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The Efficacy of the Back School

A Randomized Trial

Jolanda F.E.M. Keijsers, Mieke W.H.L. Steenbakkens, Ree M. Meertens, Lex M. Bouter, and Gerjo Kok

Although the back school is a popular treatment for patients with low back pain, especially in Scandinavian countries, very few well-designed studies into the effectiveness of this type of treatment have been performed. Back schools are programs in a group setting, directed toward pain management and consisting of elements of education and/or training of skills. The Maastricht Back School is designed to be a combination of all those elements about which we consider a back school should give information and training. In order to determine the effectiveness of the Maastricht Back School, we conducted a randomized trial ($n = 77$) comparing a group that attended back school with a waiting list control group. The most important measures of effect were pain management, pain, medical consumption, and absenteeism from work. The overall response was 85.5%. The results of an intention-to-treat analysis of the data collected 2 and 6 months after randomization consistently suggested inefficacy of the Maastricht Back School for all effect parameters (except for the effect parameter knowledge). Though the present study certainly had some limitations, we question the clinical relevancy of back schools.

One of the possible treatments for patients suffering from low back pain is the so-called back school, which is of Swedish origin [1, 2]. Back schools offer an education and skills program in a group setting (10 to 12 patients per group) and primarily are aimed at pain management: information is given about ways of dealing with pain, so that the patient is able to control his or her pain problem more effectively [3]. Although the back school is a popular treatment for patients suffering from low back pain, the results of the few well-designed studies into the effectiveness of this treatment indicate, at most, borderline effects for the back school [4].

The Maastricht Back School consists of seven sessions, each lasting 2.5 hours, plus a refresher session after 6 months. A course instructor is present at every session. In addition, various guest lecturers are invited to give information and training. The Maastricht Back School approaches pain in a multidimensional way, which is generally accepted to be a desirable method [4]. This school is designed to be a combination of all elements about which we consider a back school should give information and/or training. In order to investigate the effectiveness of the Maastricht Back School, we conducted a randomized trial in primary health care, comparing a group receiving the Maastricht Back School treatment with a waiting list control group. Patients in the waiting list control group were promised back school treatment at the end of the study. If the Maastricht Back School turns out to be effective, it will be implemented in Dutch outpatient care. This implies that up till now, the Maastricht Back School does not form a part of the primary health care system and that it was initially developed for the research project.

After presenting the inclusion and exclusion crite-

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ria and the effect parameters, this article describes the methods of data analysis. Next, the principal results of the evaluation study are presented. Finally, results and validity of the study are discussed.

MATERIALS AND METHODS

Selection of Patients

The inclusion criteria for the study required the presence of low back pain for at least 2 months, with a maximum of 3 years. Patients eligible for medical and surgical treatment were excluded, as were those who were unable to participate in a physical exercise program and a relaxation training (since these are essential parts of the Maastricht Back School). Prospective participants were judged on all these criteria by the general practitioners recruiting the study population.

Effect Parameters

The most important effect parameters in this study were (1) pain management; (2) pain, measured by (a) the West Haven–Yale Multidimensional Pain Inventory (WHYMPI), subdivided into influence of pain on daily life, reactions from the environment, and activities [5] and (b) a visual analogue scale (VAS) [6]; (3) medical consumption, subdivided into consultations with health care providers, treatments, and medicine taking; and (4) absenteeism from work. Pain and pain management were both measured by a VAS. For pain, the anchor words were “no pain” and “much pain”; for pain management, they were “not able to manage the pain” and “very much able to manage the pain.” The number of consultations with health care providers was determined by adding the frequencies of consultations with a general practitioner, a physical or manual therapist, a specialist, or some alternative physician. The number of treatments were determined by adding the number of common methods of treatments for patients with low back pain. Medicine taking was computed by adding the number of types of medicine usually prescribed for low back pain. Absenteeism from work was expressed in number of days. Other outcome measures were functional restrictions (measured by the Sickness Impact Profile [7]), knowledge of the Course Content, general well-being, and satisfaction. General well-being as well as satisfaction with the Maastricht Back School were measured by a VAS. For general well-being, the anchor words were “feeling very bad” and “feeling very well”; for satisfaction with the course, they were “very dissatisfied” and “very satisfied.”

