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A 3-year follow-up of a multidisciplinary rehabilitation programme for back and neck pain

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Abstract

The aim of the present study was to evaluate the long-term outcome of a behavioural medicine rehabilitation programme and the outcome of its two main components, compared to a 'treatment-as-usual' control group. The study employed a 4×5 repeated-measures design with four groups and five assessment periods during a 3-year follow-up. The group studied consisted of blue-collar and service/care workers on sick leave, identified in a nationwide health insurance scheme in Sweden. After inclusion, the subjects were randomised to one of the four conditions: behaviour-oriented physiotherapy (PT), cognitive behavioural therapy (CBT), behavioural medicine rehabilitation consisting of PT+CBT (BM) and a 'treatment-as-usual' control group (CG). Outcome variables were sick leave, early retirement and health-related quality of life. A cost-effectiveness analysis, comparing the programmes, was made. The results showed, consistently, the full-time behavioural medicine programme being superior to the three other conditions. The strongest effect was found on females. Regarding sick leave, the mean difference in the per-protocol analysis between the BM programme and the control group was 201 days, thus reducing sick leave by about two-thirds of a working year. Rehabilitating women has a substantial impact on costs for production losses, whereas rehabilitating men seem to be effortless with no significant effect on either health or costs. In conclusion, a full-time behavioural medicine programme is a cost-effective method for improving health and increasing return to work in women working in blue-collar or service/care occupations and suffering from back/neck pain.

Keywords: Randomised controlled trial; Physiotherapy; Cognitive behaviour therapy; Multidisciplinary intervention; Cognitive behavioural; Rehabilitation; Gender; Back pain; Neck pain; Cost-effectiveness; Return to work

1. Introduction

In an earlier report, we presented results from a short-term follow-up (18 months) of a component analysis of a multidisciplinary rehabilitation programme for spinal pain (Jensen et al., 2001). In that report, the analysis showed that effects of treatment were dependent on gender, i.e. cognitive behavioural therapy was more effective on women than on men. As pointed out in the recent systematic reviews (Karjalainen et al., 2003a,b; Nachemson and Jonsson, 2000), there is a lack of high-quality studies with long-term follow-ups and studies evaluating return to work/sick leave in this area. One could argue that 12–18 months post-treatment is long-term follow-up, and it has indeed been treated as such in earlier studies. However, in earlier studies, we found repeatedly that after 18 months the effects on sick leave evened out. Thus, the difference in sick-leave found during the first six months after treatment even out during 12–18 months post treatment (Jensen, 1993; Jensen et al., 1997, 2001). The results showed that the control groups decreased their sick leave at a slower pace, but during the follow-up periods they reached the level of the treated group, which was approximately 25% sick leave from a full-time job (Jensen and Bodin, 1998; Jensen et al., 2001). Thus, we conclude that multidisciplinary treatment helps subjects return to work earlier than if they are not treated, but it seems that for those who have suffered from long-term

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back pain there is little chance of returning to work full-time (Mayer et al., 2001; Schonstein et al., 2003).

The cost-effectiveness of multidisciplinary rehabilitation programmes has been questioned (Goossens, 1999), but the need for more studies investigating the cost-effectiveness is evident (Borghouts et al., 1999; Maniadakis and Gray, 2000; Turk, 2002; Turk and Okifuji, 1998). In a recent evidenced-based review, the authors state that there is insufficient knowledge of the effects of multidisciplinary programmes on return to work (Linton, 2000). In the review, it is concluded that the cost-effectiveness of rehabilitation has still not been evidenced (Nachemson and Jonsson, 2000). Thus, to further investigate the effects of a multidisciplinary programme, we designed a study to investigate the effects during a 3-year follow-up with a cost-effectiveness analysis included.

The purpose of the present report was to evaluate 3-year outcome of a multidisciplinary rehabilitation programme, and the outcome of its two main components, as compared to a 'treatment-as-usual' control group. It was hypothesised that the treatment conditions should be superior to the control condition, and that the full-time multidisciplinary rehabilitation programme should be superior to its main components in the primary endpoints. Subgroup comparisons were planned with regard to gender. It was hypothesised that females would benefit more than men from the multidisciplinary and the cognitive behavioural program.

