



Chronic low back pain: Physical training, graded activity with problem solving training, or both? The one-year post-treatment results of a randomized controlled trial

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Received 3 July 2006; received in revised form 4 April 2007; accepted 16 April 2007

Abstract

Several treatment principles for the reduction of chronic low back pain associated disability have been postulated. To examine whether a combination of a physical training and an operant-behavioral graded activity with problem solving training is more effective than either alone in the long-term, a cluster randomized controlled trial was conducted. In total 172 patients, 18–65 years of age, with chronic disabling non-specific low back pain referred for rehabilitation treatment, were randomized in clusters of four consecutive patients to 10 weeks of aerobic training and muscle strengthening of back extensors (active physical treatment; APT), 10 weeks of gradual assumption of patient relevant activities based on operant-behavioral principles and problem solving training (graded activity plus problem solving training; GAP), or APT combined with GAP (combination treatment; CT). The primary outcome was the Roland Disability Questionnaire adjusted for centre of treatment, cluster, and baseline scores. Secondary outcomes were patients' main complaints, pain intensity, self-perceived improvement, depression and six physical performance tasks. During the one-year follow-up, there were no significant differences between each single treatment and the combination treatment on the primary outcome, the Roland Disability Questionnaire. Among multiple other comparisons, only one significant difference emerged, with GAP and APT showing higher self-perceived improvement than CT. We conclude that the combination treatment integrating physical, graded activity with problem solving training is not a better treatment option for patients with chronic low back pain. © 2007 International Association for the Study of Pain. Published by Elsevier B.V. All rights reserved.

Keywords: Randomized controlled trial; Chronic low back pain; Exercise; Cognitive-behavioral therapy; Multidisciplinary treatment; Rehabilitation

1. Introduction

Chronic non-specific low back pain (CLBP) and its resulting disability have become a huge and epidemic

health and socioeconomic problem (Meerding et al., 1998). To reduce this burden, treatments aimed at increasing activity levels and functional ability are widely being used. Physical treatments are based on the assumption that increased muscle strength and aerobic capacity are crucial for the resumption of activities, and hence for the restoration of functional abilities (Mayer et al., 1998; Verbunt et al., 2003). Fordyce (Fordyce, 1976),

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however, postulated that contingency management techniques and graded activity based on operant learning processes can differentially increase health behaviors at the cost of dysfunctional illness behaviors. Aldrich et al. (Aldrich et al., 2000) assumed that CLBP patients tend to persevere in their attempt to solve an unsolvable problem, namely pain, despite experiencing repeated failure. This perseverance keeps them stuck in a vicious circle of chronic pain, which can be altered by helping patients to identify and deal with the consequences of pain. Problem solving training provides a variety of response alternatives for a problem, and helps patients to select the most effective response available (D'Zurilla and Goldfried, 1971). This cognitive-behavioral treatment has successfully been applied in CLBP (van den Hout et al., 2003; Linton et al., 2005).

Muscle strengthening combined with aerobic exercises, operant-behavioral graded activity, problem solving training, and multidisciplinary treatment combining several treatment modules are superior to no treatment (Morley et al., 1999; van Tulder et al., 2000; Guzman et al., 2002; Ostelo et al., 2005). Nevertheless, evidence is lacking that one of these treatments is more effective than the other (Guzman et al., 2002; Hayden et al., 2005a; Ostelo et al., 2005; Smeets et al., 2006c).

Examining the content of the available treatments suggests that many are not solely based on one of the above-mentioned causative mechanisms, but are treatment packages with various elements. For example, exercise therapy is added to graded activity and problem solving training (van den Hout et al., 2003), making it indistinct whether integrating physical training and graded activity with problem solving training is more effective than the single treatment components alone. Furthermore, many exercise therapies are of insufficient intensity and duration to classify them as reconditioning/strengthening treatments (ACSM, 1998; Hilde and Bo, 1998; Liddle et al., 2004).

We therefore designed a randomized controlled trial (RCT) to compare the effectiveness of a treatment based on physiologic training principles (reconditioning/strengthening exercises), a treatment based on operant-behavioral and cognitive principles (graded activity with problem solving), and one combining both treatments. Since the combination treatment addresses physical reconditioning as well as increasing health behavior and problem solving skills, we hypothesized that this combination treatment is more effective in reducing disability than the single component treatments.

The immediate post-treatment results of this RCT showed that all three treatments were more effective than a waiting list group, but the combination treatment was not more effective than the single treatments (Smeets et al., 2006a). The current paper describes the 6 and 12 months post-treatment results.

2. Methods

2.1. Patients

Between April 2002 and December 2004, patients for the first time referred by general practitioners or medical specialists to three Dutch outpatient rehabilitation centres were seen by a rehabilitation physician. When judged that a rehabilitation treatment was necessary to resolve or reduce the functional limitations due to low back pain, the patient was invited to participate in this trial. A research assistant checked the inclusion criteria: age between 18 and 65 years, non-specific low back pain for more than 3 months resulting in disability (Roland Disability Questionnaire score [RDQ] > 3) (Roland and Morris, 1983), and ability to walk at least 100 m. The exclusion criteria were: vertebral fracture, spinal inflammatory disease or infection, malignancy, current nerve root pathology, spondylolysis, spondylolisthesis, lumbar spondylosis, medical co-morbidity making exercising impossible (e.g. cardiovascular disease), clear treatment preference, not proficient in Dutch, pregnancy, and substance abuse interfering with treatment. The Symptom Checklist (SCL-90) (Arrindell and Ettema, 1986) and the Dutch Personality Questionnaire (NPV) (Luteijn et al., 1985) were used to exclude patients based on scores suggesting psychopathology that might hamper individual or group processes (Vlaeyen et al., 1996). (For more details, see Appendix). Patients meeting the inclusion criteria were informed about the purpose and procedures of the study and were enrolled after giving informed consent.

The Medical Ethics Committee of the Rehabilitation Foundation Limburg and the Institute for Rehabilitation Research in Hoensbroek, the Netherlands, approved the study protocol.

The trial was assigned an international trial identification number (www.controlled-trials.com; ISRCTN22714229), and the results are reported according to the Consolidated Standards of Reporting Trials (CONSORT) (Moher et al., 2001).

2.2. Randomization

Each cluster of four consecutive patients was assigned to one of the three active treatments or a waiting list, using block randomization. Randomization used blocks of size eight and for each rehabilitation centre separately, a randomization list was generated under the supervision of an independent statistician. Opaque, sequentially numbered, sealed envelopes were prepared for each rehabilitation centre before enrollment started. The envelope contained a sheet of paper indicating one of the four treatments. After the patient completed the baseline measurement, the research assistant handed over the envelope.

