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INTENSIVE GROUP TRAINING VERSUS COGNITIVE INTERVENTION IN SUB-ACUTE LOW BACK PAIN: SHORT-TERM RESULTS OF A SINGLE-BLIND RANDOMIZED CONTROLLED TRIAL

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Objective: **To evaluate the short-term effect of physical exercise and a cognitive intervention in low back pain.**
Design: **Randomized controlled trial.**
Subjects: **Ninety-three patients sick-listed for 8–12 weeks for sub-acute low back pain were randomized to an exercise regime ($n = 30$), a cognitive intervention ($n = 34$) or a control group ($n = 29$).**
Methods: **Primary outcome measures were pain, disability, sick-listing and satisfaction with care. Secondary outcome measures were self-efficacy for pain and for function, fear-avoidance beliefs, emotional distress, generic health status and life satisfaction.**
Results: **Eighteen percent of subjects dropped out. Drop-out was most frequent in the exercise group. At 18 weeks after inclusion fear-avoidance beliefs were reduced in both intervention groups. The cognitive group demonstrated significant improvement in disability, self-efficacy for pain, emotional distress, general health and life satisfaction. Patients in the exercise group were significantly more satisfied with the treatment, and patients following the exercise protocol reduced pain significantly. No effect on sick-listing was seen.**
Conclusion: **Cognitive intervention improved disability and may be feasible for most patients sick-listed in the sub-acute phase. Physical exercise reduced patients' symptoms, but requires high motivation by patients. Despite positive effects in intervention groups on variables considered as negative prognostic factors for long-term disability and sickness absence, interventions had no effect on sick-listing.**

Key words: low back pain, sub-acute, sick-listing, exercise, cognitive, physical therapy, randomized controlled trial

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INTRODUCTION

Patients sick-listed for low back pain (LBP) have an increased risk of developing chronic pain, disability and permanent work incapacity (1, 2). Long-term disability, sickness absence and work incapacity has an immense impact for the patients and society, and early interventions to prevent the development of long-term problems have been requested (1). However, preventing long-term disability resulting from spinal pain seems to be difficult, and there is no consensus about what intervention strategies to choose (3). An important challenge is the multifactorial nature of long-term disabling LBP, involving a complexity of psychological, physiological and social factors (2, 4, 5).

Work absenteeism, work incapacity and early retirement are the most expensive consequences of LBP in western countries (1). In Norway, LBP is the largest single cause both for sick-listing and disability pension, accounting for 15% of all sick-leave and 14.4% of all new disability pensions (6). Total costs are estimated to be at least 13 billions Norwegian kroner every year, corresponding to 1–1.3% of the Norwegian gross national product.

Waddell (1) suggests that the sub-acute phase is the phase where treatment is likely to be most effective. In this phase, psychosocial factors such as attitudes, beliefs, mood state, social- and work-related factors, disability, compensation and time off work, often termed "yellow flags", seem to be of importance for developing chronicity (1, 7). Hence, interventions aimed to reduce disability and "yellow-flags" and enhance return to work for patients sick-listed in the sub-acute phase have been recommended (7). Only a few studies have investigated the effect of treatment in patients with sub-acute LBP sick-listed for 8–12 weeks. Interventions focusing on physical exercise with a behavioural approach (8), work place visit and/or occupational interventions (8, 9), and reassurance and information of LBP as a benign and self-limiting condition have all shown to be promising (10, 11).

To date, the effect of exercise has not been compared with a cognitive intervention in a randomized controlled trial (RCT). A previous study evaluating the effect of intensive group exercise in chronic LBP showed promising results in terms of improved functional capacity and reduced depression (12). The aim of the present study was to compare the effect of 2 active interventions, both of which aimed to improve back function and reduce "yellow-flag"-variables in patients sick-listed for 8–12 weeks for LBP, with a control group receiving usual care.

METHODS

Patients sick-listed for non-specific LBP were recruited from the local National Insurance Offices and from general practitioner's (GPs) in 2

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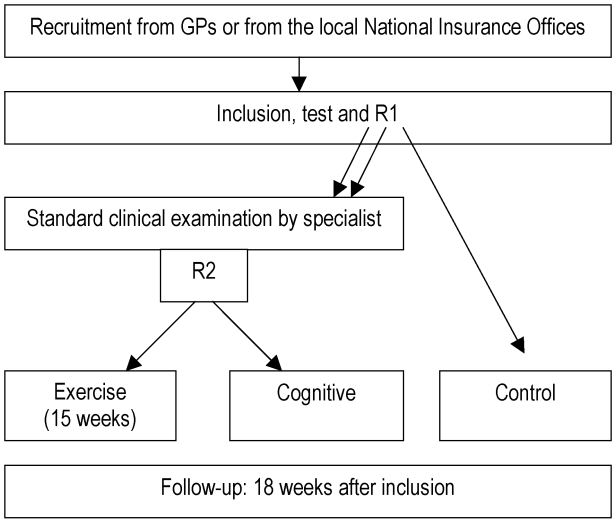

Fig. 1. Design of recruitment, inclusion, randomization (R) and follow-up.

counties with a total population of about 150,000 persons near Oslo, Norway. The inclusion period was from March 1998 to April 2001. Participants were entered into the study after clarification for the following inclusion and exclusion criteria:

Inclusion criteria

Sick-listed for 8–12 weeks due to non-specific LBP (receiving at least 50 sickness benefit, and with no sick-leave due to LBP during a period of 12 weeks before the current sick-listing period), sick-listed from a permanent job, aged 20–60 years, understanding Norwegian, accessibility to follow all 3 treatment alternatives, and conducting regular physical exercise less than 3 times per week for the last 6 months.

