

ORIGINAL REPORT

EFFECTIVENESS OF BACK SCHOOL FOR TREATMENT OF PAIN AND FUNCTIONAL DISABILITY IN PATIENTS WITH CHRONIC LOW BACK PAIN: A RANDOMIZED CONTROLLED TRIAL

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Objective: To evaluate the effectiveness of the addition of back school to exercise and physical treatment modalities in relieving pain and improving the functional status of patients with chronic low back pain.

Design: A randomized controlled trial.

Patients: A total of 146 patients with chronic low back pain were enrolled in the study.

Methods: Subjects were divided into 2 groups: the back school group received exercise, physical treatment modalities and a back school programme; and the control group received exercise and physical treatment modalities. Treatment efficacy was evaluated at the end of treatment and 3 months post-treatment, in terms of pain, measured with the Visual Analogue Scale, and functional status, measured with the Oswestry Low Back Pain Disability Questionnaire.

Results: In both groups, Visual Analogue Scale and Oswestry Low Back Pain Disability Questionnaire were significantly reduced after therapy ($p < 0.01$), but the difference between the scores at the end of treatment and 3 months post-treatment was not significant. There was a significant improvement in Visual Analogue Scale and Oswestry Low Back Pain Disability Questionnaire in the back school group compared with the control group at the end of therapy and 3 months post-treatment ($p < 0.05$).

Conclusion: The addition of back school was more effective than exercise and physical treatment modalities alone in the treatment of patients with chronic low back pain.

Key words: low back pain; back school; physiotherapy; exercise.

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severe spinal pathology; neurological involvement; and non-specific low back pain (2). The majority of low back pain is non-specific and has no clear diagnostic, prognostic or treatment protocols (2).

Chronic low back pain (CLBP) is defined as pain that lasts for more than 12 weeks (3). CLBP may be associated with incorrect interpretation of pain, stress or increases in other somatic findings, increase in anxiety level, physical mobility limitations, reduced physical activity, lack of participation in social activities, and decline in physical condition (4–6). The diminishing level of physical activities can lead to psychological states such as depression and anger. The aim of conservative treatment for CLBP is to increase mobility, to enable exercise, and to increase physical and psychological abilities in order to eliminate the negative symptoms mentioned above (4–6). To achieve these goals, the first stage in therapy involves an increase in tolerance of physical activity. The subsequent stages of therapy aim to increase physical capacity, diminish socio-economic burdens and improve psycho-social well-being (6).

Various non-surgical approaches, such as physical therapy modalities, exercise, and back school, have been used in the treatment of CLBP. Exercise is one of the main recommended treatments for CLBP. Low back and abdominal muscle strengthening exercises may decrease the frequency and duration of low back pain (1, 7–10). Physical treatment modalities are used to decrease symptoms for a short period of time (1, 3, 11, 12). Although there are some studies indicating that back schools have favourable effects on parameters such as pain and disability, their efficacy is not clear (2, 7, 8, 13).

There is insufficient evidence on the effectiveness of back schools run as educational programmes in addition to exercise and physical treatment modalities. The aim of this study was to evaluate the effectiveness of the addition of back school to exercise and physical treatment modalities in relieving pain and improving the functional status of patients with CLBP.

INTRODUCTION

Worldwide, 65–80% of the population experience low back pain at some stage of their lives. The most common cause of disability is related to the musculoskeletal system; particularly low back pain and spinal disorders (1). It is convenient to classify low back pain into 3 groups (diagnostic triage):

METHODS

Subjects

This study was designed as a randomized controlled trial with a 3-month follow-up undertaken in the Physical Medicine and Rehabilitation Clinic of Meram Medical Faculty of Selcuk University. A total of 160 patients, who were referred or self-referred to our outpatient clinic with CLBP, were evaluated. Patients who had had non-specific

low back pain for longer than 12 weeks without neurological deficits were enrolled in the study. Exclusion criteria were: subjects who had continuous pain with a score above 8 on the Visual Analogue Scale (VAS), age ≤ 18 years, those who had already attended the back school programme, subjects who had undergone previous surgery, who had structural anomalies, spinal cord compressions, severe instabilities, severe osteoporosis, acute infections, severe cardiovascular or metabolic diseases, who were pregnant, and those with a body mass index above 30kg/m^2 (Table I). A total of 150 patients were included in the study. Physical examinations included inspection and palpation of the lumbar region, lumbar mobility measurements, lumbar range of motion measurements, neurological examination and some other specific tests of the lumbar region. All patients were examined by the same physician, who was blind to the type of therapy. The study was approved by the local ethics committee at the Meram Faculty of Medicine of Selcuk University and was carried out in accordance with the principles of the Declaration of Helsinki. All patients were fully informed about the trial and their written/oral consent was obtained.