2.3. Masking

The research assistants collecting data were blinded to treatment allocation. All patients were repeatedly asked not to reveal information about their treatment allocation. Patients and therapists were not blinded to treatment allocation.

2.4. Interventions

The overall goal of the three active treatments was to improve functioning (decrease of functional limitations/disability). Emphasis was put on the responsibility of the patient for making plans to keep on being active after the treatment (generalization). Each treatment lasted 10 weeks and started with the explanation of the rationale of that particular treatment. A written summary of the rationale was provided to the patients. The treatments were given to groups with a maximum of four patients. Patients were allowed to continue medication prescribed at baseline, but other co-interventions were discouraged. No other interventions than the allocated took place. In case of acute and severe psychosocial stress or pathology (severe depression, high risk for suicide, or personal problems the patient did not wish to discuss during the group treatment), a consultation of a clinical psychologist or social worker was possible. During this consultation the therapist tried to find out what the exact problem was and subsequently, when judged necessary, arranged for professional help outside the rehabilitation centre.

In the 4th and 10th week, the rehabilitation physician responsible for the whole treatment, together with the patient, evaluated the treatment and checked the generalization plans.

Only therapists who volunteered to deliver a specific treatment module were recruited. Each therapist only delivered the treatment module he was specifically trained for. After several extensive training sessions preceding the trial, they were once again asked whether they were willing to adhere to the treatment protocol they were going to provide. If not, the therapist did not participate. All selected therapists attended annual refresher courses. For each intervention detailed treatment manuals were used by all therapists.

2.4.1. Active physical treatment (APT)

APT was based on the assumption that an increased aerobic capacity and muscle reconditioning, especially of the deep lumbar extensor muscles (multifidus muscle), are needed for better functioning (Smeets et al., 2006c). The duration and intensity of APT were chosen according to the physiologic principles of training (ACSM, 1998). In a group of maximum four, patients were invited to perform 30 min of aerobic training on a bicycle (65–80% heart rate maximum) and 75 min of strength and endurance training of their lower back and upper leg muscles (three series of 15–18 repetitions in a dynamic–static manner with a training intensity of 70% of the 1-Repetition Maximum, which was reassessed every fifth session), three times a week during 10 weeks. Two physiotherapists supervised the training.

2.4.2. Graded activity with problem solving training (GAP)

GAP was based on the assumption that how individuals with CLBP behave is a resultant of learning, both through environmental contingencies as through information processing (Morley et al., 1999). It is assumed that CLBP patients tend to persevere in their attempt to solve an unsolvable problem, namely pain, despite the experience of repeated failure (Aldrich et al., 2000). This perseverance may keep them hypothetically stuck in a vicious circle of chronic pain. In order to

intervene in this process it may be more important to help patients to identify and cope with the consequences of pain in everyday life than with pain itself. Problem solving training can help patients to redefine their problem(s) and focus more on other individually relevant daily life goals that can be achieved by using graded activity techniques.

GAP consisted of operant-behavioral graded activity training (GA) (Fordyce, 1976; Sanders, 1996) and problem solving training (PST) (van den Hout et al., 2003). During GA, a skilled physiotherapist or occupational therapist focused on a time-contingent increase or pacing of three activities being important and relevant for the patient's personal situation. After the establishment of a baseline, the activity tolerance level was calculated and final treatment goals were set. The patient started performing the selected activities following quotas for each day, starting from 70% to 80% of the baseline with gradually increasing activity levels towards the final treatment goals. The patient was given the instruction only to perform the agreed level of activity and not perform less or more, even when he felt capable of doing so. During the training sessions the patient performed one or more of the selected activities, but the most important part of the treatment session was the evaluation of the level of the activities the patient had performed at home. The patient graphically registered in a personal diary his daily performance. The therapists were requested to discuss these graphs regularly with the patient, while positively reinforcing any progress towards the pre-set goals. In order to create as much contrast as possible with the APT, no physical training element (e.g. muscle strengthening or aerobic exercises) was incorporated. GA started with three group sessions followed by a maximum of 17 individual sessions of 30 min. The frequency of the sessions gradually decreased from three to one session a week. The GAP did not systematically include relaxation training, nor family interventions, except that the partner was invited to attend the first session (explanation of treatment rationale) and a GA-session in the 4th week. In this way, the partner was informed, and instructed to reinforce healthy behavior (gradual increase of activities) of the patient. PST started with three sessions in which the rationale and the skill of positive problem orientation were discussed. Sessions 4–10 focused on problem definition and formulation, generation of alternatives, decision-making, implementation and evaluation. Patients received a course book with a summary of each session and homework assignments. A clinical psychologist or social worker, specifically trained to guide this intervention, provided 10 sessions of 1 1/2 h to a maximum of four patients at a time.

2.4.3. Combination treatment (CT)

CT aimed at restoring functional ability through increased fitness, the reinforcement of healthy behaviors and the modification of problem solving abilities. For CT, we specifically tried to integrate all three treatment modules (APT, GA and PST) and in the treatment rationale, the patient was told that benefits may be expected from redefining his problems and focusing more on other individually relevant daily life goals (activities), which can be achieved by using graded activity techniques. However, parallel increase in aerobic fitness and strength is expected to facilitate the application of the graded activity in daily life.

The CT started with APT and PST, both offered in the same frequency and duration as in APT and GAP, respectively. Furthermore, based on the above-mentioned rationale, GA started in the 3rd week with the selection of three patient-specific activities. By the end of the 4th week, the gradual increase of these three activities was started. A total of 19 GA-sessions were delivered.

The APT sessions were given three times a week, PST once a week, and GA initially three times a week, and gradually decreasing to once a week. The patients did not have to come to the treatment centre more often than three times a week, meaning that once a week, a patient received APT, GA and PST, all at one day.

All therapists were trained in one specific treatment module (APT, GA or PST), and delivered this module in CT as well. However, the therapists were explicitly informed about the integrative aspects of CT. For example, the therapists who delivered APT were requested to periodically ask the patient to present the individual graphs of patient-specific activities and to use positive reinforcement to further encourage healthy behavior (increase of activities). GA therapists also inquired about the progress made in APT and used this information to set quotas and when necessary adjust final treatment goals.

2.4.4. Waiting list (WL)

Patients were requested to wait 10 weeks after which they were offered regular individual rehabilitation treatment. During the waiting period, patients were not allowed to participate in diagnostic or therapeutic procedures for their CLBP. For these patients only data were collected before and immediately after the 10 weeks of no treatment.