Data on all of these parameters were collected at

TABLE 1

Data Collection Schedule

Instrument	Baseline	2 Months	6 Months
Pain management	X	X	X
Pain (WHYMPI)	X	X	X
Pain (VAS)	X	X	X
Medical consumption	X		X
Work absenteeism	X		X
Functional restrictions (SIP)	X		X
Knowledge		X	X
General well-being	X	X	X
Satisfaction		X	X

WHYMPI, West Haven–Yale Multidimensional Pain Inventory; VAS, visual analogue scale; and SIP, Sickness Impact Profile.

baseline, and 2 and 6 months after assignment to treatment or control groups. All information was gathered by way of questionnaires and filled out by the patients. Table 1 shows the schedule of data collection.

Methods

In order to examine the effect of the Maastricht Back School, we performed univariate analyses of variance (ANOVAS) and, if there was more than one dependent variable, multivariate analyses of variance (MANOVAS) of the repeated measures data (also called mixed between-within-subjects MANOVA, split plot, or randomized block factorial design), using the SPSS-X package [8]. The independent variables were “condition,” with two levels (experimental and control group), and “time,” with three levels (baseline, 2 months after randomization, and 6 months after randomization). The ANOVA and MANOVA repeated-measures techniques provided a general test of whether groups with and without Maastricht Back School treatment differed over time for the effect parameter at issue. In other words, the ANOVA and MANOVA repeated measures tested (1) the difference between the two treatment groups without considering levels of time (effect of condition); (2) the difference in time without considering levels of condition (effect of time); and (3) the difference across time between the two treatment groups (effect of interaction, that is, the effect of condition $\times$ time). If the effect of interaction is significant, this indicates that one type of treatment (Maastricht back school or waiting list control) “works best.” Hence, the effect of interaction gives us information about the main research question, which was: Is there a difference in effect between a group

receiving back school treatment and a waiting list control group? An alternative to ANOVA of the repeated measures data would have been a separate analysis for each moment of data collection and for each dependent variable. However, due to the number of effect parameters, this would lead to an excessive number of significance tests and, thus, to chance capitalizing. The results of an evaluation of the main assumptions of ANOVA and MANOVA [8] were satisfactory.

Furthermore, univariate analyses of covariance (ANCOVAs) and multivariate analyses of covariance (MANCOVAs) of the repeated measures data were performed on most of the dependent variables, in order to determine the effectiveness of the Maastricht Back School after adjustment for differences between the groups in baseline scores, pain duration, cause of the pain, sex, level of education, and age. These covariates were used because they were found to correlate strongly with most dependent variables (Pearson correlation coefficients). If in an ANCOVA or MANCOVA the effect of interaction is significant, this indicates that after adjustment for the covariate (such as baseline scores) one type of treatment "works best." The results of an evaluation of the main assumptions of ANCOVA and MANCOVA [8] were satisfactory.

RESULTS

Of the 96 patients who applied for the Maastricht Back School, six were not willing to sign the informed consent. Of the remaining 90 patients, 13 dropped out (defined as not filling out the questionnaires at all three moments of data collection); six patients were of the experimental group and seven of the waiting list control group. The main reasons for not completing the trial were of a practical (for example, an operation on a patient's knee) or private nature (for instance, illness of a family member). Six of the 13 dropouts were lost at the first moment of data collection. Therefore, no baseline data were available for these six dropouts. The remaining seven patients dropped out at either the second or third moment of data collection. The mean age of these seven patients, who were all men, was 42.1 years, and they had an average pain duration of 9.8 years.

The patients included 39 men and 38 women, with a mean age of 35.8 years. Although the general practitioners selected on pain duration, we inquired after patients' pain duration. The average pain duration was 7.5 years, which is not in accordance with the inclusion criterion of low back pain for at least 2 months, with a maximum of 3 years. The educational

level of most of the patients was that of vocational school. Forty-four patients had at the time of the study a full-time or part-time job. Due to their back pain, 14 patients received a state disability benefit. Compared to the waiting list control group, the experimental group included more women (14 in the experimental group and 24 in the waiting list control group) and more patients receiving a state disability benefit (11 in the experimental group, and three in the waiting list control group). Furthermore, the educational level in the experimental group was lower. For all other demographic variables, no meaningful differences between the experimental and waiting list control group were found. As shown by the means presented in Table 2, at baseline both groups differed substantially on almost all effect parameters used.