Interventions

Exercise programme. Subjects were given the low back exercise programme, which includes lumbar flexion exercises, lumbar extension and lumbar stretching exercises, and strengthening exercises for the thighs. The exercise programme was run by the same physiotherapist, who was blinded to which group the patient was allocated to, in patient groups of 5 in an exercise room. In addition, a written exercise programme was given to the patients. The exercises were repeated 5 times a week for 2 weeks (total of 10 sessions) in the exercise room and were controlled. Afterwards, the patients were told to perform the exercises at home 3 times a week for 3 months.

Physical therapy. A physical therapy programme, including transcutaneous electrical nerve stimulation (TENS) once daily, 5 days a week for 2 weeks, totalling 10 sessions, ultrasound and hot pack application was applied by a physiotherapist. TENS was applied as 100 Hz, 40 μsN in continuous waveform for 30 min/session. Therapeutic ultrasound was applied as a continuous wave with 1 MHz frequency and 1.5 W/cm^2 intensity for 5 min (1, 3, 11, 12). The physical therapy programme was applied once daily for 5 days a week for 2 weeks before the exercise programme was started.

Back school programme. Patients were included in the back school, which consisted of 2 sessions per week for 2 weeks; a total of 4 sessions. Each session lasted 1 h and included both didactic and practical training. The programme was administered by a physiatrist (NS). The aim of the back school was to teach patients about the functional anatomy of the low back, the function of the back, pain, the correct use of the lower back in daily life, and skills to enable them to cope with low back problems, increase self-esteem and improve their quality of life, leading to a decrease in recurrence of low back pain. In this programme, patients were given written information by the physician. Sessions included 4–6 subjects. In addition, the physiatrist

Table I. Exclusion criteria in the study

Continuous-VAS > 8 low back pains
Age 18 years and under
Attended the back school programme
Previous surgery
Structural anomalies
Spinal cord compressions
Severe instabilities
Severe osteoporosis
Acute infections
Severe cardiovascular or metabolic diseases
Pregnancies
Body mass index above 30 kg/m^2

VAS: visual analogue scale.

interviewed and assessed each patient's lifestyle, physical activity, and risk factors. Each patient who joined the programme explained his or her problems, problem-solving skills, and was instructed in how to use low back movements in their daily life during the programme. Each subject was asked to perform the programme described.

Group 1 (back school group: BSG) received physical treatment modalities, exercise and the back school programme. Group 2 (control group: CG) received physical treatment modalities and exercise. Patients in all groups received 500 mg paracetamol tablets as needed, up to 2 g per day (up to 4 tablets a day) from the beginning of the study. None of the patients was given any treatment other than that described above, and they were not examined by any other clinical departments during the study.

Evaluation criteria

Patients were evaluated at the beginning, after the treatment and at 3 months post-treatment for pain severity by VAS (motion) (14), and for functional aspects with the Oswestry Low Back Pain Disability Questionnaire (ODQ) (15–17).

- **Pain evaluation:** patients were evaluated in terms of low back pain during activity, on a scale ranging from 0 to 10 by VAS over the past 7 days (0 point = no pain, and 10 points = severe pain) (14).
- **Functional status:** the ODQ comprises 10 questions evaluating pain, personal care, weight-bearing, walking, sitting, standing, sleeping, social life, taking a trip and the degree of change in pain, with each item scored from 0 to 5. The ODQ score is then calculated as a percentage, where 0% represents no pain and disability and 100% represents the worst possible pain and disability. Validation and reliability studies have been performed for this questionnaire on patients with CLBP in Turkish populations (17).

Sample size calculation

The sample size was calculated using a formula in order to have a confidence interval (CI) of 95%, with a standard deviation (SD) of $\sigma = 2$, a significance level of 5% and a statistical power of 88% (difference of 2 points on VAS values in the third month after physiotherapy, as reported in previous studies of CLBP) (9, 18, 19). We required 75 participants per group (20).