2.5. Data collection

During the pre-treatment assessment, data were collected on age, gender, level of education, employment status, duration of complaints and disability, previous treatment, level of radiating pain, traumatic onset, pain-related fear (Tampa Scale for Kinesiophobia) (Goubert et al., 2000, 2004; Roelofs et al., 2004), VO_2 max (modified Åstrand sub-maximal bicycle test) (Smeets et al., 2006d), negative problem orientation (Social Problem Solving Inventory-Revised) (D'Zurilla et al., 1997), and physical activity (Baecke Physical Activity Questionnaire) (Baecke et al., 1982; Jacob et al., 2001). Immediately after the explanation of the treatment rationale, treatment credibility and expectancy were assessed (Credibility/Expectancy Questionnaire) (Deville and Borkovec, 2000).

2.6. Outcome measures

Outcome measures were recorded at baseline, immediately post-treatment and 6 and 12 months post-treatment. The primary outcome measure was the Roland Disability Questionnaire (RDQ), as recommended by several experts on low back pain research (Deyo et al., 1998). It is a reliable, valid, and responsive outcome measure (Roland and Morris, 1983; Beurskens et al., 1996; Gommans et al., 1997).

Secondary outcomes included the severity of three individual main complaints regarding activities on 100-mm visual analogue scales (Beurskens et al., 1999), current back pain on a 100-mm visual analogue scale and the Pain Rating Index of the McGill Pain Questionnaire (Melzack and Katz, 1992; van der Kloot et al., 1995), self-perceived improvement of disability (7-point Likert scale, 1 = vastly worsened, 7 = completely recovered) (Beurskens et al., 1996), and depression according to the Beck Depression Inventory (Beck et al., 1988). Six performance tests were used (Mayer et al., 1988, 1990; Harding et al., 1994; Simmonds et al., 1998): (1) 5-min walking (m), (2) 50 foot walking (s), (3) five times sit to stand (s), (4) forward reaching by holding a stick with a weight of 4.5 kg at shoulder height (cm), (5) 1-min stair climbing (number of stairs), (6) progressive isoinertial lifting evaluation; the patient lifts a box with a weight four times within 20 s from floor up to a 75 cm high table. After each cycle of four lifting movements, the weight is increased in a standardized way (completed cycles).

A reduction of 18–24 points for the main complaints, (Beurskens et al., 1996), $\geq 30\%$ reduction of the baseline score of the current back pain (Farrar et al., 2000), and 20–48% improvement of the performance tasks (Smeets et al., 2006e), have been defined as clinically relevant. For the Pain Rating Index, self-perceived improvement and depression, no such data are available.

2.7. Content of treatment

Treatment content was validated by checklists filled out by therapists after each treatment session. Patients attending at least 2/3 of all assigned treatment sessions for each training elements were classified as having sufficient treatment compliance. Co-interventions were documented by cost-diaries filled out by patients during the treatment period (Goossens et al., 2000).

2.8. Statistical analyses

A difference of 2.5 points in RDQ score between treatment groups was considered to be clinically relevant (Roland and Fairbank, 2000). Based on a 2-sided α of 0.05 and a $1-\beta$ of 0.90, with a standard deviation (SD) of the RDQ change of 4, 55 patients per group were needed to test the hypothesis that the active treatment groups are more effective than the waiting list immediately post-treatment, and the hypothesis that CT is more effective than APT and GAP, respectively.

Distribution of baseline characteristics was calculated to determine the prognostic similarity of groups.

Outcome measures were analyzed by using longitudinal analysis of covariance. The follow-up measurement was the dependent variable and the baseline value of the particular outcome was added as covariate. The coefficients of the longitudinal analysis of covariance were estimated using a mixed linear model with a random intercept for individuals to allow for dependence within patients (Twisk, 2003), and with a random intercept for patient clusters to account for possible dependence of the outcome within the clusters of four patients who were randomized together. Adjustments were always made for age, gender and centre of treatment. In case, despite

randomization, other baseline variables were unequally divided between treatment groups ($P < 0.10$), they were always controlled for (covariates). Furthermore, the interaction effect of treatment with pain-related fear, level of disability and pain intensity was checked. Finally, potential prognostic variables (baseline score of duration of disability, duration of pain, work status, education level, level of pain radiation, traumatic onset, pain-related fear, disability, pain intensity, and depression) were forced in the model of the outcome measure of interest, and eliminated one by one when non-significant ($P > 0.05$). In this way only statistically significant prognostic variables for each outcome measure separately were selected, and controlled for.

All statistical analyses were performed according to the intention-to-treat principle, using SPSS statistical software, version 12.0 (SPSS, Inc., Chicago, Illinois).

While using longitudinal analysis of covariance, no imputation at all is better than applying any of the available imputation techniques (Twisk, 2003). Nevertheless, for the primary outcome (RDQ), we also calculated the results presuming that the reasons for missing were completely at random, by replacing missing values by the previously available value of that patient (last value carried forward). Furthermore, presuming that the reasons for missing were due to drop out because of deterioration or lack of success, we replaced the missing values by the 10th percentile score of the total group (worst case scenario) (Twisk, 2003).

3. Results

3.1. Recruitment and follow-up

Of the 309 eligible patients, 82 patients were excluded. Reasons for exclusion are shown in Fig. 1. Eighteen patients were excluded due to psychopathology that could hamper individual or group processes.

Additionally, four patients were excluded before start of treatment because of another medical diagnosis preventing participation (one in APT, two in GAP, one in CT). A total of 223 patients were randomly assigned to either APT ($n = 53$), GAP ($n = 58$), CT ($n = 61$), or WL ($n = 51$). The unequal number of patients in each treatment group is the result of the block randomization carried out for each rehabilitation centre, separately.

Since no 6 and 12 months post-treatment data for WL were collected, only the results of the patients allocated to an active treatment will be further discussed ($n = 172$).

Follow-up rates for the questionnaires remained high, even at 12 months (156 of 172 patients). The reasons for not responding ($n = 16$) were not clearly related to the type of treatment: stopped treatment prematurely due to low baseline level of disability (1 in GAP, 2 in CT), no more complaints post-treatment but other medical problems (1 in CT), no more complaints 6 months post-treatment (3 in GAP), dissatisfaction (2 in both APT and GAP, 1 in CT), unreachable (2 in CT), other medical problems (1 in CT), and logistic reasons (1 in

CT). The treatment groups did not significantly differ in loss to follow-up at 12 months (Fisher's exact test, $P = 0.22$). The non-responders were significantly younger (mean, 34.3 versus 42.7 years) and showed lower sufficient treatment compliance (25% versus 74%).

The number of patients with missing data of performance tasks decreased to 56 (of 172), 12 months post-treatment (15 in APT, 17 in GAP, 24 in CT). The reasons for not performing tasks were also not clearly associated with the type of treatment. The non-responders were significantly younger (mean, 37.9 versus 43.9 years), had lower sufficient treatment compliance (39% versus 84%), and lower 5-min walking baseline score (mean, 357.9 versus 387.5 m).