Exclusion criteria

Sciatic pain, spinal stenosis with neurological affection, spondylolysis or spondylolisthesis > grade 2, spinal fracture, tumour or infection, abuse of drugs or alcohol, rheumatic diseases, back surgery, pregnancy or diseases that might interfere with participation, and conducting regular physical exercise more than 3 times per week for the last 6 months.

Design

The study was a single-blind randomized controlled trial. Figure 1 shows a draft of the recruitment, inclusion and randomization procedure.

Randomization

Randomization was conducted by an engineer working at the hospital, who was not involved in the trial. Information about decoding the randomization was kept locked in the engineer's office and was not accessed until all data were cleaned and finalized. Subjects drew a sealed opaque envelope with disclosure of randomization and a smaller envelope inside. Patients randomized to the control group were informed of group allocation directly. Patients randomized to the exercise or the cognitive groups were informed that they were randomized to 1 of these groups, but not which group, and that they were going to undergo a standard clinical examination by a specialist in physical medicine and rehabilitation. After the specialist examination, the patient opened the small opaque envelope with information of the final group allocation (exercise or cognitive). This procedure ensured that the specialist was blinded for patients' group allocation when conducting the standard clinical examination. The specialist did not collect any of the outcome measures.

Interventions

The standard clinical examination both intervention groups underwent consisted of a routine back examination, explanation of X-rays and CT-scans, and general encouragement to resume daily activities and work. Additionally, answers to a questionnaire completed at inclusion were discussed with the patient. A report was sent to the GP and to the local National Insurance Office.

Cognitive intervention

Patients were assigned a new appointment at the outpatient clinic as soon as possible after the standard clinical examination. The consultation was teamwork between the specialist in physical medicine conducting the standard clinical examination and a physical therapist. The following items were dealt with:

- Explanation of pain mechanisms.
- The questionnaire completed at inclusion was discussed once more in-depth.
- Functional examination with individual feedback and advice.
- Instruction in activation of deep stabilizing muscles (i.e. the transverse abdominal muscle) and advice on how to use it actively in functional and demanding tasks of daily life.
- Instruction in the squat technique when lifting is required.
- How to cope with new attacks.
- Reassure and emphasize that it is safe to move and to use the back without restriction.

Patients were offered 2 consultations, each lasting between 30 and 60 minutes. After the last consultation, patients were invited to telephone the specialist or the physical therapist for advice or consultations. No treatments were referred (i.e. chiropractic, physical therapy or medication).

Intensive group training

Patients randomized to the exercise group were entered into ongoing back training groups at a large physical therapy practice. The exercise period was 15 weeks with a minimum of bi-weekly exercise sessions, preferably 3 sessions per week. Each session lasted for 1 hour. The group training was a modification of The Norwegian Aerobic Fitness Model. This concept is based on both exercise physiology and ergonomic principles, and designed to increase overall fitness and functional capacity (cardiovascular, strength—particularly in the thighs, back-abdominal (including the transverse abdominal muscle) and pelvic floor muscles, flexibility, body awareness, and relaxation) (12, 13). The whole program is accompanied by music. Modifications of the training model for the patients with LBP are:

- A physical therapist choreographed the program and every training session was led by experienced physical therapists.
- Focus on ergonomic principles and functional tasks.
- No pain focus.
- It is safe to move.

The physical therapy practice offers back training groups at different intensity levels. Patients started at the lowest level and increased the intensity by entering into more advanced classes. Subjects with the best progress were transferred to ordinary classes for healthy people outside the physical therapy practice, organized in accordance with the same exercise model and by the same physical therapist responsible for the program in the back training classes. Patients' attendance at the training classes was registered in training diaries kept in the physical therapy practice.

Control

Patients in the control group were treated by their GP and had no restrictions of treatments or referrals.

Questionnaires

Background variables, including anthropometrical and sociodemographic information (education, marital status, family responsibilities, social support, leisure time physical activity (14), occupational background (job satisfaction, social support from colleagues, mental stress of