Randomization

Concealed randomization was conducted. Using sealed, opaque envelopes, coded according to a computerized random number generator, 150 patients were allocated randomly into 2 groups in a 1:1 ratio, as group 1 (BSG) and group 2 (CG). The assignment of patients was performed by 2 researchers after patients had completed a baseline questionnaire to collect demographic and prognostic information by anamneses. The researchers, who were not involved in the treatment of patients, prepared the envelopes. The evaluating physician, who was blind to the type of therapy, was not aware of the randomization outcome.

Compliance

During the study, 2 subjects from each group dropped out; 2 because they could not get leave from their jobs, 1 because of low back trauma due to falling, and 1 for private reasons. All of the subjects who completed the study attended their 3-month follow-up visits (Fig. 1).

Statistical analysis

Categorical and continuous data was assessed using the χ^2 and Mann-Whitney *U* tests. A paired-samples *t*-test was used in the group evaluations, whereas a general linear univariate model was used for comparisons between the groups for VAS and ODQ scores. Time-dependent changes in ODQ and VAS scores for both groups were evaluated by analysis of covariance (ANCOVA). Analyses were adjusted for baseline data of VAS and ODQ scores that differed between the BSG and the CG. The mean of the difference in change was given between both groups with regression coefficients (95% CI). *p*-values < 0.05 were accepted as statistically significant.

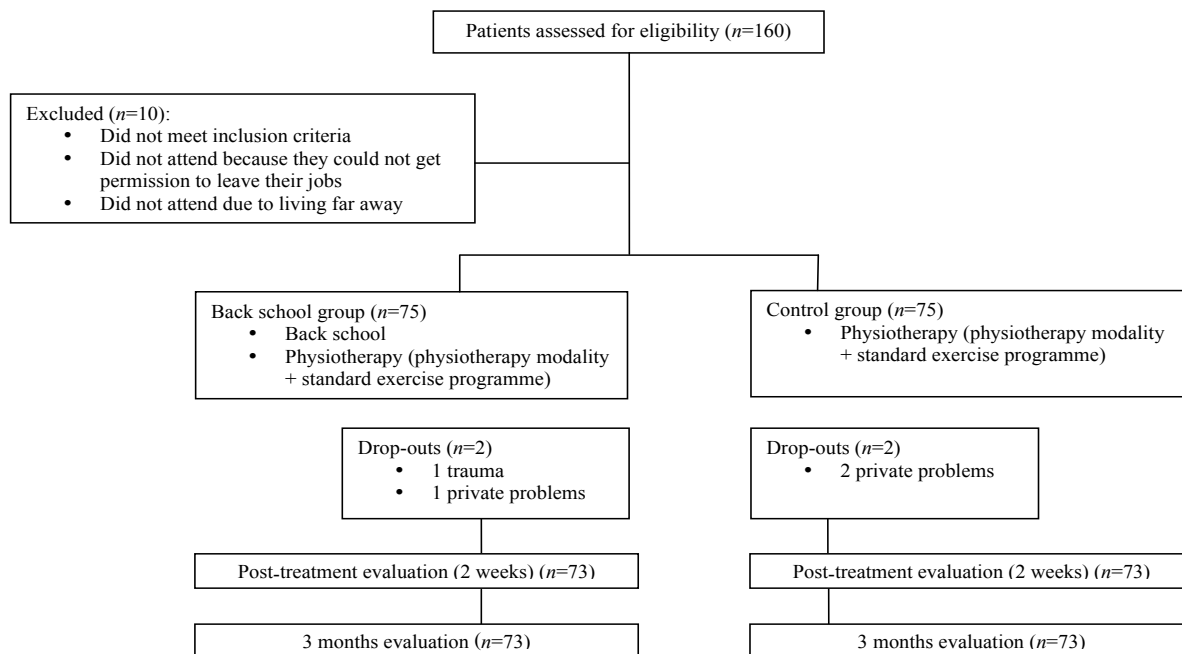


Fig. 1. Study group formation, numbers and drop-outs.

RESULTS

A total of 146 patients completed the study and attended the third-month control visits (Fig. 1). The mean age in the BSG was 47.25 years (SD 11.22 years), whereas it was 51.36 years (SD 9.65 years) in the CG. There was no statistically significant difference between the groups in terms of age, gender, body mass index, occupation or education ($p > 0.05$). The demographic characteristics of the patients are shown in Table II.

Within-groups

The decrease in VAS and ODQ values pre- and post-treatment was statistically significant in both study groups (VAS: 95% CI = 4.68–5.15; 5.12–5.58, ODQ: 95% CI = 39.83–42.18; 43.59–45.94, for BSG-CG, respectively). These results were statistically significant ($p < 0.01$). However, there was no significant difference between post-treatment and third-month controls in both groups (VAS: 95% CI = 3.29–3.91; 4.00–4.62,

ODQ: 95% CI = 34.75–37.51; 38.55–41.31, for BSG-CG, respectively). These results were not statistically significant ($p > 0.05$).