Primary endpoints were work absenteeism (sick leave and disability pension) and health-related quality of life (SF-36). Cost for production losses was calculated using work absenteeism.

2. Methods

The methods will be described in brief. A more in-depth report on the methods has been presented elsewhere (Jensen et al., 2001).

2.1. Design

The study was a randomised, controlled multicentre trial employing a 4×5 repeated-measures design with four groups and five assessment periods (pre-treatment, post-treatment, 6-, 18- and 36-month follow-up). A block randomisation procedure was employed to ensure an even distribution of the treatment conditions. The randomisation was carried out according to the sealed envelope technique. The screening personnel were blinded to the results of the randomisation.

2.2. Subjects

The subjects were 97 men and 117 women suffering from long-term non-specific spinal pain. Data were gathered between May 1995 and October 1999. The inclusion criteria were as follows: non-specific spinal pain, currently and continuously sick-listed for spinal pain at least 1 month and a maximum of 6 months, fluency in Swedish and 18–60 years of age. Exclusion criteria were: serious spinal pathology, exposure to physical trauma within 6 months before examination, objective neurological signs indicating a need for surgery, co-morbidities, ongoing rehabilitation, and verified pregnancy.

The source population was persons covered by the AGS[1] insurance scheme, which is a health insurance plan covering 2.4 million employees in Sweden. All those who were sick-listed for a period of 1–6 months for spinal pain were identified from the sick-listing register. Descriptive information for the subjects in each treatment condition and for the controls is presented in Table 1. The Committee on Ethics of Karolinska Institutet, Stockholm, approved all ethical considerations regarding the study.

2.3. Treatment conditions

Common features of the three treatment conditions were as follows: (i) the interventions lasted for 4 weeks and were conducted in groups of 4–8 participants; (ii) all treatments included a physician who examined the patients and was available throughout the intervention for consultations; (iii) all treatments included in total six didactic sessions addressing psychological aspects of chronic pain, ergonomics and medical aspects of chronic pain; (iv) all treatments included scheduled times for visits to the workplace. Works managers and rehabilitation officials were invited to participate in the discharge session at which a rehabilitation plan was agreed upon. Six booster sessions were held over a period of 1 year after the treatment.

2.3.1. Behaviour-oriented physiotherapy (PT)

The PT intervention was carried out on a part-time basis (approximately 20 scheduled hours per week) and was aimed at enhancing the physical functioning and facilitate a lasting behaviour change of the individual. Each participant was assigned to an individually tailored training program. The program included individual goal setting, gradually increased exercises to improve muscular endurance, aerobic training (e.g. cycling on a test bicycle), pool training, relaxation techniques according to Jacobson (1938) and Westin (1985) and body awareness therapy. Homework assignments for physical activities were given according to the individual's interests and problem areas.

2.3.2. Cognitive behavioural therapy (CBT)

The CBT intervention comprised, on average, 13–14 scheduled hours per week and was aimed at improving the subjects' ability to manage their pain and resume a normal level of activity. The techniques used in the CBT were those described in Philips (1988) and Turk et al. (1983). The CBT program included activity planning and goal setting, problem solving, applied relaxation (Lisspers and Hallgren, 1994), cognitive coping techniques (e.g. distracting imagery, external focusing, coping self-statements), activity pacing, the role of vicious circles and how to break them, the role of significant others and assertion training. Individually tailored homework assignments were given at the end of each session.

[1] AGS is a sick pay and disability pension insurance scheme which is part of the agreement between the Swedish Employers' Confederation (SAF) and the Swedish Trade Union Confederation (LO).

