 42 minutes per session. Except the cable machines, all devices were manufactured by milon industries ltd., Emersacker, Germany. All devices are certified according to DIN 9001.

2.3.2 Training intensities

For the adaptive and cable devices, subjects had to contract for 1.5 seconds in the concentric and eccentric mode each with a subjective intensity of 7-8 in the concentric phase on a 0-10 scale (0 = no effort, 10 = maximal effort). Loads were adjusted during an initial familiarization session and kept constant until the 6th session. Thereafter, loads could be increased to meet the subjective 70% to 80% of maximal effort throughout the remaining training period. The load of the endurance devices were adjusted via heart rate (HR) by means of the formula

$$HR_{exercise} = (220\text{-age}) \times 0{,}65$$

2.4 Questionnaires

A commercially available internet-based survey software (Survio) was used for technical construction of the questionnaires. Patients had to fill out the surveys without any supervision of the local staff. So, all data were exclusively accessible to the authors. The identity number of patients included training location and group affiliation. The anthropometric data consisted of sex, age, height, and weight. The educational qualification asked for the highest level of education in school or university. For physical training history the initial question asked for regular physical training during the last 12 months. If so, the following questions specified frequency, duration, and content of training. In order to screen the risk of chronification of low back pain the items of the Heidelberg Short Questionnaire (HKF-R10) were used. Comorbidities and concomitant drug consumption were evaluated for diabetes mellitus type 1 and 2, arterial hypertension, diseases of lipid metabolism, thyroid diseases, and others. The duration of the actual back pain period was divided into < 6 weeks, 6 to 12 weeks, and > 12 weeks. Physician visits considered the number and causes during the last 6 months. Physiotherapy focused on the actual low back pain. The Veterans Rand 12 item

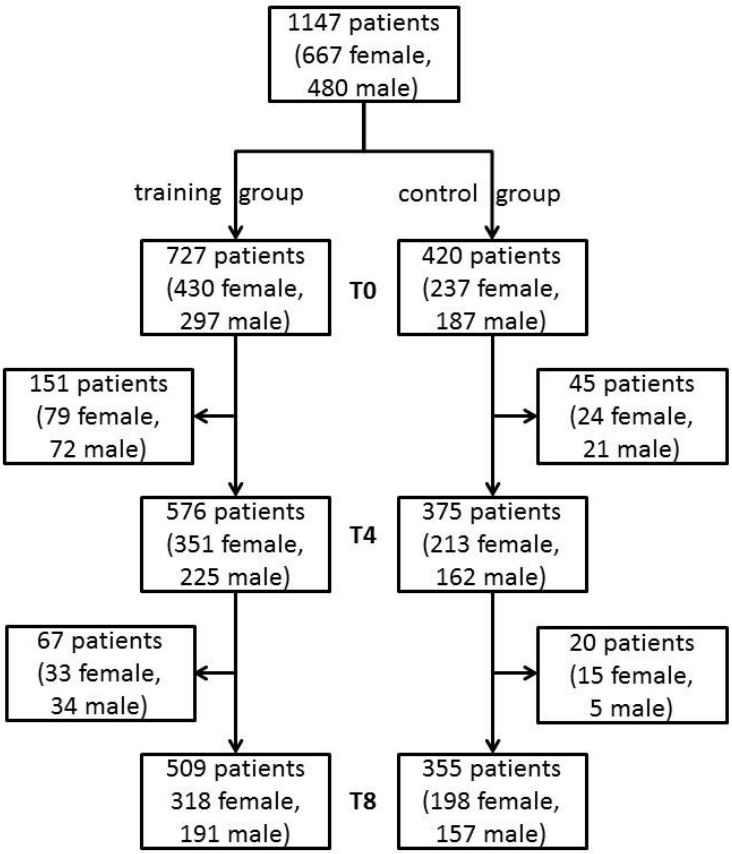

Fig. 1. Flowchart of dropouts and finishers.
T0 = Begin of the study, T4 = midterm after 4 weeks, T8 = end of study after 8 weeks