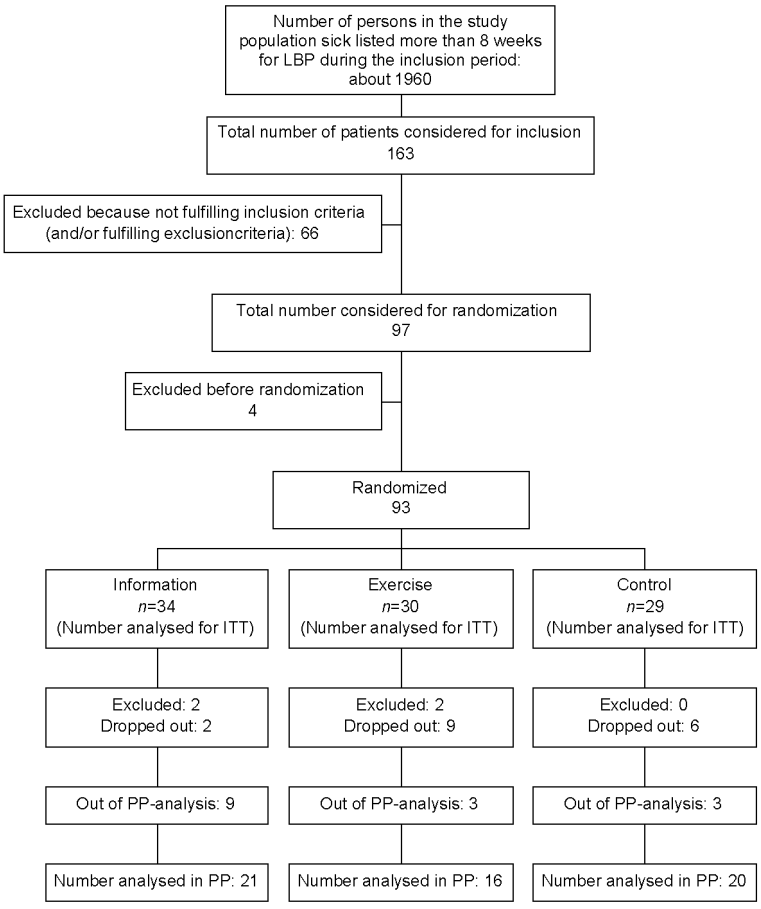

Fig. 2. Trial profile. ITT = intention to treat; PP = per protocol.

work, heaviness of work load), smoking- and alcohol habits, co-morbidity, LBP history, pain distribution (15), and somatization (16)) were collected by questionnaire before randomization. The questionnaire also included outcome measures covering all domains recommended by international panels of experts (pain, back specific function, work disability, generic health status and patient satisfaction) (17).

Primary outcome measures

Pain. LBP and lower limb pain (greatest pain at present) were assessed using 2 separate horizontal visual analogue scales (VAS) (18). A pain diary was completed 3 times a day for 7 days before and after treatment (2 VAS scales; how strong is your pain (sensory pain) and how distressing is your pain (affective pain)). Consumption of painkillers was registered at a 4-point scale (1 = daily, 2 = weekly, 3 = less than every week, 4 = never).

Disability. Disability was evaluated by the Roland and Morris Questionnaire (19).

Sick-listing. Data were collected from the local National Insurance Offices. Dependent of degree of sick-listing (full-time or part-time), number of working days lost during the 18-week study period was calculated. Maximal number of working days lost in 18 weeks is 90.

Secondary outcome measures

Self-efficacy beliefs for pain and function. Self-efficacy beliefs for pain were registered using the self-efficacy subscale for pain developed by Lorig et al. (20). Self-efficacy beliefs for function were assessed by eight questions regarding basic physical activities (21).

Fear-avoidance beliefs. Fear-avoidance beliefs for physical activity and for work were evaluated using Waddell et al.'s Fear-Avoidance Belief Questionnaire (FABQ) (22). The questionnaire is divided into 2 sub-scales, in which 4 questions are scored for physical activity (FABQ-PA) and 7 for work (FABQ-W).

Emotional distress. Emotional distress was assessed by the short version of the Hopkins Symptom Checklist (HSCL-25) (23).

Generic health status and life satisfaction

Generic health status was evaluated by the SF-36 Health Survey (24). This instrument is divided into 9 sub-scales (physical function, role physical, bodily pain, general health, vitality, social function, role emotional, mental health and health transition).

Life satisfaction was estimated by Cantrils Ladder Scale, a 10-point vertical numerical rating scale where 1 = very dissatisfied and 10 = very satisfied (25).

The questionnaire after the intervention period also included questions about co-interventions, change in pain intensity from before to after intervention (measured at a 100 mm + 100 mm VAS scale where 0 = unchanged (middle of the line), 100 mm to the left totally deterioration and increase in pain, and 100 mm to the right totally improvement and no pain) (26), physical activity during the intervention period (back training classes for patients randomized to the exercise group excluded), and satisfaction with care (graded at a 5-point scale as follows; 1 = very satisfied, 2 = somewhat satisfied, 3 = neither satisfied nor dissatisfied, 4 = somewhat dissatisfied, 5 = very dissatisfied) (17).

The personnel responsible for data collection (KS and IH) were not involved in the treatments and were blinded to which group the subjects were allocated.