3.2. Comparability at baseline

Baseline status of patients, including distribution of baseline RDQ score and the level of treatment expectancy and credibility, did not differ significantly between treatment groups (Table 1).

3.3. Content of treatment and side effects

Compared with CT, the percentage of patients with sufficient treatment compliance to the different treatment modules was 11% and 15% higher in APT and GAP, respectively (Fig. 1). In APT, 9 patients (17%) and in CT, 17 patients (28%) had insufficient compliance with the physical treatment. Thirteen patients in GAP (22%) and 23 patients in CT (38%) had insufficient compliance with GA and PST. The reasons for insufficient compliance were: dissatisfaction (4 in APT (8%), 8 in GAP (14%), 11 in CT (18%)), other medical problems 3 in APT (6%), 1 in GAP (2%), 7 in CT (11%), logistic problem (6 in both GAP (10%) and CT (10%)), and no complaints anymore (1 in GAP (2%)). Three patients, all CT (5%), stopped treatment because of increased back pain. One patient (APT, 2%) developed nerve root pathology needing neurosurgical intervention and did not complete treatment, one patient (APT, 2%) stopped aerobic training because of knee complaints, but completed the strengthening training. Another one (APT) developed vascular leg pain during cycling, that could be resolved by vascular surgery, after which she could complete APT.

Eleven patients (7 in GAP (12%), 4 in CT (7%)) were offered one or two additional visits to a clinical psychologist, mainly to discuss specific psychosocial problems that could not be addressed during the PST group sessions. Two patients (both GAP, 3%) reported severe psychosocial problems, resulting in referral to a psychologist outside the treatment centre.

Analysis of the cost-diaries of 159 patients (92%; 51 in APT (96%), 52 in GAP (90%), 56 in CT (92%)) showed that 17 patients (5 in APT (10%), 8 in GAP

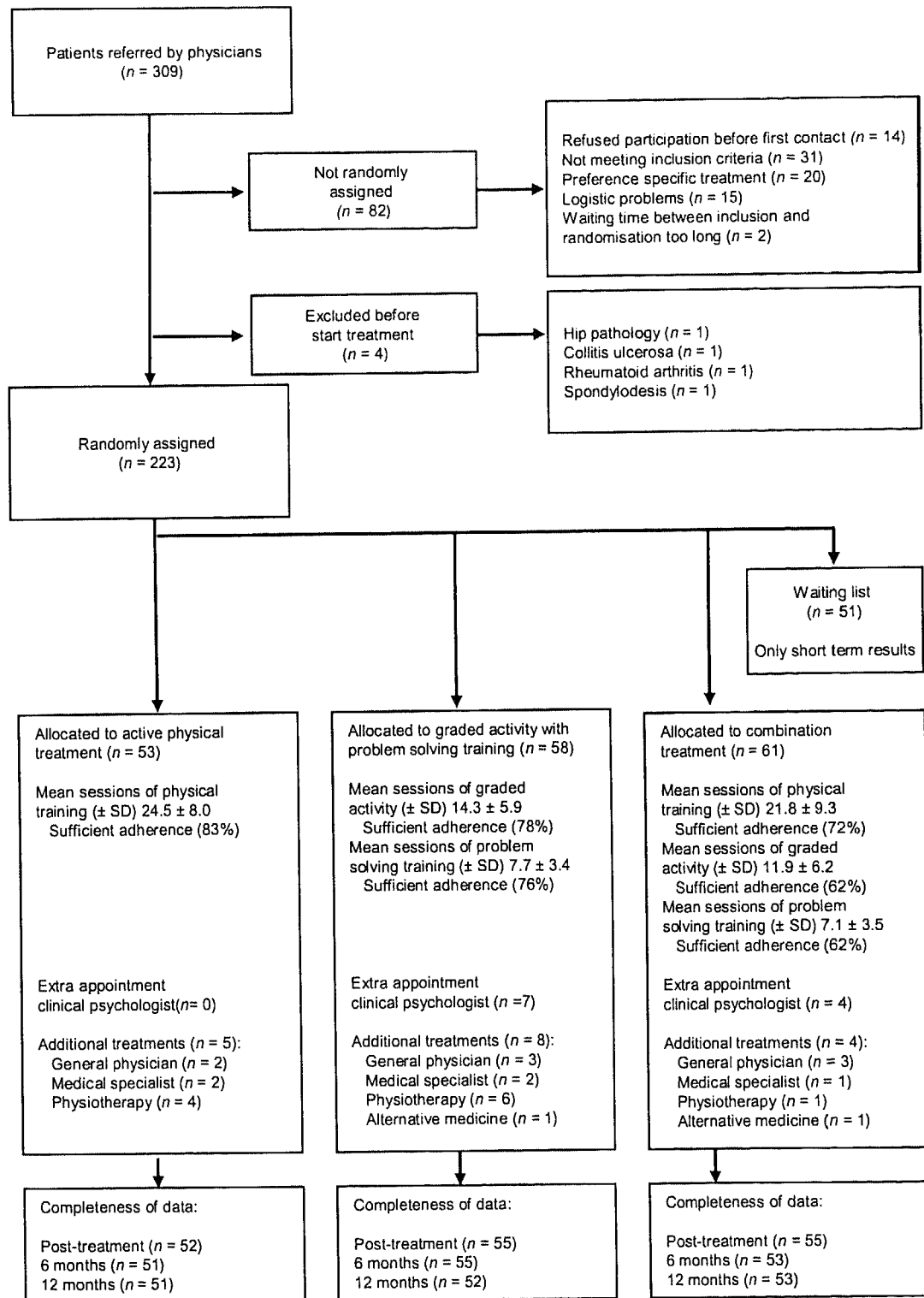


Fig. 1. Flow chart describing the progress of patients through the trial.

Table 1
Baseline variables for the total population and the three therapy groups (total $n = 172$)