Table 3. Composition of surveys and the total number of questions

Survey	T0T	T0C	T4T	T4C	T8T	T8C
identity number	X	X	X	X	X	X
anthropometric data	X	X				
educational qualification	X	X				
training history	X	X				
HKF-R10	X	X				
comorbidities	X	X				
regular drug consumption	X	X				
duration of the actual pain period	X	X				
physician visits	X	X	X	X	X	X
physiotherapy treatment	X	X	X	X	X	X
VR-12	X	X	X	X	X	X
pain location(s)	X	X	X	X	X	X
pain intensity	X	X	X	X	X	X
number of training sessions			X		X	
patient´s opinion about the influence of training			X		X	
total number of items	52	52	25	22	25	22

X = Items included in the questionnaire, HKF-R10 = Heidelberg short questionnaire for the risk of chronification, VR-12 = Veterans Rand 12 item health survey, T0T = initial survey of the training group, T0C = initial survey of the control group, T4T = survey of the training group after 4 weeks, T4C = survey of the control group after 4 weeks, T8T = survey of the training group after 8 weeks, T8C = survey of the control group after 8 weeks

health survey (VR-12) was taken to access health related physical (PQL) and mental quality of life (MQL). Potential pain locations were low back, thigh, the whole leg, and the whole body. Whole body pain was included to detect potential fibromyalgia patients. For pain intensity, the week before was taken into account and split in mean pain and pain when it was best. In addition, patients of the training group rated the influence of training on changes in pain reduction. To this end, a 5 point scale with 1 = very strong, 2 = strong, 3 = noticeable, 4 = a bit, and 5 = not at all was used.

Table 3 depicts the composition of questionnaires before (T0), after 4 weeks (T4), and after 8 weeks (T8) of intervention.

2.5 Statistics

If not otherwise stated data are presented as mean ± standard deviation (SD). The comparisons of all parameters between the two groups (training, control) and between finisher and non-finisher for anthropometric data, educational qualification, training history, HKF-R10, comorbidities, regular drug consumption, pain duration, pain intensity, pain locations, physician visits, physiotherapy, VR-12 were performed applying a Mann-Whitney-U-Test. Three-way ANOVA was applied to pain intensity and quality of life items with factors time (T0, T4, T8; as a repeated factor), group, and pain duration followed by Bonferroni test for multiple comparisons. Correlations were analyzed applying a Spearman Rank coefficient. Statistical significance was set to an alpha level of 0.05. All statistical analyses have been performed with IBM SPSS statistics 25.

3. RESULTS

3.1 Comparison between Dropouts and Finishers

The comparison between finishers and those who did not complete the 8 week intervention period yielded in none of the investigated parameters (anthropometric data, educational qualification, training history, HKF-R10, comorbidities, regular drug consumption, pain duration, pain intensity, pain locations, physician visits, physiotherapy, VR-12) a significant difference. The percentage of drop-outs in the individual centers was very inhomogeneous, ranging from 0 to 60 percent.

3.2 Pain Intensity

In the training group, mean pain intensity significantly decreased from initial 50 ± 21 to 32 ± 23 and 26 ± 23 after 4 and 8 weeks, respectively. Significant reductions were also observed for the least amount of pain from 22 ± 20 to 16 ± 18 (T4) and 14 ± 18 (T8). A slight relief of mean pain from initial 47 ± 20 to 45 ± 25 (T4) and 43 ± 26 (T8) was found in the control group, too. Fig. 2 shows the pain intensities of the acute, subacute, and chronic subgroups.

3.3 Quality of Life

Both the initial physical and mental quality of life were comparable between control (physical: 37,8 ± 9,1; mental: 52,9 ± 11,2) and training group (physical: 38,4 ± 8,9; mental: 53,2 ± 11).The training intervention led to a significantly enhanced PQL but did not affect MQL. PQL and MQL did not change significantly in the control group.

3.4 Patient`s Rating of the Training Influence on Pain Reduction

After 8 weeks of intervention, from the 509 finishers of the training group 42 patients quoted that the training influence on pain reduction was “very strong”, 102 patients “strong”, 189 patients “noticeable”, 141 patients “a bit” and 35 marked “not at all”. The percentage distribution is given in Fig. 4.

3.4.1 Analysis of rating-subgroups

The evaluation of the rating subgroups yielded that a 82 ± 4,6% reduction in pain intensity was needed to quote “very strong” while the weakest positive attitude (“a bit”) corresponded to a 25 ± 5,4 % pain decrease (Fig. 5). Fig. 6 presents the absolute changes in VR12 scales within subgroups.