Between-groups

There was a significant reduction in VAS in the BSG compared with the CG after the treatments and at 3 months post-treatment (0.665, 95% CI = 0.564–0.767 and 0.205, 95% CI = 0.070–0.340). These results were statistically significant ($p = 0.010$ and $p = 0.002$, respectively). Disability (ODQ scores) were significantly lower in the BSG compared with the CG after the treatments and at 3 months post-treatment (1.011, 95% CI = 0.929–1.093 and 0.844, 95% CI = 0.748–0.941). These results were statistically significant ($p < 0.001$) (Table III).

No adverse events related to treatments were observed in the study groups. All patients who completed the control examinations reported doing regular exercises at home. All patients attended every session of the back school programme.

Table II. Baseline characteristics of the 2 groups

	BSG (n=73)	CG (n=73)	p
Age, years, mean (SD)	47.25 (11.22)	51.36 (9.65)	0.210 ^a
Women, n	55	57	0.328 ^b
BMI, mean (SD)	27.24 (2.05)	26.14 (2.12)	0.349 ^a
Pain duration, months, mean (SD)	6.48 (7.31)	7.33 (6.46)	0.275 ^a
Education, n			0.578 ^b
Primary	45	46	
Secondary/higher	19	19	
College	9	8	
Occupation, n			0.210 ^b
Employed	25	24	
Housewife	48	49	

^aMann-Whitney U test; ^b χ^2 test.

BSG: back school group; CG: control group; SD: standard deviation.

DISCUSSION

In this randomized controlled trial, we observed that a back school programme has an effect on pain and disability when given in addition to physical treatment modalities and exercises. This effect was observed post-treatment and at 3 months follow-up.

Limiting factors of the present study are the short-term follow-up, lack of cost-analysis and few assessment criteria.

The initial aim of treatment was to increase patient's physical activity and functional capacity and to decrease pain, but as the observation time was short, accurate assessment of the impact on functional status was limited. Studies on the effec-

Table III. Comparison of adjusted means of VAS and the ODQ between the 2 groups

	BSG (n=73) Mean±SEM (95% CI)	CG (n=73) Mean±SEM (95% CI)	F	p	Regression coefficient (95% CI)
VAS					
Baseline	5.69±2.14	6.52±1.12			
Post-treatment	4.91±0.11 (4.68–5.15)	5.35±0.11 (5.12–5.58)	6.765	0.010*	0.665 (0.564–0.767)
3 months	3.60±0.15 (3.29–3.91)	4.31±0.15 (4.00–4.62)	9.963	0.002*	0.205 (0.070–0.340)
ODQ					
Baseline	54.50±14.13	55.65±11.80			
Post-treatment	41.01±0.59 (39.83–42.18)	44.76±0.59 (43.59–45.94)	19.942	<0.001*	1.011 (0.929–1.093)
3 months	36.13±0.69 (34.75–37.51)	39.93±0.69 (38.55–41.31)	14.792	<0.001*	0.844 (0.748–0.941)

* $p < 0.05$

BSG: back school group; CG: control group; SEM: standard error of the mean; CI: confidence interval; VAS: Visual Analogue Scale; OLBPDQ: Oswestry Low Back Pain Disability Questionnaire.

tiveness of exercise therapy on CLBP, have shown a significant improvement in the pain scale in the first 6 months, but no additional improvement in the subsequent 6 months (21). The follow-up period in our study was too short to evaluate long-term effects.

Most of the patients were housewives. However, we believe that this fact did not affect the results, because housewives do a considerable amount of physical activities, but the external validity regarding other groups of patients has not been strictly evaluated. The number of housewives was equally distributed in the intervention groups. Furthermore, spinal disorders are more common among women than men (1, 22, 23). Thus, having more women than men in our study would affect generalization of the results.

Due to the known effects of obesity on several areas of the musculoskeletal system besides the lumbar region, patients defined as obese (body mass index above 30 kg/m²) were excluded from this study (24). Patients who had not previously received back school education were also included in our study in order to determine when exactly the effectiveness of this education begins.

The main strengths of this trial are the blinded evaluations, the use of validated outcome, concealed randomization, high compliance, and the low number of drop-outs.