Variables	Total ($n = 172$)	APT ($n = 53$)	GAP ($n = 58$)	CT ($n = 61$)	P -value ^a
Age (years)	41.91 ± 9.65	42.68 ± 9.06	42.52 ± 9.67	40.67 ± 10.14	0.458
Gender (% male)	54.1	58.5	41.4	62.3	0.054
Education (%)					
Low	62.2	67.9	62.1	57.4	
Middle high	37.8	32.1	37.9	42.6	0.511
Work status (%)					
Full time	30.8	32.1	36.2	24.6	
Partial sick leave/disability pension	25.6	18.9	24.1	32.8	
Full sick leave/disability pension	36.6	43.4	31.0	36.1	
No job/retired	7.0	5.7	8.6	6.6	0.532
Duration of LBP (months)	60.48 ± 72.22	56.91 ± 75.86	68.33 ± 74.21	56.13 ± 67.50	0.598
Duration of functional limitations (months)	38.54 ± 52.51	28.85 ± 37.43	49.12 ± 61.40	36.90 ± 53.57	0.121
Radiation of pain (%)					
No radiation	13.4	9.4	17.2	13.1	
Above knee	35.5	35.8	27.6	42.6	
Below knee	51.2	54.7	55.2	44.3	0.400
Previous physical/medical treatment (%)	96.5	94.3	96.6	98.4	0.500
Previous back surgery (%)	14.0	17.0	10.3	14.8	0.587
Trauma preceding LBP (%)	15.7	17.0	19.0	11.5	0.508
BPAQ-sport index score (1–5)	2.08 ± 0.70	2.07 ± 0.67	2.14 ± 0.78	2.04 ± 0.65	0.739
BPAQ leisure time index score (1–5)	2.86 ± 0.68	2.96 ± 0.69	2.79 ± 0.74	2.84 ± 0.60	0.435
TSK (17–68)	39.16 ± 6.81	39.02 ± 6.52	38.72 ± 6.88	39.69 ± 7.08	0.733
VO ₂ max (ml/kg/min)	28.61 ± 7.23	27.26 ± 6.76	28.23 ± 6.69	30.06 ± 7.88	0.155
SPSI-NPO (0–40)	13.54 ± 7.12	13.37 ± 7.42	13.90 ± 6.29	13.34 ± 7.71	0.895
Treatment credibility (3–27)	19.78 ± 3.61	20.28 ± 3.27	19.19 ± 3.65	19.96 ± 3.82	0.219
Treatment expectancy (3–27)	16.35 ± 4.41	16.89 ± 4.03	15.36 ± 4.43	16.84 ± 4.60	0.112
RDQ (0–24)	13.78 ± 3.75	14.15 ± 3.70	13.74 ± 3.65	13.51 ± 3.92	0.658
Main complaints (0–100)	73.84 ± 15.97	74.52 ± 14.59	74.71 ± 16.19	72.44 ± 17.03	0.694
Current pain (0–100)	48.56 ± 24.58	51.23 ± 26.55	48.84 ± 23.51	45.98 ± 23.95	0.524
PRI-T (0–63)	18.09 ± 10.03	18.34 ± 11.32	17.86 ± 9.94	18.08 ± 9.04	0.969
BDI (0–63)	10.18 ± 7.07	10.38 ± 7.62	10.45 ± 7.06	9.75 ± 6.68	0.842
Walking (m)	377.61 ± 77.80	375.37 ± 68.03	385.29 ± 75.36	372.40 ± 88.03	0.649
Fast walking (s)	10.18 ± 2.40	9.92 ± 2.27	10.28 ± 2.40	10.31 ± 2.51	0.632
Sit to stand (s)	21.85 ± 8.41	20.98 ± 7.33	22.67 ± 9.99	21.86 ± 7.65	0.594
Loaded forward reach (cm)	52.44 ± 13.00	52.04 ± 12.27	50.12 ± 14.97	55.00 ± 11.24	0.118
Stair climbing (number of stairs)	72.79 ± 21.84	72.02 ± 18.22	75.10 ± 24.76	71.26 ± 21.95	0.605
Lifting (stages)	4.25 ± 2.96	4.31 ± 2.58	4.29 ± 3.22	4.16 ± 3.05	0.963

Values presented are means ± SD or percentage. APT, active physical treatment; GAP, graded activity plus problem solving training; CT, combination treatment; LBP, low back pain; BPAQ, Baecke Physical Activity Questionnaire; TSK, Tampa Scale for Kinesiophobia; SPSI-NPO, Social Problem Solving Inventory–Negative Problem Orientation; RDQ, Roland Disability Questionnaire; PRI-T, Pain Rating Index Total score; BDI, Beck Depression Inventory.

^a χ^2 test and one-way ANOVA comparisons by treatment groups.

(15%), 4 in CT (7%); χ^2 test, $P = 0.37$) reported additional treatments during treatment (Fig. 1).

3.4. Effectiveness of the interventions

Twelve months post-treatment, the observed change on the RDQ without any correction was -3.20 ± 4.81 for APT, -3.15 ± 4.33 for GAP, and -1.74 ± 4.55 for CT, respectively.

In Tables 2 and 3, the results of the longitudinal random coefficient analysis with correction for dependence within patient clusters, gender, age, centre of treatment and significant prognostic variables are presented. In the footnotes of Tables 2 and 3, for each outcome measure separately, the prognostic variables that were significantly contributing, and hence controlled for, are

shown. The results represent the difference in adjusted improvement over time within each treatment group, and between the CT and the single treatments. Due to non-normal distribution at baseline of fast walking and sit to stand scores, the inverse score (1/time needed to perform the task) had to be used. The inverse score should be interpreted as the number of tasks performed per second. This transformation resulted in a normal distribution of the scores of both performance tasks.

During follow-up, the improvement regarding disability, self-perceived improvement and main complaints persisted or even increased for APT and GAP, and diminished slightly to modestly for CT. All treatment groups showed small significant, but clinically irrelevant, persistent improvements on depression and all performance tasks except lifting. Fast walking and

Table 2
Mean improvement from baseline, and differences of mean improvement between APT-CT and GAP-CT, respectively, in primary and secondary outcome measures assessed by questionnaires