4. DISCUSSION

4.1 Pain Intensity and Health Related Physical Quality of Life

The main finding of the present study is that an eight-week structured and supervised strength-endurance training leads to a significant reduction in both acute, subacute, and chronic low back pain. In the control-group of the acute low-back patients, mean pain also significantly

decreased after 8 weeks. However, this effect could not be obtained at T4 and even after 8 weeks the amplitude was far away from being clinically important. The clinically important reduction was also missed in the subacute control-patients. The chronic patients of the control group did not improve in any way. In contrast, the training effect is not only significant but also clinically relevant in all three groups: Based on literature dealing with different chronic forms of pain [39], Hayden et al. [40] considered a pain reduction greater than 20 points (on a scale from 0 to 100) as a clinically important difference for low back-pain patients. In the present investigation, mean pain reductions at the end of treatment amounted to 28,7 points, 30,0 points, and 22,0 points for acute, subacute, and chronic low back pain, respectively. Simultaneously, the health related quality of life significantly increased in all three groups. While the results for the subacute and chronic stages are in agreement with the existing literature, at first sight the findings of the acute phase appears to be in strong conflict with previous findings: The European guidelines for the management of acute nonspecific low back pain in primary

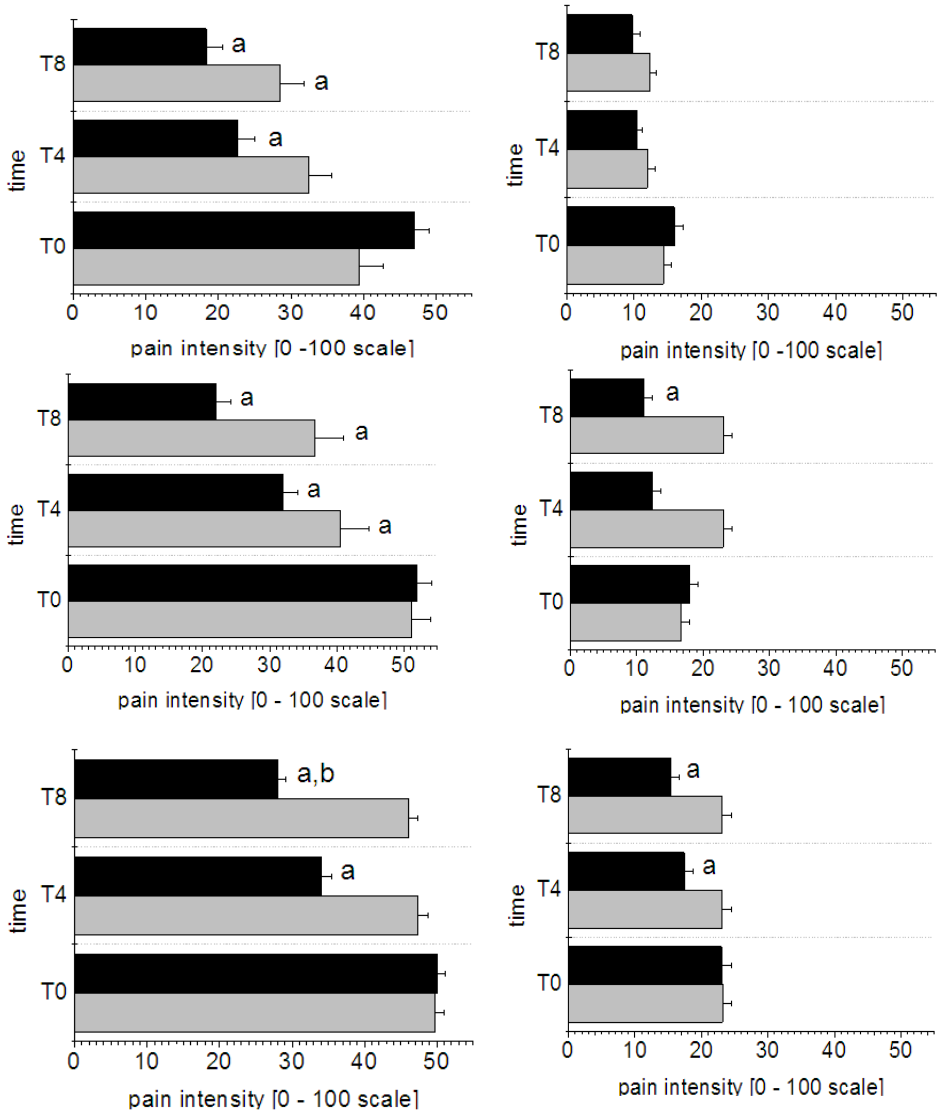

Fig. 2. Pain intensities for the training (black bars) and control group (grey bars) in the acute (top panel), subacute (middle panel), and chronic state (bottom panel)