Table 1
Baseline descriptive information about the subjects per conditions

	BM ($n=63$)	PT ($n=54$)	CBT ($n=49$)	CG ($n=48$)	Male ($n=97$)	Female ($n=117$)
Age, mean (SD)	43 (12)	43 (9)	44 (10)	44 (11)	45 (11)	42 (10)
Gender, females, *n* (%)	30 (48)	37 (68)	22 (45)	28 (58)		
Married, *n* (%)	39 (63)	34 (63)	36 (74)	33 (70)	68 (70)	74 (63)
Swedish origin, *n* (%)	52 (82)	48 (89)	35 (71)	39 (81)	77 (79)	97 (83)
Employed, *n* (%)	52 (84)	42 (78)	42 (86)	44 (94)	82 (85)	98 (84)
Education, *n* (%)						
Compulsory School	35 (56)	31 (57)	29 (60)	27 (57)	56 (58)	66 (56)
Upper Secondary School	23 (37)	19 (35)	11 (23)	16 (34)	31 (32)	38 (33)
Further Education	4 (6)	4 (7)	8 (17)	4 (8)	8 (8)	12 (10)
Pending litigation, *n* (%)	17 (31)	11 (20)	21 (43)	16 (36)	36 (37)	29 (25)
Clinical depression,[a] *n* (%)	6 (10)	10 (18)	6 (12)	4 (8)	11 (11)	15 (13)
Clinical anxiety,[a] *n* (%)	14 (22)	12 (22)	11 (22)	12 (25)	24 (25)	25 (21)
Hazardous alcohol consumption,[b] *n* (%)	7 (11)	4 (7)	9 (18)	7 (15)	21 (22)	6 (5)
Pain duration in months, mean (SD)	35.6 (68.0)	36.9 (67.1)	22.7 (38.4)	27.3 (39.2)	24.7 (49.2)	36.7 (62.2)
Median	8	8.5	9	8	7	10
Total sick leave the year prior to inclusion, mean (SD)	162 (61)	136 (64)	153 (62)	135 (60)	156 (61)	140 (62)
Primary pain sites, *n* (%)						
Cervical/thoracic	23 (36)	22 (41)	20 (41)	24 (50)	39 (40)	50 (43)
Lumbar	34 (54)	22 (41)	22 (45)	21 (44)	51 (53)	48 (41)
Mixed pain areas	6 (10)	10 (18)	7 (14)	3 (6)	7 (7)	19 (16)
Spinal mobility, mean (SD)[c]	86 (26)	84 (24)	90 (26)	93 (22)	87 (26)	89 (24)
Total neck mobility, mean (SD)[d]	297 (69)	281 (53)	304 (62)	288 (65)	294 (68)	290 (59)
Impaired reflexes, *n* (%)						
Upper extremities	1 (2)	2 (4)	2 (5)	1 (2)	4 (4)	2 (2)
Lower extremities	3 (6)	4 (9)	2 (5)	3 (7)	9 (9)	3 (3)
SLR, *n* (%)	1 (2)	0	0	0	1 (1)	0
Past back surgery *n* (%)	2 (3)	0)	1 (2)	(0)	2 (2)	1 (1)

[a] The Hospital Anxiety and Depression Inventory was used to assess depression and anxiety (Zigmond and Snaith, 1983). The cut-off scores were set to ≥ 11 points.
[b] The Alcohol Use Disorders Identification Test, AUDIT (Saunders et al., 1993) was used as a measure of alcohol consumption. The cut-off score for hazardous consumption was set to ≥ 8 points.
[c] Spinal mobility = Thoracic + lumbar mobility measured with a kyphometer (Öhlén et al., 1989).
[d] Total neck mobility measured with a Myrin goniometer (American Academy of Orthopaedic Surgeons, 1966).

2.3.3. Full-time behavioural medicine rehabilitation (BM)

This condition included both the PT and CBT programmes.

2.3.4. 'Treatment-as-usual' control group

The control group was not offered any type of intervention in the research project. Consequently, they underwent the normal routines in health-care. Research indicates that only a minority of individuals with long-term spinal pain are offered more comprehensive rehabilitation programmes in Sweden (Jensen et al., 2000).

Licensed physiotherapists, psychologists, and physicians were involved in the programmes. Therapist compliance was monitored by checklists and telephone interviews with participants, and the result showed that 95% of the scheduled activities were carried out in accordance with the specifications.[2] The participants' attendance rates were 94% per treatment alternative. The corresponding figures for the booster sessions were: BM (65%); PT (64%); CBT (65%).

[2] For a more detailed description, see Jensen et al. (2001).

2.4. Measures

Absence from work and health-related quality of life were primary endpoints.

Absence from work was obtained from the National Social Insurance Board (NSIB) for a period of 18 months before inclusion in the study and 36 months post-rehabilitation. Absence from work was defined as sick-listing plus early retirement.