Outcome measure	Participants <i>n</i>	Mean improvement APT (95% CI) ^a	Mean improvement GAP (95% CI) ^a	Mean improvement CT (95% CI) ^a	Between APT-CT difference (95% CI) ^a	Between GAP-CT difference (95% CI) ^a
RDQ^b						
Post-treatment	162	2.42 (1.14–3.69)	3.04 (1.79–4.29)	2.47 (1.25–3.86)	-0.05 (-1.71 to 1.62)	0.58 (-1.08 to 2.24)
6 months follow-up	159	3.15 (1.88–4.43)	3.65 (2.40–4.90)	2.54 (1.31–3.76)	0.62 (-1.06 to 2.30)	1.11 (-0.56 to 2.79)
12 months follow-up	156	3.28 (2.00–4.58)	3.74 (2.48–5.01)	2.12 (0.89–3.36)	1.16 (-0.52 to 2.84)	1.62 (-0.06 to 3.31)
Main complaints^b						
Post-treatment	161	11.11 (4.11–18.10)	15.74 (8.98–22.51)	17.48 (10.78–24.18)	-6.38 (-16.00 to 3.25)	-1.74 (-11.23 to 7.75)
6 months follow-up	159	10.58 (3.60–17.57)	17.67 (10.90–24.44)	12.85 (6.08–19.62)	-2.26 (-11.94 to 7.41)	4.82 (-4.74 to 14.38)
12 months follow-up	154	12.27 (5.28–19.26)	20.19 (13.32–27.05)	11.95 (5.15–18.74)	0.33 (-9.36 to 10.02)	8.24 (-1.40 to 17.88)
Self-perceived improvement^{b,c}						
Post-treatment	162	4.33 (3.91–4.74)	4.71 (4.30–5.11)	4.53 (4.13–4.93)	-0.20 (-0.75 to 0.35)	0.18 (-0.37 to 0.73)
6 months follow-up	159	4.38 (3.97–4.80)	4.76 (4.36–5.17)	4.00 (3.60–4.40)	0.38 (-0.18 to 0.94)	0.76 (0.21–1.31) ^d
12 months follow-up	156	4.50 (4.08–4.91)	4.54 (4.13–4.95)	3.89 (3.49–4.29)	0.61 (0.05–1.16) ^d	0.65 (0.10–1.21) ^d
Current pain^b						
Post-treatment	162	4.72 (-1.87 to 11.32)	10.25 (3.81 to 16.69)	4.90 (-1.52 to 11.32)	-0.18 (-9.34 to 8.99)	5.35 (-3.73 to 14.42)
6 months follow-up	158	2.81 (-3.82 to 9.44)	4.08 (-2.41 to 10.56)	-2.17 (-8.70 to 4.35)	4.98 (-4.29 to 14.25)	6.25 (-2.94 to 15.44)
12 months follow-up	156	2.31 (-4.32 to 8.94)	3.15 (-3.41 to 9.71)	-5.73 (-12.25 to 0.79)	8.04 (-1.23 to 17.31)	8.88 (-0.36 to 18.13)
PRI-T^b						
Post-treatment	162	0.50 (-2.25 to 3.25)	3.52 (0.82–6.22)	1.45 (-1.19 to 4.10)	-0.95 (-4.59 to 2.68)	2.06 (-1.55 to 5.68)
6 months follow-up	159	3.13 (0.36–5.89)	2.21 (-0.50 to 4.91)	1.15 (-1.53 to 3.84)	1.97 (-1.71 to 5.65)	1.05 (-2.60 to 4.71)
12 months follow-up	156	1.70 (-1.06 to 4.46)	1.84 (-0.91 to 4.60)	-0.94 (-3.63 to 1.74)	2.64 (-1.04 to 6.32)	2.79 (-0.91 to 6.48)
BDI^b						
Post-treatment	161	2.86 (1.42–4.29)	2.31 (0.91–3.72)	0.69 (-0.71 to 2.09)	2.17 (0.18–4.17) ^d	1.62 (-0.36 to 3.61)
6 months follow-up	158	2.63 (1.18–4.07)	2.41 (1.00–3.81)	2.14 (0.71–3.57)	0.49 (-1.54 to 2.51)	0.26 (-1.74 to 2.27)
12 months follow-up	156	3.23 (1.78–4.67)	2.08 (0.65–3.52)	2.17 (0.75–3.60)	1.05 (-0.97 to 3.07)	-0.09 (-2.11 to 1.93)

^a Adjusted for the baseline value of the outcome measure, age, gender and treatment centre based on a longitudinal random coefficient analysis with an extra random intercept for clusters of four patients being randomized together.

^b Additional correction for statistically significant contributing prognostic variables: RDQ – work status, duration disability and TSK; main complaints – TSK, Self-perceived improvement – work status, current pain and duration disability; current pain – RDQ, TSK and BDI; PRI-T – work status, RDQ and duration disability; BDI-RDQ.

^c Mean score on scale ranging from 1 to 7.

^d $P < 0.05$. APT, active physical treatment; GAP, graded activity plus problem solving training; CT, combination treatment; RDQ, Roland Disability Questionnaire; PRI-T, Pain Rating Index Total score; BDI, Beck Depression Inventory.

Table 3
Mean improvement from baseline, and differences of mean improvement between APT-CT and GAP-CT, respectively, in performance tasks

Outcome measure	Participants <i>n</i>	Mean improvement APT (95% CI) ^a	Mean improvement GAP (95% CI) ^a	Mean improvement CT (95% CI) ^a	Between APT-CT difference (95% CI) ^a	Between GAP-CT difference (95% CI) ^a
Walking (m) ^b						
Post-treatment	149	30.10 (14.26–45.93)	16.85 (8.88–32.82)	35.14 (20.18–50.10)	–5.00 (–26.75 to 16.66)	–18.30 (–40.19 to 3.60)
6 months follow-up	122	37.90 (21.49–54.30)	27.83 (11.41–44.25)	37.63 (21.16–54.09)	0.27 (–22.90 to 23.44)	–9.80 (–33.12 to 13.53)
12 months follow-up	116	35.76 (18.96–52.56)	25.09 (9.58–43.00)	35.76 (19.35–52.16)	0.00 (–23.40 to 23.40)	–10.67 (–34.07 to 12.74)
Inversion fast walking (1/s) ^{b,c}						
Post-treatment	150	0.003 (–0.002 to 0.009)	0.007 (0.002 to 0.012)	0.005 (0.000–0.009)	–0.001 (–0.008 to 0.006)	0.003 (–0.005 to 0.010)
6 months follow-up	123	0.005 (0.000–0.010)	0.007 (0.002–0.012)	0.004 (–0.001 to 0.010)	0.001 (–0.007 to 0.008)	0.003 (–0.005 to 0.010)
12 months follow-up	116	0.008 (0.002–0.013)	0.006 (0.001 to 0.012)	0.004 (–0.001 to 0.010)	0.004 (–0.004 to 0.011)	0.002 (–0.005 to 0.010)
Inversion sit to stand (1/s) ^{b,c}						
Post-treatment	150	0.014 (0.009–0.019)	0.010 (0.006–0.015)	0.013 (0.008–0.017)	0.002 (–0.005 to 0.008)	–0.002 (–0.009 to 0.004)
6 months follow-up	123	0.017 (0.012–0.021)	0.013 (0.008–0.018)	0.013 (0.009–0.018)	0.003 (–0.004 to 0.010)	–0.001 (–0.008 to 0.006)
12 months follow-up	115	0.018 (0.013–0.023)	0.016 (0.011 to 0.021)	0.013 (0.008–0.018)	0.005 (–0.002 to 0.012)	0.003 (–0.004 to 0.010)
Loaded forward reach (cm) ^b						
Post-treatment	149	4.32 (0.83–7.82)	4.98 (1.46–8.51)	4.63 (1.35–7.91)	–0.31 (–5.07 to 4.45)	0.35 (–4.46 to –5.16)
6 months follow-up	119	3.70 (0.01–7.39)	2.27 (–1.41 to 5.95)	0.39 (–3.34 to 4.12)	3.31 (–1.90 to 8.53)	1.88 (–3.36 to 7.12)
12 months follow-up	115	5.42 (1.64–9.19)	3.80 (0.10–7.51)	2.35 (–1.38 to 6.07)	3.07 (–2.21 to 8.36)	1.46 (–3.81 to 6.72)
Stair climbing (stairs)						
Post-treatment	150	11.02 (5.56–16.48)	5.85 (0.48–11.22)	11.65 (6.54–16.77)	–0.64 (–8.07 to 6.80)	–5.81 (–13.19 to 1.57)
6 months follow-up	121	10.63 (5.06–16.21)	6.54 (1.06–12.03)	10.19 (4.76–15.62)	0.44 (–7.30 to 8.18)	–3.65 (–11.35 to 4.05)
12 months follow-up	115	11.38 (5.72–17.04)	8.21 (2.68–13.74)	7.83 (2.40–13.26)	3.54 (–4.26 to 11.34)	0.37 (–7.36 to 8.10)
Lifting (cycles)						
Post-treatment	147	0.89 (0.23–1.55)	0.36 (–0.29 to 1.00)	0.51 (–0.08 to 1.09)	0.38 (–0.50 to 1.26)	–0.15 (–1.02 to 0.71)
6 months follow-up	116	0.59 (–0.11 to 1.29)	0.33 (–0.35 to 1.00)	0.16 (–0.049 to 0.81)	0.43 (–0.52 to 1.38)	0.17 (–0.77 to 1.10)
12 months follow-up	112	0.29 (–0.42 to 0.10)	–0.44 (–1.11 to 0.24)	–0.03 (–0.70 to 0.63)	0.32 (–0.65 to 1.29)	–0.40 (–1.34 to 0.55)