Before (T0), after 4 weeks (T4), after 8 weeks (T8) of intervention. Left side: mean pain, right side: least amount of pain; mean ± SE; a = significant different from T0, b = significant different from T4

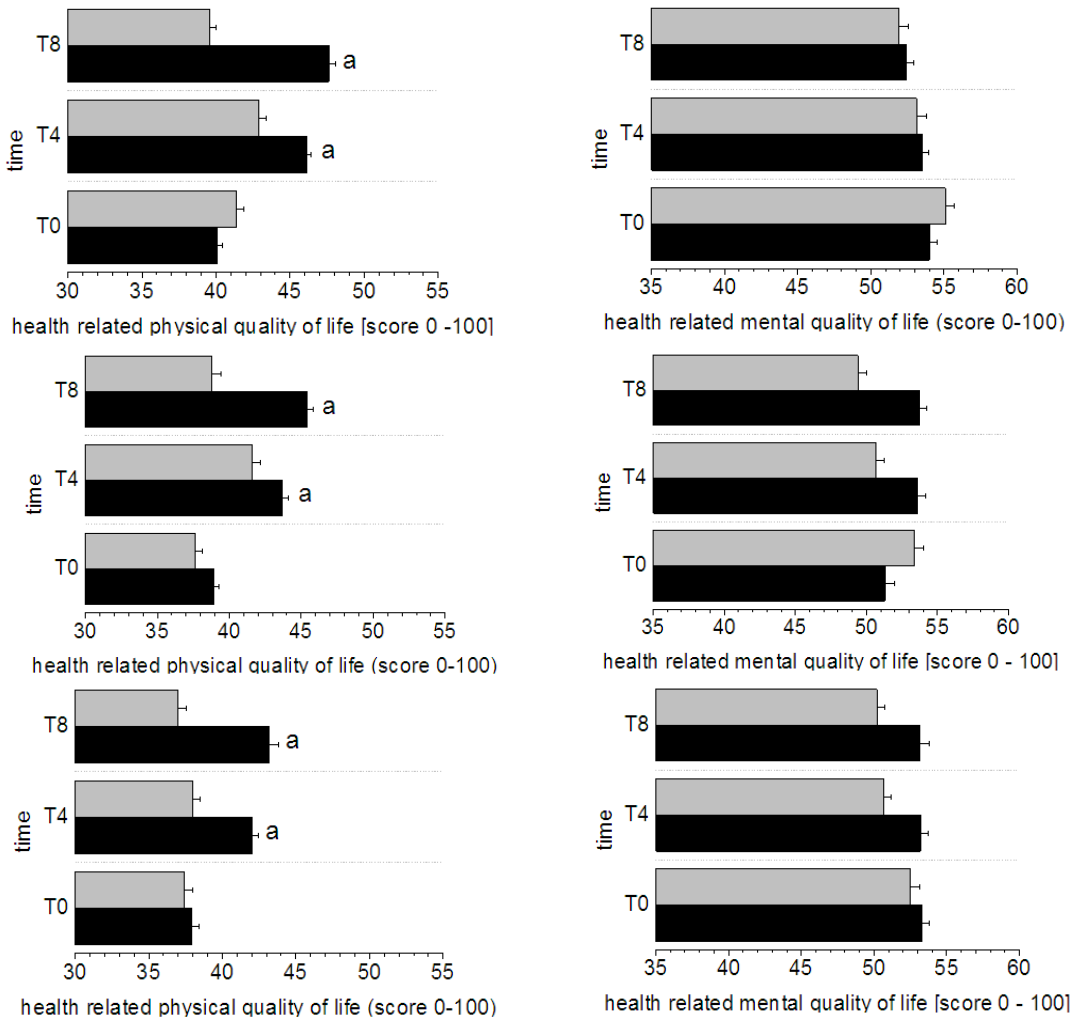

Fig. 3. Health related quality of life for the training (black bars) and control group (grey bars)
acute = top panel, subacute = middle panel, chronic = bottom panel; before (T0), after 4 weeks (T4), after 8 weeks (T8) of intervention. Left side: physical quality of life, right side: mental quality of life; mean ± SE. a = significantly different from T0