The Short Form-36 (SF-36) was used to assess health-related quality of life (McHorney et al., 1994; Sullivan et al., 1995). It has shown to be sensitive to change in chronic pain population (Wittink et al., 2004). A global score of health-related quality of life was calculated by taking the mean of the eight constructs mentioned above (Bronfort and Bouter, 1999). In this report, only the global score will be used in the analyses.

Health-care utilisation was obtained by asking subjects to record on a questionnaire if during the past 3 or 6 months they had visited a doctor, physiotherapist, the social services, practitioners of complementary medicine, or if they had participated in a rehabilitation programme (defined only by the duration of the programme—at least 4 h/day during at least

4 days/week). Response alternatives were yes or no. No attempt was made to assess the number of visits, since our main focus was to assess if any health-care was utilised. During the first two quarters post-intervention the questionnaire was administered every third month, and after that it was posted every sixth month.

2.5. Economic aspects of rehabilitation

From a firm perspective rehabilitation should be considered as an investment, and firm productivity and profit is assumed to increase as a result of rehabilitation activities. The firm specific effects of rehabilitation should be seen as long-term improvements on firm performance, or activities in order to maintain performance.

An investment in health may change the likelihood that an individual can achieve personal goals, for example working and doing hobbies. The individual as an investor in health has been suggested in the health economic literature by Grossman (1972) and Muurinen (1982). Rehabilitation may or may not increase possibilities to work, but it has a positive effect on other aspects of living. From society's point of view, we have to consider effects on firm performances as well as changes in living for the individual. Costs for society due to individuals being unable to work can be calculated as the value of production losses. It should be noted that hardly anyone returns to work after being granted a disability pension in Sweden (RFV, 2003b).

The relative benefit for society is analysed by calculating the total cost for each programme and comparing costs between the intervention groups and the control group. The total cost includes in this case loss of production, in terms of indirect cost of disability pension granted during the follow-up period post-intervention and cost of changes in days on sick leave, based on sick leave the year before compared to the years post-intervention, and the direct cost of the intervention programmes. Direct costs are health-care costs (Korthals-de Bos, 2002), based on the cost of the actual rehabilitation intervention and treatment that the patient underwent in the study, including follow-up sessions during the year post-treatment.

In the evaluation of production losses the Human Capital Approach (HCA) (Gold et al., 1996) was applied. In the cost-effectiveness analysis two of the three outcome parameters, sick leave and retirement, are included into the cost analysis by using their monetary values calculated as production losses.

2.5.1. Basic assumptions underlying the economic analysis

(1) The average cost of work absenteeism is estimated to be 26,422 € per year (Aronsson and Malmquist, 2002), which constitutes the amount that each employee has to produce in order to cover a cost of a minimum monthly salary of about 1211–1321 € per month with overall costs and indirect taxes. (2) The costs are calculated using the year 1995 tariffs. Exchange rate used was 1 €=9.08 Skr. (3) All subjects are working full-time with no subsidies. (4) Full-time work is approximately 220 working days per year. (5) All subjects granted disability pension would have been working until the age of 65. (6) All subjects will live to at least 65 years of age.

2.6. Procedure

Data for the pre-treatment assessment were gathered during the medical and functional examination, 1–2 weeks prior to rehabilitation.

During follow-ups, the questionnaires were mailed to the participants.

2.7. Attrition rates

2.7.1. Intention to treat (ITT)

The data obtained from the NSIB on sick-listing and early retirement was complete for all individuals. At the 3-year follow-up, the overall non-response rate for the questionnaires was 26% and per condition 25% (BM), 7% (PT), 28% (CBT), and 42% (CG).

2.7.2. Per protocol (PP)

Twenty eight participants dropped out of treatment (Fig. 1). These proportions did not differ significantly between treatments and were not expected to bias the results ($X^2=2.6$; d$f=2$; $P=0.28$). The main dropout happened between the randomisation and the start of the treatment. At the 3-year follow-up, the overall non-response rate in the PP group was 24% and per condition 22% (BM), 8% (PT), 24% (CBT), and 42% (CG).

An analysis of the 49 non-respondents (ITT) at the 3-year follow-up revealed that six subjects had died (5 men, 1 woman) during the follow-up period (PP 5 subjects). The only statistically significant differences found between non-responders and responders were that men responded to a lower degree compared with women. The non-response rate for men ranged between 14% (BSG) and 50% (CG).