In order to explain in detail the procedure of data analysis, the effect of the Maastricht Back School on medicine taking (a subdivision of the medical consumption) is presented by way of example. Data on other effect parameters were analyzed in exactly the same way. Because the findings were consistent, they are not discussed in detail for all other effect parameters. Patients were asked about their medicine taking at baseline and 6 months after randomization. They were asked what medication they had been using for their back pain during the last 6 months. Medicine taking per patient was then calculated by counting the types of medicine (for example, tranquilizers) they used. The maximum number of types was seven. If a patient used all types of medicine, the score was 7; if a patient used none of them, the score was 0. Step one of the general procedure followed consisted of an analysis of the calculated means. The means of each data collection for the experimental group and the waiting list control group are presented graphically in Figure 1.

Given the random procedure, it is somewhat surprising that the means for the experimental and the waiting list control groups already differed substantially at baseline (a *t* test between the groups showed that this difference was statistically significant at $P = 0.031$). Six months after randomization, the means for the two groups still differed substantially. The next step, which was the most interesting one with regard to the central question of the study, was to find out whether the change in the experimental group was larger than that in the waiting list control group. This effect of interaction turned out not to be statistically significant ($df = 1.75$; $F = .079$; $P = .779$); however, the effects of time ($df = 1.75$; $F = 14.68$; $P = .001$) and condition ($df = 1.75$; $F = 11.84$; $P = .001$) were significant. This indicates that with regard to medicine taking, there was no difference between

TABLE 2

Means of the Experimental and Control Groups for Each Effect Parameter and Data Collection^a

Condition	Experimental			Control		
	Baseline	2 Months	6 Months	Baseline	2 Months	6 Months
Pain management (range, 1–10)	4.79 (1.86)	5.88 (1.97)	5.82 (2.05)	5.43 (1.93)	5.65 (1.96)	6.25 (1.85)
Pain (WHYMPI)						
Influence of pain on daily life (range, 0–6)	3.53 (1.23)	3.38 (1.25)	3.14 (1.39)	3.25 (1.30)	3.10 (1.28)	2.86 (1.32)
Reactions from the environment (range, 0–6)	2.47 (1.14)	2.26 (1.08)	2.19 (1.10)	2.13 (1.15)	1.94 (1.11)	2.11 (1.23)
Activities (range, 0–6)	2.96 (1.33)	2.91 (1.31)	2.84 (1.30)	3.00 (1.39)	2.97 (1.32)	3.11 (1.45)
Pain (VAS) (range, 1–10)	6.49 (2.33)	5.35 (2.38)	5.35 (2.84)	5.77 (2.74)	5.15 (2.65)	4.10 (2.75)
Medical consumption						
Consultations (range, 0–∞)	23.27 (22.38)		9.00 (10.99)	16.08 (15.31)		6.63 (9.04)
Treatments (range, 0–22)	3.27 (2.66)		1.84 (2.03)	2.63 (2.05)		1.00 (1.22)
Medicine taking (range, 0–7)	1.22 (0.98)		0.81 (1.08)	0.63 (0.70)		.28 (0.51)
Work absenteeism (range, 0–∞)	27.00 (43.28)		19.00 (43.18)	21.26 (25.44)		3.43 (10.16)
Functional restrictions (SIP)						
Physical impairment (range, 0–3)	0.17 (0.28)		0.12 (.20)	0.05 (0.09)		0.04 (0.06)
Psychosocial impairment (range, 0–4)	0.42 (0.58)		0.38 (.51)	0.14 (0.23)		0.14 (0.22)
Knowledge (range, 0–25)		18.78 (4.26)	17.62 (4.53)		14.20 (4.30)	13.70 (4.88)
General well-being (range, 1–10)	5.18 (2.33)	5.65 (2.44)	5.82 (2.47)	5.85 (2.24)	6.08 (2.32)	7.13 (2.40)

WHYMPI, West Haven–Yale Multidimensional Pain Inventory; VAS, visual analogue scale; and SIP, Sickness Impact Profile.

^a For all ranges except "pain management," "activities," "knowledge," and "general well-being" the higher the figure given, the worse was the score on that relevant effect parameter. All data are means and standard deviations. **Figure 1.** Means for data on medicine-taking at baseline and 6 months after randomization (sum of types; range, 0–7): —, experimental; and ----, control.