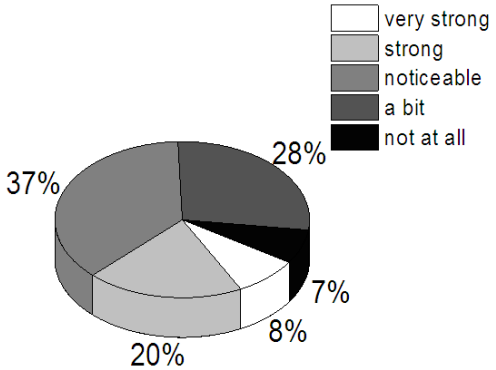

Fig. 4. Percentage distribution of patient´s rating about the influence of training with respect to pain reduction

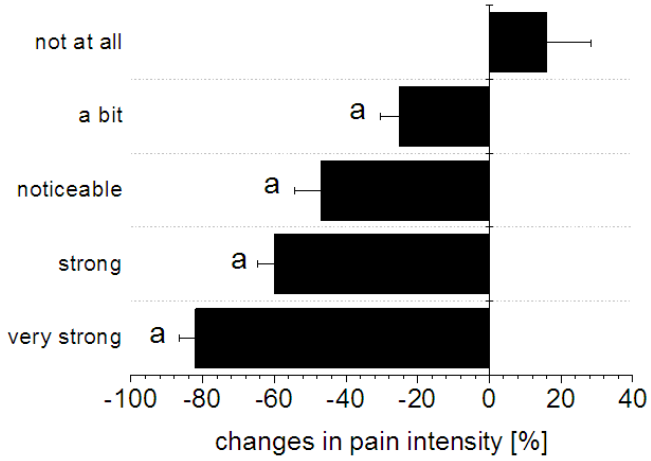

Fig. 5. Percentage changes in pain intensity within rating-subgroups of the training group at T8. mean ± SE. a = significantly different from T0

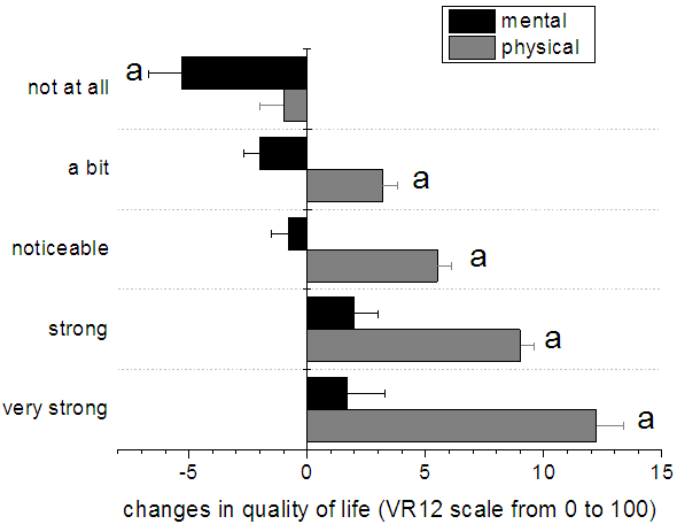

Fig. 6. Changes in quality of life within rating-subgroups of the training group at T8. Black bar = mental quality of life, gray bar = physical quality of life. mean ± SE. a = significantly different from T0

care [12] recommend: "Do not advise specific exercises (for example strengthening, stretching, flexion, and extension exercises) for acute low back pain" (Recommendation T4). The recent American College of Physicians Practice Guideline on Noninvasive Treatments [41] also does not support exercise as an acute-phase treatment. These statements are based on systematic reviews. One important fundament of this approach is the meta-analysis of Hayden et al. [40], who included 11 original articles dealing with exercise treatments in acute low back-pain patients. However, none of these articles gave a comprehensible description of the training method. Either the intensity, the number of repetitions, the number of sets or combinations of these parameters was not mentioned. Moreover, 5 publications exclusively focused on one muscle group [42,43,44,45,46], in 4 studies patients were just instructed to perform unsupervised home exercises [45,46,47,48], and one study applied "manipulative types of physiotherapy" [49]. Moreover, the ratio of articles included in the meta-analysis of Hayden et al. [40] was 1:4 for acute and chronic low back pain, respectively. All in all, in contrast to chronic

low back pain, the existing literature concerning physical exercises in acute low back pain is relatively rare and qualitatively almost inadequate with regard to the training method.