All patients were informed about the study in writing and orally and signed an informed consent before inclusion. The project was performed according to the Helsinki Declaration. Approval was obtained from the

Table I. *Background variables (mean, range and standard deviation (SD))*

	Group training ($n = 30$)			Cognitive ($n = 34$)			Control ($n = 29$)		
Variable	Mean	Range	SD	Mean	Range	SD	Mean	Range	SD
Age (years)	42.3	24–59	9.2	41.3	20–60	9.4	38.9	20–59	11.9
Height (cm)	175.2	156–198	9.7	173.6	160–192	8.5	173.7	160–186	7.3
Weight (kg)	79.3	52–111	14.8	79.6	57–120	17.4	76.3	52–124	16.3
Body Mass Index (kg/m^2)	25.7	19.8–32.5	3.8	26.6	16.8–35.4	4.5	25.3	18.7–48.4	5.5
Gender (% male)	46.7			52.9			44.8		
Married (%)	73.3			85.3			65.5		
Smokers (%)	46.7			47.1			51.7		
Time since first LBP episode (years)	12.1	0–40	10.7	14.0	0–40	10.6	8.5	3–41	9.7
LBP at present (VAS; 0–100 mm)[a]	53.2	11–97	23.2	55.7	6–86	19.6	58.3	6–100	21.6
Pain Drawing (cells drawn;0–265)[a]	5.8	1–30	5.7	8.4	1–38	7.5	8.5	2–33	6.9
Roland and Morris Questionnaire (0–24)[a]	8.2	3–14	3.5	8.9	3–15	3.4	9.3	3–16	3.6
MSPQ (0–39)[a]	5.4	0–14	4.1	6.7	0–19	5.0	8.2	0–16	4.7
Physical activity during leisure time[(1)b]	2	1–3		2	1–3		2	1–3	
Highest education (%)									
Primary school (9 years)	20.0			20.6			10.3		
High school (12 years)	56.7			61.8			65.5		
College/university	23.3			17.6			24.1		
Work status (%)									
Full time	80.0			73.5			75.9		
Part time	20.0			26.5			24.1		
Heaviness of workload (%)									
Office working / sedentary	43.3			38.2			31.0		
Light manual handling	23.3			32.4			44.8		
Heavy manual handling	33.3			29.4			24.1		
Degree of sick-listing at inclusion (50–100 %)	87.3			86.6			85.2		
Job satisfaction (% satisfied)	86.7			79.4			86.2		

LBP = low back pain. MSPQ = modified somatic pain questionnaire.
[a] For all scales; 0 = best score (indicating no pain/disability/somatization)
[(1)] Registered on a four point scale: 0 = sedentary, 1 = moderate activity, 2 = intermediate activity, 3 = great activity (14).
[b] Data are presented as median and range.

Regional Committee of Medical Research Ethics and from the Data Inspectorate.

Power calculations

Lack of information from studies of comparable LBP populations in the literature made it difficult to make precise power calculations in outcome measures covering all domains recommended in the literature. Assumptions of sample size were based on a pilot-study (12), on isolated results from other former published studies and on recommendations from Koes et al. (27). When the trial was initiated, the ambition was to include at least 50 patients in each intervention group. Given a SD of 3.5, 50 patients in each treatment group would have provided 82% power at the 5% significance level to detect a 2-point difference between the groups in the mean change in Roland and Morris Questionnaire. For FABQ-PA a SD of 6 would provide 91% power to detect a 4-point difference in change.

Statistical analysis

Data were analysed according to both intention to treat (ITT) and per protocol (PP). In the ITT analysis, the population included all randomized patients. Last values were carried forward and replaced missing post-baseline values. The PP-population excluded patients according to the following predefined criteria: co-morbidity, less than 50% adherence to the exercise protocol, or co-interventions. Only statistically significant differences different from the ITT analysis will be reported.

Non-parametric statistics were used for the analysis. Comparability of groups at baseline and differences in change at follow-up were analysed using Kruskal-Wallis test (global test) and Mann-Whitney test (pair wise comparison between treatment groups). For categorical variables, group differences were analysed using chi-square, Fischer's exact test or McNemar test. Sick-listing was analysed both by non-parametric statistics and by analysis of covariance to test the difference in numbers of sick-listing days between groups, adjusting for degree of sick-listing at baseline.

Means, standard deviations (SD) and 95% confidence intervals (CI) for differences between groups are given by ANOVA. p-values ≤ 0.05 were considered statistically significant.

RESULTS

Ninety-three patients fulfilled the inclusion criteria and were randomized (Fig. 2). All together 17 persons (18.3%) dropped out during the 15-week intervention period; 2 (5.9%) from the cognitive group, 9 (30.0%) from the exercise group, and 6 (20.7%) from the control group. Another 19 patients (20.4%) were excluded according to the PP-criteria, leaving 57 persons (61.3%) for the PP analysis.

Figure 2 shows that patients in the cognitive group return for new assessments at follow-up, although they had not followed the protocol and were excluded from the PP analysis. Patients in the exercise group dropped out during the intervention period and refused to meet for follow-up assessments, resulting in a 5-fold of baseline values carried forward in the ITT analysis in the exercise group compared with the cognitive group. More men than women dropped out for reasons connected to the

Table II. *Primary outcome variables for the three treatment groups; mean and standard deviation (SD) before the treatment period, mean change and standard error (SE) after the treatment period (ITT analysis)*