^a Adjusted for the baseline value of the outcome measure, age, gender and treatment centre based on a longitudinal random coefficient analysis with an extra random intercept for clusters of four patients being randomized together.

^b Additional correction for statistically significant contributing prognostic variables: walking/inversion sit to stand – RDQ and education level; Loaded forward reach – TSK.

^c Due to not normal distribution at baseline, the inverse of these measures was used; a higher inverse score indicates a faster performance. APT, active physical treatment; GAP, graded activity plus problem solving training; CT, combination treatment; RDQ, Roland Disability Questionnaire.

loaded forward reach did not improve significantly 12 months post-treatment in CT. Although all treatments showed a modest decrease of pain immediately post-treatment, this decrease almost disappeared 12 months post-treatment, and even showed an increase in CT.

Follow-up measurements consistently did not show that CT was more effective than APT or GAP. At 6 and 12 months, the level of disability, main complaints, pain, depression and performance tasks did not differ significantly between treatments. Only GAP showed a significantly higher self-perceived improvement (score range from 1 to 7) than CT at 6 months (0.76 [95% CI 0.21–1.31]) and 12 months (0.65 [95% CI 0.10–1.21]), as did APT compared to CT at 12 months (0.61 [95% CI 0.05–1.16]).

Since there is no consensus on the clinically relevant reduction of the RDQ score for the individual CLBP patient (Roland and Fairbank, 2000), we used a 2-point RDQ score reduction as a clinically relevant improvement as suggested recently (Vollenbroek-Hutten et al., 2004). At one-year post-treatment, 53% of the patients in the APT, 58% in the GAP and 51% in the CT could be classified as having reached a clinically relevant reduction of disability.

Although the power calculation of our study was not intended to be sufficient to compare APT versus GAP also, we did not find statistically significant differences between both treatments on any outcome measure (data not presented).

3.5. Alternative analysis

The last value carried forward analysis showed similar results. Although the amount of missing data due to attrition is limited and appears to be mostly at random, a worst case scenario was performed showing that the reduction of the RDQ reached significance for APT versus CT (1.84 [95% CI 0.04–3.64]), but not for GAP versus CT (1.23 [95% CI –0.55 to 3.01]), 12 months post-treatment.

4. Discussion

Although the mean score of our population is indicative for a moderate to severe level of disability, comparable to populations being treated in other trials and daily practice in The Netherlands (Roland and Fairbank, 2000; VRIN/VRA, 2000), and most of them had been treated previously, all treatments showed improvement of disability and most secondary outcomes over time. The mean improvement on main complaints was still fair, although this was only clinically relevant for GAP (Beurskens et al., 1996). APT and GAP still reported moderate global improvement. None of the treatments showed a clinically relevant reduction of pain, depression or improvement of performance tasks.

The most important results, however, are the differences between CT and the two single treatments, respectively. The hypothesis that CT is more effective than the single treatments could not be confirmed. At 12 months, APT and GAP, compared with CT, showed a higher, but both statistically and clinically insignificant, reduction of RDQ: 1.16 [95% CI –0.52 to 2.84], and 1.62 [95% CI –0.06 to 3.31], respectively. However, several researchers argue that a 1–1.5 point additional reduction of the RDQ at a group level is worth the effort (Moffett et al., 1999; UK BEAM Team, 2004). Furthermore, self-perceived improvement was moderately higher and reached statistical significance at 12 months for GAP and APT.

Since we did not find a tendency of CT being better, it is not likely that a higher powered study would change our conclusion that CT is not more effective than the single treatments. The two alternative analyses also confirmed our findings. No relevant differences were found regarding depression and performance tasks. Given that CT implies a higher burden for patients, our study does not support CT as the preferred treatment option.

This trial compared treatments explicitly based on a supposedly causative factor(s) for the development and maintenance of CLBP associated disability. The overall results of each of the treatments are comparable to other active treatment trials, and even trials that used more extensive selection procedures (Guzman et al., 2002; Hayden et al., 2005a,b; Ostelo et al., 2005).

The interventions were delivered according to the study protocol with only a few protocol deviations. CT consisted of the APT and GAP program combined, and was carried out by the same, well-trained therapists as in the single treatments. Treatment groups did not differ on baseline characteristics, treatment credibility and expectancy. That CT is not more effective than the single treatments is puzzling, and suggests opposing rather than synergetic effects, despite the fact that we specifically made efforts to integrate the different treatment modules into one treatment. Indeed, according to the treatment credibility and expectancy scores, patients seemed to perceive the combination treatment as a comprehensive, credible and worthy treatment. Nevertheless, CT required a higher effort of patients, which seems to be reflected by the lower compliance rate. On the other hand, the compliance rate was quite similar to multidisciplinary treatments used in RCTs (Kole-Snijders et al., 1999; Moffett et al., 1999), and daily practice (Woby et al., 2004). Furthermore, the different rationales of the CT elements might have been counteractive. The increase of exercise load in APT was based on training physiology, and in GAP a time-contingent increase of activities was used. This could have confused patients, resulting in insufficient generalization of the learned principles during follow-up. Otherwise, the total treatment duration of 78 h in CT

might not have been sufficient, since it is still lower than the 100 h of multidisciplinary treatment, showing higher effectiveness than non-multidisciplinary treatment (Guzman et al., 2002). It should, however, be taken into account that the conclusions of this meta-analysis are only based on two studies and that there is no consensus about the content, intensity and frequency of the different training sessions. Additionally, these multidisciplinary treatments differ from our combination treatment in that they used specific cognitive treatment modules as well as functional restoration, that all participating patients were at risk or absent from work due to low back pain, and that these patients might have been better motivated since their employer as well as insurance company advised them to participate.