2.8. Statistical analyses

Analysis of co-variance (ANCOVA) using a mixed model approach, Cox regression, and logistic regression was employed to evaluate effects of treatment on absence from work, full-time early retirement, and the SF-36 global score at the 3-year follow-up. Absence from work was analysed in three ways: (1) total absence from work over the whole follow-up period (ANCOVA); (2) a semi-parametric model using Cox regression for time from the start of treatment until the end of absence from work during the 3-year follow-up period. In the Cox model, we were less sensitive to the skew nature of the time variable and were able to make allowance for censored observations in a more optimal way, i.e. persons who were still absent from work at the end of the follow-up period. The control group was used as reference and; (3) the risk of being withdrawn from the work force completely due to full-time early retirement during the follow-up period (logistic regression). Data on sick leave during the quarter before treatment were used as a covariate in all the analyses of absence from work.

For the SF-36, analysis was made by using the global score of health-related quality of life as outcome variable. This was chosen in order to minimise the risk of 'type I error' due to multiple comparisons and spurious significances. Data from pre-treatment, post-treatment and the 3-year follow-up were analysed by applying ANCOVA with a repeated-measures design. The pre-treatment values of the outcome variables were used as covariates in the analyses.

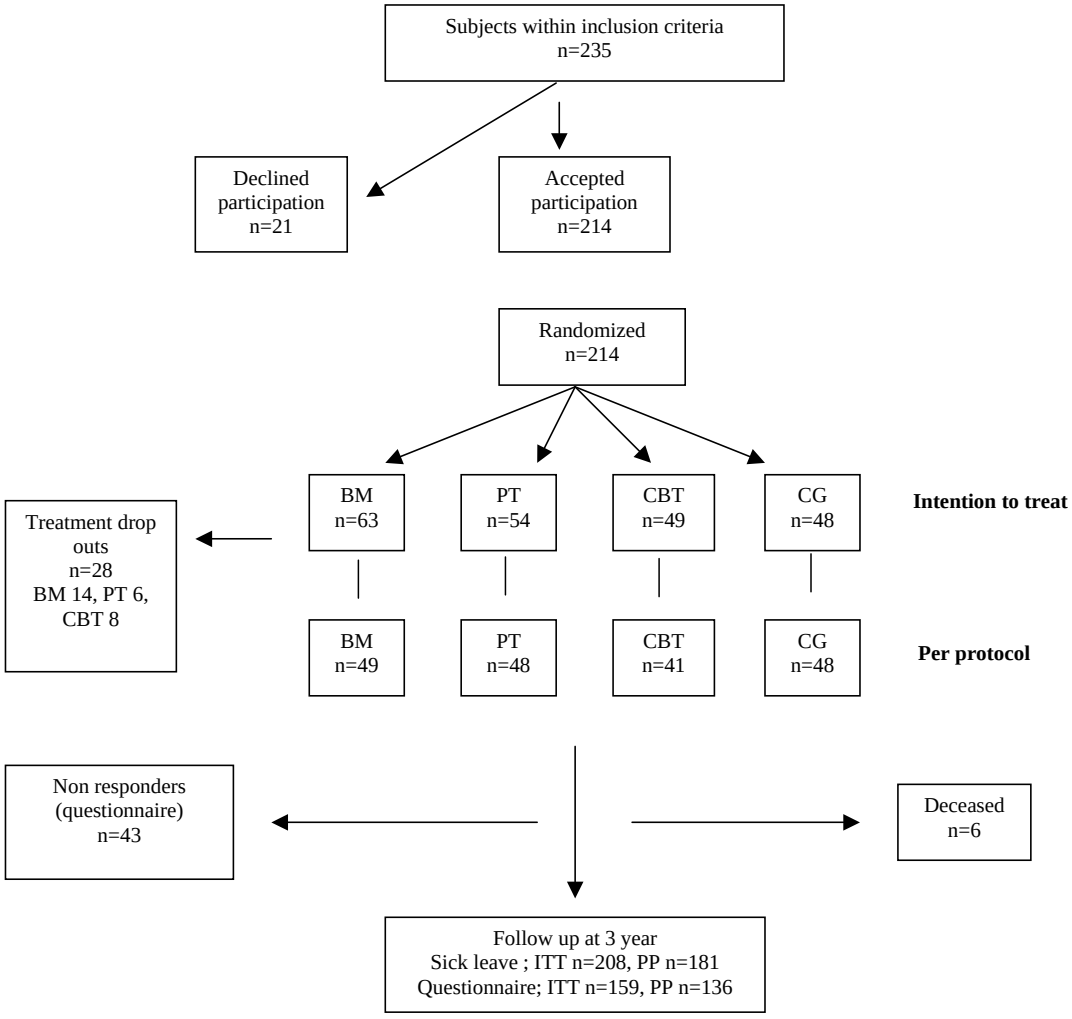

Fig. 1. Patient flow chart. Inclusion and reasons for exclusions and drop out.

Health-care utilisation was calculated as the number of reported 'yes' responses during five time points. It may be that the same individual has responded 'yes' on, e.g. 'visit to a physician' at every assessment point, so the proportions do not reflect the number of subjects in the group but rather the number of visits made, regardless of whom in the group actually made them. χ^2 analysis was used to analyse differences between groups.

Cost-effectiveness analysis of two of the three outcome parameters, sick leave and retirement, are included into the cost analysis by using their monetary values. If the cost-effectiveness analyses reveal results where it is not clearly evident which interventions should be preferred, according to the Briggs and Fenn (1998) model of cost-effectiveness plan an incremental cost-effectiveness ratio is calculated with a confidence interval calculation using the bias corrected percentile method (Polsky et al., 1997).