	Exercise ($n = 30$)		Cognitive ($n = 34$)		Control ($n = 29$)	
Variable	Before (mean/(SD))	Change (mean/(SE))	Before (mean/(SD))	Change (mean/(SE))	Before (mean/(SD))	Change (mean/(SE))
Low back pain (0–100)[a]	53.2 (23.2)	−14.9 (4.1)	55.7 (19.6)	−20.9 (4.3)	58.3 (21.6)	−10.0 (3.7)
Lower limb pain (0–100)[a]	16.2 (21.9)	−2.1 (1.5)	19.4 (22.7)	−5.8 (4.7)	28.8 (29.3)	−9.8 (3.2)
Pain dairy						
Sensory (0–100)[a]	42.1 (18.4)	−11.3 (2.8)	45.5 (19.9)	−9.6 (4.1)	43.0 (19.6)	−5.0 (2.2)
Affective (0–100)[a]	42.3 (18.6)	−10.4 (3.0)	45.5 (21.4)	−9.7 (4.4)	43.7 (21.6)	−6.6 (2.2)
Change in pain intensity (−100–+100)[b]		39.70 (9.4)		32.6 (8.6)		11.04 (9.0)
Disability (0–24)[a]	8.2 (3.5)	−2.1 (0.7)	8.9 (3.4)	−3.5 (0.7)	9.3 (3.6)	−1.6 (0.7)

[a] 0 indicates no pain/disability.
[b] Positive score indicates a positively change in pain intensity.

intervention in the exercise group (drop out type B). Analysis of background variables and baseline scores of outcome variables in dropouts vs non-dropouts showed that more dropouts were living alone (divorced, separated or single). Additionally, FABQ-W was higher in dropouts (dropouts 30.9, non-dropouts 26.3, $p = 0.05$). Analysis comparing compliants and non-compliants at baseline (compliants = patients included in PP analysis) detected no differences in background variables, but there was a significant higher report of lumbar pain (VAS) in non-compliers (non-compliants 60.7 mm, compliants 52.5 mm, $p = 0.05$). Otherwise, no differences were found between dropouts/non-complaints and participants following the entire study protocol.

Mean adherence to the group training classes for patients not dropping out after the first session was 80.4% (range 20–100%). Three persons carried out less than 15 exercise sessions and were excluded from the PP analysis. Mean number of sessions for the reminding subjects was 31 (range 16–46). Hence, most patients fulfilling the training protocol attended the group training classes bi-weekly or more.

In the cognitive group, about one-fifth of the patients came back for more than the 2 recommended consultations. About one-third phoned the specialist or the physical therapist for advice.

There were no statistically significant differences between the groups in background variables at randomization, except that the mean time since first LBP episode was shorter in the control group (Table I).

Table II and III show baseline values of primary outcome variables for the 3 treatment groups, mean change after the treatment period, global treatment effect and pair wise comparison between the treatment groups (ITT analysis). No significant differences between groups were found at baseline. The main results after the treatment period were a significant positive change in pain intensity in the exercise group, and a significant reduction in disability in the cognitive group. There was no significant reduction in consumption of painkillers in any of the groups. The only new significant result from PP analysis was a significant reduction in sensory pain measured by the 7-days pain diaries in the exercise group compared with the

Table III. *Treatment effect in primary outcome variables; global test for differences between all treatment groups, and pair-wise comparison between treatment groups (ITT analysis)*

	Global test (KW)		Pair wise comparison between 2 treatment groups (MW)								
			Exercise$^{(n = 30)}$/Control$^{(n = 29)}$			Cognitive$^{(n = 34)}$/Control$^{(n = 29)}$			Exercise $^{(n = 30)}$/Cognitive$^{(n = 34)}$		
Variable	KW	*p*-value	Delta	95% CI	*p*-value	Delta	95% CI	*p*-value	Delta	95% CI	*p*-value
Low back pain	2.683	0.26	−4.9	−16.0 to 6.2	0.71	−10.9	−22.3 to 0.4	0.12	6.0	−5.8 to 17.9	0.24
Lower limb pain	1.909	0.39	7.7	0.7 to 14.7	0.13	4.0	−7.4 to 15.3	0.40	3.7	−6.3 to 13.7	0.79
Pain dairy											
Sensory	1.831	0.40	−6.3	−13.5 to 0.9	0.14	−4.6	−13.9 to 4.8	0.60	−1.7	−11.6 to 8.3	0.54
Affective	0.359	0.84	−3.8	−11.3 to 3.7	0.53	−3.1	−12.9 to 6.7	0.81	−0.7	−11.3 to 10.0	0.76
Change in pain intensity	4.870	0.09	28.7	2.4 to 54.9	**0.04**	21.5	−3.3 to 46.4	0.09	7.1	−18.5 to 32.8	0.62
Disability	5.825	0.05	−0.6	−2.5 to 1.3	0.38	−1.9	−3.8 to −0.06	**0.02**	1.3	−0.5 to 3.2	0.11

CI = 95% confidence interval. CI is based on ANOVA. KW = Kruskal-Wallis test. MW = Mann-Whitney test. Delta = net difference between groups.