TABLE 3

Test Statistics from MANOVA Repeated Measures for the Interaction Effects Condition $\times$ Time for the Effect Parameters

Effect parameters	F	df	P value
Pain management	2.21	2,71	.12
Pain (WHYMPI)	.91	12,64	.59
Pain (VAS)	1.32	2,73	.27
Medical consumption			
Consultations	.36	5,58	.87
Treatments	1.32	16,60	.22
Medicine taking	.08	1,75	.78
Work absenteeism	.56	1,42	.46
Functional restrictions (SIP)	1.33	2,74	.27
General well-being	1.05	2,70	.36

WHYMPI, West Haven–Yale Multidimensional Pain Inventory; VAS, visual analogue scale; and SIP, Sickness Impact Profile.

the back school treatment and waiting list control groups. Looking again at Figure 1, it can be seen that the two groups differed over time (the effect of time) and that the means for the experimental group differed from those for the waiting list control group (the effect of condition). With regard to medicine taking, the gain for the experimental group was not larger than the gain for the waiting list control group (effect of interaction).

This same procedure was carried out for all effect parameters. Because the results were in general similar for all measures of effect, they are not discussed in detail. Instead the effects of interaction for the effect parameters are presented, because these are the most interesting ones with regard to the research question. Table 3 summarizes these effects of interaction. It shows that there are no significant effects of interaction. In Table 2, the corresponding means for the experimental and control groups are given for each data collection and effect parameter.

ANCOVAS and MANCOVAS for the repeated measures data did not reveal significant effects of interaction either. Nor did subgroup analyses based on several prognostic variables (sex, pain duration, age, and level of education) show statistically significant effects of interaction.

Summarizing the results, it can be said for all effect parameters that:

1. Both the experimental group and the waiting list control group showed progress with time (significant effects of time). However, the experimental group did not show significantly more progress (effects of interactions were not significant).

2. Although patients were randomly assigned to treatment groups, there were substantial differences in some prognostic variables (for example, sex).
3. After adjustment for these differences, there was still no difference in effect between the group receiving back school treatment and the waiting list control group.

DISCUSSION

The present study failed to reject the null hypothesis stating that there is no difference in effect between a group receiving back school treatment and a waiting list control group. Besides the apparent inefficacy of the Maastricht Back School, some problems concerning the validity of the study need to be discussed.

1. The number of patients in the study was relatively small [77] and, therefore, only relatively large effects could be detected (lack of power of the study) [9].
2. Internationally acknowledged reliable and valid effect parameters with regard to (low back) pain are scarce. Moreover, the available reliable and valid effect parameters might be insensitive to changes with time. For the Sickness Impact Profile, for example, interim surveys have shown satisfying results regarding its reliability and validity [7]. On the other hand, the Sickness Impact Profile may have been insensitive to changes with time [10].
3. The differences at baseline may be due to data collection after randomization instead of before. Filling out questionnaires knowing whether one can start with the back school might bias one's answers.
4. It might be argued that the differences in baseline scores were responsible for the nonexistence of the expected significant effects of interaction. We do not think, however, that this is the case. More serious patients, who seem to be more prevalent in the experimental group, might have been expected to profit more from the treatment than the less serious patients in the control group. That is to say that the differences at baseline might in this case be expected to enhance the probability of finding significant effects of interaction.
5. Back pain complaints often fluctuate with time. Patients who sign up for a back school probably have serious complaints at that time and thus score extremely high, so that scores 2 and 6 months after randomization tend to be lower, due

to fluctuations that are intrinsic to the natural history of back pain. This implies that it will be difficult to show effects of the Maastricht Back School, which are small compared to these fluctuations with time. On the other hand, it can be argued that such small effects lack clinical relevance anyhow.

6. A waiting list control group is not entirely comparable to a control group receiving a different or placebo intervention. In a waiting list control group, the knowledge that one will enter the desired back school treatment within half a year might already have some therapeutic effect. Another possibility is that patients on a waiting list may seek some alternative treatment while waiting, or already start behaving in accordance with the ideas of the back school.

Although bias cannot be excluded from our study results, it does not seem very likely that the Maastricht Back School is an effective method of managing low back pain. Furthermore, due to the required multidimensional approach of pain in the Maastricht Back School, the results of this study further reduce the likelihood of any back school in its present setup being effective. The limited evidence available from other randomized trials indicates, at most, borderline effects for other back schools [3, 4]. Very large trials with perfect methodology, avoiding the shortcomings of our own and other studies, might yet show some beneficial effects, although we do not think such trials deserve high priority.

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