Finally, the APT was more effective during follow-up than originally expected (Liddle et al., 2004; Hayden et al., 2005a). APT might have resulted in both attitude and behavior changes similar to those achieved by GAP, making the addition of GAP to CT redundant. Recently, we found that APT, although not using cognitive-behavioral techniques, resulted in a similar decrease of pain catastrophizing which also mediated outcome, as did GAP and CT (Smeets et al., 2006b). This is in line with the suggestion that not improved physical fitness, but cognitive processes are responsible for the effectiveness of exercise training (Mannion et al., 1999; Helmhout et al., 2004).

Different from the role of pain catastrophizing in the effectiveness of APT, the resumption of activities by offering GAP could not be explained by an increase of aerobic capacity (Smeets et al., 2006a).

The total group was moderately to severely disabled, a high percentage was on sick leave or disability pension because of low back pain, and for all patients a rehabilitation physician decided that rehabilitation treatment was indicated, making the results highly applicable to patients normally being referred for rehabilitation, at least in the Netherlands (VRIN/VRA, 2000). However, the mean level of depression was rather low and generalization of the results to highly specialized pain clinics should be done with caution. In our opinion, this low mean level of depression cannot be explained by the use of the SCL-90 and NPV, since not the level of depression, but criteria for severe psychopathology were used to exclude patients. The low number of patients being excluded on the basis of these criteria (18/309) further underscores this assumption. Additionally, due to possible floor effects for measuring change, the BDI seems to have been a poor choice for measuring patients' level of distress.

The study also has limitations; the high number of non-responders on the performance tasks for whom we did not impute missing values. Otherwise, the reasons for not responding were equally distributed across treatment groups. Although the use of objective performance

tasks is recommended (Simmonds et al., 1998; Waddell, 1998), this high percentage of non-responders as in other studies (Kole-Snijders et al., 1999; Ljungquist et al., 2003), and the rather low capability of most performance tasks to detect clinically relevant changes in CLBP samples (Smeets et al., 2006e), urges us to develop more patient-specific performance tasks. Furthermore, blinding of patients was not possible, but since no differences regarding treatment credibility and expectancy between treatment groups were found, we consider bias unlikely.

We conclude that the single treatments are at least equally effective as the combination treatment one-year post-treatment. Future research might focus on the question whether subgroups of patients can be identified, who benefit most from one specific treatment. Although we did not find any interaction between the level of disability, pain and pain-related fear and the different treatments, future trials could include treatments that target more systematically on putative mechanisms of change, such as pain catastrophizing. Furthermore, in daily rehabilitation practice compared to the treatments studied is in this trial, treatments can be more fine-tuned by selecting treatment modalities based on patient's characteristics, problems and needs. A next step could be comparing our highly structured treatments to these individually designed treatments (Vlaeyen and Morley, 2005). Indeed, we did not include a treatment that is directly derived from the fear-avoidance model, such as exposure in vivo with behavioral experiments that is shown to be a strong intervention for the reduction of disability in highly fearful patients (Vlaeyen and Linton, 2000; Vlaeyen et al., 2002). Exposure in vivo has been examined in the subgroup of CLBP patients with increased levels of pain-related fear. The results so far, mainly based on single-case experimental designs, have shown that exposure in vivo treatments are significantly more effective than graded activity in this subgroup of patients (Vlaeyen et al., 2001, 2002; Boersma et al., 2004; de Jong et al., 2005). In the future, clinicians and researchers alike will be faced with the continuing challenge to offer the most evidence-based treatment for patients with CLBP.

Acknowledgements

The authors thank the rehabilitation centres Breda, Leijpark and Blixembosch and the many people who contributed to the successful completion of this study, particularly the participating patients, the rehabilitation centre contact persons, therapists, research-assistants, especially Ria Laros, Frederieke Berendsen and Saskia Beelen. We are also grateful to Stephen Morley for his valuable comments on a previous version of this manuscript. This study is supported by Zorgonderzoek Nederland/Medische Wetenschappen (ZonMw) Grant No. 014-32-007.

Appendix A

Criteria used for exclusion due to psychopathology hampering individual or group processes.

A patient is excluded in case he exceeds *one or more* of the following SCL-90 scores:

Insufficient thinking and behavior scale:	>34 (men), >36 (women)
Distrust and interpersonal sensitivity scale:	>49 (men), >53 (women)
Hostility scale:	>14 (men), >15 (women)
Total score:	>247 (men), >269 (women)

A patient is excluded in case he exceeds *all* of the following NPV scores:

Rigidity:	>28 (age 18–24 yr, middle/higher education level) >31 (age 18–24 yr, low education level) >31 (age 25–54 yr, middle/higher education level) >35 (age 25–39 yr, low education level) >35 (age 55–65 yr, middle/higher education level) >38 (age 40–65 yr, low education level)
Hostility:	>21 (middle/higher education level) >24 (low education level)
Self-satisfaction/egoism:	>15 (middle/higher education level) >17 (low education level)

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A089032829
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KOPIE PERIODIEK EGB

(107)
18-11-2008

Datum indienen : 17-11-2008 10:52
Datum plaatsen : 17-11-2008 10:52
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Aanvraagident :
Aanvragerident : 0036/9999
Eindgebruiker : UM106915

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Datum plaatsen : 17-11-2008 10:52
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Aanvraagident :
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37910-1 mw.M.J.G.Moll-Zwart Voorspijntal
Universiteit Maastricht
Epidemiologie, Postbus 616 (DEB I)
6200 MD MAASTRICHT

tav

14

PPN Titel : 213893584,8
Titel : Pain : the journal of the International Association for the
Study of Pain

Auteur :
Deel/Supplem. :
Corporatie : International Association for the Study of Pain
Jaar/Editie : 1995 Extern nummer :
Uitgave : [Amsterdam] Elsevier Science
Serie/Sectie :
Pag-ISSN/ISBN : 1872-6623

Plaatscode : 803155824 ; QA ; ; 2005 V115 -

18/11

Jaar : 2008-00-00
Volume : 134
Aflevering : 3
Auteur : Smeets R. et al Aanvragerident. : MW.M.J.G.MOLL-ZWART VOORSPUI
Artikel : Chronic low back pain: physical training, graded activity....
Bladzijden : 263-276
Bron :
Opmerking :