Table IV. *Secondary outcome variables for the 3 treatment groups; mean and standard deviation (SD) before the treatment period, mean change and standard error (SE) after the treatment period (ITT analysis)*

	Exercise ($n = 30$)		Cognitive ($n = 34$)		Control ($n = 29$)	
Variable	Before (mean/(SD))	Change (mean/(SE))	Before (mean/(SD))	Change (mean/(SE))	Before (mean/(SD))	Change (mean/(SE))
Self efficacy for pain (1–7)[a]	4.3 (1.1)	0.2 (0.2)	4.3 (1.2)	0.7 (0.3)	4.0 (1.3)	−1.2 (0.3)
Self efficacy for function (8–64)[a]	40.9 (10.0)	2.5 (1.9)	39.9 (10.6)	4.7 (1.9)	39.0 (9.0)	1.0 (1.2)
FABQ						
physical activity (0–24)[b]	13.3 (5.2)	−3.8 (1.1)	14.1 (4.4)	−3.1 (1.0)	14.6 (3.8)	0.4 (0.7)
work (0–42)[b]	25.9 (9.7)	−3.3 (1.2)	26.7 (9.1)	−5.9 (1.6)	29.1 (8.2)	−0.2 (1.3)
HSCL-25 (1–4)[b]	1.4 (0.4)	−0.006 (0.03)	1.5 (0.4)	−0.2 (0.1)	1.6 (0.4)	0.003 (0.04)
SF-36[a]						
Physical function (0–100)	64.7 (19.3)	6.5 (2.3)	62.7 (15.9)	12.7 (3.8)	60.9 (17.2)	6.0 (2.3)
Role physical (0–100)	4.2 (11.5)	30.8 (7.8)	11.0 (14.0)	27.2 (8.5)	7.8 (17.8)	18.1 (32.7)
Bodily pain (0–100)	30.8 (12.9)	14.7 (3.1)	29.1 (13.1)	21.5 (4.8)	25.8 (10.8)	12.6 (3.4)
General health (0–100)	68.4 (20.5)	0.9 (2.4)	65.8 (17.1)	2.1 (2.4)	63.8 (17.7)	−2.9 (2.0)
Vitality (0–100)	51.5 (16.5)	4.0 (2.8)	37.8 (18.2)	16.5 (3.3)	40.3 (16.2)	3.9 (4.0)
Social function (0–100)	72.1 (17.9)	8.3 (3.7)	61.8 (23.6)	11.4 (4.6)	63.8 (22.2)	9.5 (3.5)
Role emotional (0–100)	53.3 (46.0)	18.9 (7.9)	46.1 (44.2)	25.5 (8.8)	62.1 (38.5)	11.5 (6.5)
Mental health (0–100)	73.1 (12.7)	4.7 (1.8)	64.5 (16.8)	12.4 (2.9)	67.7 (17.8)	5.6 (2.5)
Health transition (0–100)	29.1 (24.4)	26.6 (7.1)	30.7 (28.5)	29.2 (7.3)	24.9 (27.3)	23.6 (6.4)
Life satisfaction (0–10)[a]	7.0 (2.1)	0.4 (0.2)	6.0 (2.1)	1.0 (0.5)	6.4 (2.1)	−0.2 (0.3)

FABQ = fear-avoidance belief questionnaire. HSCL-25 = Hopkins symptom checklist. SF-36 = SF-36 health survey.
[a] High score indicates good self-efficacy/health state/life satisfaction
[b] 0/1 = best score, indicating no fear-avoidance/emotional distress.

control group (mean change = –18.1 mm, $p = 0.04$). However, at the same time the significant change in pain intensity in the exercise group and the significant improvement in disability in the cognitive group was lost.

Sick-listing showed no differences between the treatment groups in number of benefited days from inclusion to 18-weeks' follow-up, neither in the ITT analysis (analysis of covariance: $p = 0.70$)/KW: $p = 0.80$), nor in the PP analysis (analysis of covariance: $p = 0.40$/KW: $p = 0.57$). Mean number of benefited days in the period was 57.6 in the cognitive group, 63.5 in the exercise group, and 56.3 in the control group (ITT analysis). Both analyses showed that patients in the exercise group were more satisfied with the care than patients in the 2 other treatment groups ($p < 0.001$).

Tables IV and V show baseline values of secondary outcome variables for the 3 intervention groups, mean change after the treatment period, global treatment effect, and pair-wise comparison between the treatment groups (ITT analysis). At baseline, there were no significant differences, except for 1 sub-scale (vitality) in the SF-36 (Table IV). Both intervention groups showed significant reduction in FABQ. The cognitive group was significantly more improved in self-efficacy for pain, emotional distress, general health and life satisfaction. PP analysis showed that the cognitive group was still significantly better than the control group in self-efficacy for pain ($p = 0.03$) and life satisfaction ($p = 0.05$). For FABQ-PA, the significant effect was enhanced in both treatment groups compared with the control group ($p = 0.01$ for the exercise group and $p = 0.006$ for the cognitive group, respectively). The only new significant finding was that the cognitive group changed more positively than the control group in HSCL-25 ($p = 0.04$).

DISCUSSION

To our knowledge, this is the first randomized controlled trial comparing a cognitive intervention, comprehensive physical group training, and control in patients sick-listed for sub-acute LBP. A significant reduction in pain was seen in the exercise group, and the cognitive group had a significant reduction in disability. "Yellow-flag"-variables were significantly reduced in both intervention groups, but more so in the cognitive group. No difference in sick-listing was seen between groups.