In our study, members of both groups received physical treatment modalities and exercises. Appropriate exercises are effective for the subjects to remain active (13). The aim of exercise therapy is to correct posture, prevent muscle spasm, strengthen body muscles and increase general aerobic capacity (10, 12, 25). There is evidence to support the idea that exercises are effective in patients with CLBP in returning to their daily activities and work at long-term follow-up (26). Some studies conclude that pain intensity and disability are significantly reduced by exercise therapy at short-term follow-up (10). Exercise is also thought to decrease the "avoidance" behaviour due to fear of chronic pain and to reduce disability (27–30).

Pain and functional status are recommended outcome criteria in patients with CLBP (31). Chronic pain causes physical limitations, depression and deterioration in the functional condition of the individuals (6, 31–33). Diminution of pain would therefore eventually improve functionality, and amelioration of disability would encourage the patient to move,

and consequently the pain may decrease. Our study evaluated these 2 criteria and observed significant improvements in both. On the other hand, VAS and ODQ scores were significantly lower in the BSG compared with the CG after the treatments and at 3 months post-treatment; however, the differences between the 2 groups were much worse than minimal important change (MIC) (34). Measurement of the MIC has shown that the improvements in pain and functional status obtained in our study were small or not important. These results, however, do not indicate that the study is worthless, the content of the discussion does not change. Further studies of the relationship between MIC and clinically relevant need in patients with CLBP are therefore required.

Physical treatment modalities used to decrease symptoms for a short period of time include cold packs, hot packs, diathermia, ultrasound and TENS (1, 3, 11, 12). The effects of such treatments in relieving pain are controversial, but they have been shown to be better than placebo in some studies (1, 11, 12, 25, 35). As we did not include a placebo group in our study, we cannot evaluate whether the exercise and physical treatment modalities were effective in both groups (21, 27).

In the present study, we observed significant improvements in the BSG. Similarly, in a review study, it is stated that the back school programme is recommended for return to work and to decrease short-term disability (8). However, the results of back school programmes related to getting back to work, pain relief and functional status improvement are based on questionable evidence; thus their effectiveness is still debated (7, 13, 36). The absence of a control group in most studies of back schools is one of the main reasons for the lack of evidence. In the majority of these studies without a control group it is reported that back school leads to effective results in the treatment of back pain (37). Some studies emphasize the necessity of combining exercise treatment with back school programmes (38, 39). Back school programmes educate patients about the anatomy of the spine and low back pain, correct ergonomics in daily life and work, and how to cope with low back problems, thus increasing their self-esteem. Back school in addition to exercises can therefore improve patients' quality of life and prevent recurrences. A new understanding of the low back problem may lead to improvement or deterioration of the condition. At present we do not know which aspect of the

back school programme is most important; however, the effect of correct ergonomics is questionable. Training given by the back school programme may reduce patients' fear-avoidance behaviour, developed due to incorrect interpretation of pain. Limitation of movement, decrease in physical activity, avoidance of social activities, and deterioration in physical condition may enhance the patient's fear-avoidance (6). However, we did not evaluate fear-avoidance beliefs and thus cannot draw any conclusions about the effect of the back school programme on fear-avoidance. Meeting the targets of back schools can decrease the risk of disability and have a positive impact on functional status (40). Back school and exercises for CLBP are compared in many studies (41–43). These studies include many different back school education programmes. Our study differs from most of the studies mentioned above in that the population included mainly housewives. Only Tavafian et al.'s (40) study had a population similar to that of our study, but they compared groups that received back school with those that did not. Furthermore, exercise and physical treatment modalities being given in addition to back school discriminate our study from the others. Similarly, in many of the studies mentioned above, back school education is reported to be effective for treatment of pain and disability. However, in some of these studies, having heterogeneous groups, missing a control group and failing to evaluate the factors affecting the treatment, bring the credibility of the results into question. In our study the patient groups were not heterogeneous, but we also defined a control group. The study would have been improved by the inclusion of an additional group that received no treatment other than back school, in order to determine the effectiveness of back school alone. Our study also differs from studies in which the back school education is given by a physiatrist rather than a physiotherapist. The background of the person in charge of providing education to the patients may affect the results; further research is required into this aspect.

In conclusion, the addition of back school was more effective than physical therapy and exercises alone for patients with CLBP. We suggest that decreased fear-avoidance and a better understanding of the back encouraged patients to use their backs more in daily activities. However, the exact mechanism for the observed significant reductions in pain and disability were not examined.

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