4.2 Structure of Exercise Intervention

To our best knowledge, the present investigation is the first which applied medical training therapy in acute low back pain patients. The term was introduced by Haber in 2001 [50] and means an exact description of therapeutic exercises including volume and intensity of the load. The training goal is disease specific and aims in an efficient improvement of musculoskeletal and/or cardiopulmonary function. The rationale of the exercise regimen used in the present study was to activate and to enhance strength and endurance of back-pain relevant muscle groups: A sufficient muscular trunk stability is a prerequisite for back-friendly everyday activities. The present training included all trunk stabilizing muscle groups. That holds for extension, flexion, lateral bending and rotation. Especially the latter, although common in everyday activities, has often been neglected in back-pain preventing or treating programs. The same holds for leg muscle strength and endurance although they are needed for back-friendly picking up and carrying heavy loads. In all exercises, the load and the time under tension were sufficiently high to create positive muscular adaptations [51,52]. For two reasons, we decided not to take strength or endurance parameters as an outcome parameter. First, according to Gruther et al. [53] "the diagnostic accuracy and reliability of muscle measurements in patients with chronic low back pain" is low due to considerable learning effects. It seems likely that the same applies to the other stages of low back pain. Secondly, from both a patient`s and a socio-economical point of view strength and endurance are not of primary importance in the treatment of low back pain but pain reduction and a good quality of life.

4.3 Drop Out and Health Related Mental Quality of Life

Independently of low back-pain duration, the improvement in mental quality of life failed to reach significance in the training group and it even tended to decline in the control-group. In the present data, one important difference between mental and physical quality of life is the baseline value at T0. Both scores are derived using an algorithm that is referenced to a metric centered at 50 and a standard deviation of 10 using the 2000–2002 US Medical Expenditure Panel Survey population. [54]. At T0, the mental quality of life in the acute, subacute and chronic groups already was above 50 while the physical quality of life just reached or even was below the lower limit of standard deviation. Obviously, the mental quality of life is more decoupled from pain sensations than the physical. This is in line with the subgroup analysis of the training group. While the physical quality of life became significantly better from the score “a bit” to “very strong” with an almost linear regression between both parameters, even the best score did not coincidence with a significant increase in mental quality of life.

In order to attain a rating of "very strong" with respect to the influence of training on pain withdrawal, a mean of more than 80% pain reduction was needed. For the rating "noticeable", the reduction still had to be around 50%. It shows that the expectations of success among patients were very high. This could have been a reason for the relatively high drop-out rate in the training group since, in contrast to pharmacologic pain killers, the effects of physical training on pain reduction are much slower. Another important influence on training-compliance may be the setting because the percentage of finishers differed between participating centers to a great extent. Since the study modalities, as well as the equipment, were identical in all centers, the human interaction between staff and patient may be a meaningful parameter. However, since patients were allowed to quit the study without mentioning reasons, the interpretation of drop-out remains speculative.

5. LIMITATIONS

The current study has several limitations. First, we have no information neither about the long lasting effect of the training nor about the long lasting compliance of patients with the training concept. Secondly, we did not manage to treat all patients in a sufficient way and 7% even worsened. Further long-lasting medical training therapy studies are encouraged focusing on prognostic parameters of training success and failure in all stages of non-specific low back pain.

6. CONCLUSION

In conclusion, an 8 week structured strength-endurance training program leads to a significant and clinically important reduction in non-specific low back pain and a significant increase in health

related physical quality of life in the acute, subacute and chronic stage. As a consequence, further studies with structured exercise programs are encouraged and the guidelines for the treatment of acute, non-specific low back pain should be reevaluated.

ETHICAL APPROVAL

All experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards lai down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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