The strengths of this study were use of a design able to distinguish between the effect of a cognitive intervention and physical training, concealed randomization, blinded data collection, ITT analysis and homogeneous length of the sick-listing period of included patients. In addition, the exercise program followed training dosages recommended by the American College of Sports Medicine (13), and only validated, sensitive and reproducible outcome measures recommended by international panels of experts were used (17). Limitations of the study were the sample size, possible selection bias and differences in reasons and time for dropout between the 2 intervention groups.

The aim of the present study was to include a sample size of 50 participants in each group. This was based on recommendations given by Koes et al. (27) and on power calculations based on results from a former study (12). However, strict inclusion and exclusion criteria and slow recruitment from GPs and the

Table V. *Treatment effect in secondary outcome variables; global test for differences between all treatment groups, and par wise comparison between treatment groups (ITT analysis)*

	Global test (KW)		Pair wise comparison between 2 treatment groups (MW)								
			Exercise$^{(n=30)}$/Control$^{(n=29)}$			Cognitive$^{(n=34)}$/Control$^{(n=29)}$			Exercise$^{(n=30)}$/Cognitive$^{(n=34)}$		
Variable	KW	*p*-value	Delta	95% CI	*p*-value	Delta	95% CI	*p*-value	Delta	95% CI	*p*-value
Self efficacy for pain	6.385	**0.04**	0.4	−0.3 to 1.0	0.17	0.8	0.03 to 1.7	**0.02**	−0.5	−1.2 to 0.2	0.11
Self efficacy for function	1.583	0.45	1.5	−3.1 to 6.1	0.85	3.7	−1.0 to 8.5	0.24	−2.2	−7.5 to 3.1	0.33
FABQ											
Physical activity	8.057	**0.02**	−4.1	−6.7 to −1.6	**0.03**	−3.5	−5.8 to −1.1	**0.007**	−0.7	−3.6 to 2.2	0.94
Work	7.520	**0.02**	−3.1	−6.6 to 0.4	**0.05**	−5.7	−9.9 to −1.5	**0.01**	2.6	−1.4 to 6.5	0.27
HSCL-25	5.160	0.08	−0.01	−0.1 to 0.1	0.86	0.2	−0.3 to 0.02	0.08	0.1	−0.009 to 0.3	**0.04**
SF-36											
Physical function	6.003	**0.05**	0.5	−6.1 to 7.1	0.65	6.6	−2.6 to 15.9	**0.04**	−6.1	−15.1 to 2.8	**0.04**
Role physical	1.451	0.48	12.7	−7.1 to 32.7	0.31	9.1	−12.5 to 30.7	0.26	3.6	−19.5 to 26.8	1.00
Bodily pain	3.089	0.21	2.1	−7.1 to 11.3	0.47	8.9	−3.3 to 21.1	0.09	−6.8	−18.4 to 4.8	0.30
General health	5.627	0.06	3.8	−2.6 to 10.2	0.15	5.0	−1.5 to 11.4	**0.03**	1.2	−8.1 to 5.7	0.24
Vitality	9.396	**0.009**	0.01	−9.6 to 9.8	0.87	12.5	2.3 to 22.8	**0.03**	−12.5	−21.0 to −3.9	**0.003**
Social function	0.258	0.88	−1.1	−11.4 to 9.1	0.86	1.9	−9.9 to 13.7	0.73	−3.1	−14.8 to 8.7	0.64
Role emotional	1.841	0.40	7.4	−13.2 to 28.0	0.58	14.0	−8.5 to 36.5	0.18	−6.6	−30.3 to 17.1	0.47
Mental health	6.500	**0.04**	−0.9	−6.9 to 5.1	0.99	6.8	−0.8 to 14.4	**0.05**	−7.7	−14.5 to −0.9	**0.02**
Health transition	0.644	0.73	2.9	−16.2 to 22.1	0.89	5.6	−13.8 to 25.0	0.46	2.7	−22.9 to 17.6	0.55
Life satisfaction	8.913	**0.01**	0.6	−0.2 to 1.4	0.16	1.1	−0.1 to 2.3	**0.007**	−0.5	−1.7 to 0.6	**0.05**

CI = 95% confidence interval. CI is based on ANOVA. KW = Kruskal-Wallis test. MW = Mann-Whitney test. Delta = net difference between groups. FABQ = Fear-Avoidance Belief Questionnaire. HSCL-25 = Hopkins Symptom Checklist. SF-36 = SF-36 Health Survey.

local National Insurance Offices resulted in a sample size of about 30 persons in each treatment group. This reduced the power of the study. Post-treatment power calculations showed that there was 58% power to detect a difference at the 5% significance level in Roland and Morris Questionnaire and 78% power for FABQ-PA. However, the observed changes are comparable or superior to results found in other studies (28, 29). Additionally, the sample size resembles several previous published studies of LBP populations with comparable interventions and criteria for attendance (30).

The study had an 18% loss of patients to follow-up. Less than 20% drop out is considered to be acceptable (27). Dropout was, however, higher in the exercise group compared to the cognitive group. Hence, in the ITT analysis more baseline values were carried forward in the exercise group, resulting in a specific loss of power in this treatment group. Per protocol analysis indicated a more equal treatment effect in the 2 intervention groups in disability. However, the effect on "yellow flag" variables (self-efficacy for pain, emotional distress and life satisfaction) was still superior in the cognitive group. In the cognitive group, the net effect of treatment was similar in both ITT- and PP analysis, suggesting that co-interventions in patients excluded from the PP analysis did not affect outcome. A possible explanation for the higher dropout rate in the exercise group may be the much higher demands on participation and adherence in this group. Additionally, training accompanied by music may be more attractive to women, and thereby explain the higher dropout rate among men in the exercise group.

Pain has both sensory and affective dimensions and is a complex variable to influence (18, 22). In order to maximize the reliability and validity of pain assessment, pain was measured by different instruments (18). The exercise group reported significant positive change in perceived pain intensity at follow-up (ITT analysis) and on sensory pain measured before and after treatment by the 7-days pain diaries (PP analysis). Patients included in the present study had a non-specific LBP diagnosis. Basic scientific knowledge speaks in favour of the benefits of training for all pain sensitive structures in the lumbar spine (31). In a systematic review, Elders et al. (32) concluded that there is evidence that ergonomic intervention is effective in the sub-acute phase for patients sick-listed for LBP. Focus on ergonomic principles in the exercise group, aimed to change behaviour and movement strategies to make the participants able to perform daily activities in a less biomechanically stressful manner, may therefore have contributed to the result.

The most surprising result of the present study was the significant effect on disability achieved only in the cognitive group in the ITT analysis. In the PP analysis, the net effect was similar between the 2 intervention groups. The exercise intervention focused more on daily activities and functional tasks than did the cognitive intervention. The effect on disability was therefore hypothesized to be superior in the exercise group. Former studies evaluating the effect of a similar (12) and a comparable (33) intervention in different LBP populations have reported significant effect on this important variable in favour of the training groups. However, Waddell (1) describe a complex interplay between physical condition, psychological state, pain and functional disability in patients with long lasting LBP. Only a weak relationship between pain and disability has been suggested (1). Disability may therefore be closer linked to

coping strategies and fear-avoidance (5). Both interventions succeeded in reducing fear-avoidance beliefs about physical activity and work. However, the individual reassurance and encouragement in the cognitive group may have been more successful in initiating a confrontational behaviour affecting disability. The superior effect in the cognitive group in "yellow-flag" variables such as self-efficacy for pain, emotional distress and life satisfaction may also contribute to the effect on disability. Another important factor is that sick-listed patients may be influenced more by psychosocial and work-related factors than patients who are not sick-listed. The chronic LBP population studied by Mannion et al. (29) reported considerably less somatization (MSPQ) and FABQ-W at baseline than the sick-listed patients included in the present study. A psychological rather than physical cause of absence from work in the present study may be supported by the observation of low score in disability at baseline (mean value of about 1/3 of maximal score). This is within the same range of disability reported by patients not being sick-listed (12, 28, 29). The cognitive intervention dealt with patients' individual self-reported functional problems and gave patients advice and responsibility for managing their problems themselves. This, together with the focus on reassurance, may be sufficient for the LBP-population included in the present study to change behaviour and resume daily functional tasks.

Positive effects in the intervention groups on several variables considered as negative prognostic factors for long-term disability and sick-listing were shown (1, 2). Nevertheless, there was no effect on short-term sickness absence. The use of sick-leave as a measure of morbidity has been discussed, and several authors have pointed out that sick leave is influenced by factors outside the domain of medical or therapeutic interventions (26, 34). The results from the present study is in accordance with other well-designed studies (26, 35). However, the results do not correspond with the reduction in sick-leave reported by Indahl et al. (10), Hagen et al. (11) and Lindström et al. (8). In contrast to in Indahl et al.'s study, sickness absence has increased and unemployment decreased in Norway during the period of the present study. This may have affected our results. Additionally, in the study of Indahl et al. every second of all patients with LBP in the county sick-listed for 8–12 weeks were sent to the spine clinic and included in the intervention group (10). Participation in the present study was voluntary and patients were included according to strict inclusion and exclusion criteria. Hence, the study populations may not be comparable. Lindström et al.'s study is the only published RCT demonstrating effect on sick leave of an intervention combining exercise and cognitive treatment. The individual exercise program with a behavioural therapy approach may be more effective than exercise or cognitive treatment alone. Additionally, Lindström et al.'s study was conducted at a single work-site. Although they did not modify patients' worksite, linking the medical intervention to the worksite may have enhanced the effect on sickness absence (9).

In the Norwegian health service system, patients on sick leave receive 100% of their salary from day 1 for a maximum of 52 weeks. It has been argued that the Nordic welfare benefits may be too generous (34) and that sociological factors like increased acceptance for LBP as a reason for sickness certification may have contributed to the enormous rise in work incapacity attributed to LBP seen in western societies over the last decades (4). This may be one explanation of why sick leave may be difficult to reduce within this system.

The present study demonstrated that the cognitive intervention group improved in disability, the exercise group improved in pain, and both intervention groups improved in "yellow flag"-variables. None of the interventions showed any effect on sick leave. A cognitive intervention may be feasible for most patients sick-listed 8–12 weeks for sub-acute LBP. An exercise intervention seems to reduce patients' symptoms in patients following the exercise protocol, but may require high motivation by the patients.

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