In all analyses, a significance level of 5% was considered as statistical evidence of effect ($P=0.05$, confidence level = 95%).

For a power of 80% (5% significance level) we needed approximately 40 subjects in each of the four study groups ($n=160$). The initial design of the study called for a gender-differentiated analysis (Jensen et al., 2001). To obtain a gender-differentiated analysis this doubled the size of the study population ($n=320$) needed to obtain a power of 80%. Thus, our aim to conduct a gender-differentiated analysis with a power of 80% could not be achieved in this study.

3. Results

Figures from PP and ITT analyses will be presented. Gender will be analysed and reported separately.

3.1. Absence from work

As mentioned, data on all subjects were obtained in the analyses of sick leave and disability pension ($n=208$). Among females, the mean total absence from work post-intervention expressed in days was 439 (SD, 329) in the BM group, 522 (SD, 386) in the PT group, 542 (SD, 446) in the CBT group and 572 (SD, 424) in the control group.

Among males the mean total absence from work expressed in days was 494 (SD, 375) in the BM group, 541 (SD, 446) in the PT group, 629 (SD, 379) in the CBT

Table 2
Total absences (days on sick leave or disability pension) and health-related quality of life

	Per protocol				Intention to treat			
	Total absences during follow up,[a] mean (CI) ($n=181$)		SF-36 Global scale,[b] mean (CI) ($n=136$)		Total absences during follow up,[a] mean (CI) ($n=208$)		SF-36 Global scale,[b] mean (CI) ($n=159$)	
	Females	Males	Females	Males	Females	Males	Females	Males
BM	−201.3* (−403.9;1.3)	−136.7 (−374.5;101.1)	8.8* (1.9;15.7)		−134.2 (−327.5;59.1)	−65.1 (−290.3;160.2)	7.3* (0.6–14.0)	
PT	−57.1 (−246.5;132.3)	25.5 (−52.3;303.2)	2.4 (−4.2;9.0)		−39.9 (−225.4;145.6)	−12.6 (−273.2;247.9)	2.6 (−4.0–9.1)	
CBT	−1.5 (−222.2;219.5)	55.6 (−185.1;296.2)	5.5 (−2.1;13.1)		−53.3 (−263.9;157.2)	105.6 (−124.9;336.1)	7 (−0.3–14.3)	
CG	0	0	0		0	0	0	

Mean difference with 95% confidence interval (CI) between each treatment compared to the control group at 3-year follow-up. Due to low response rate in the control group no statistical testing was made on SF-36. Absence was collected from national register data and thus obtained on all subjects. *$P \leq 0.05$.
[a] Negative values shown are interpreted as an improvement compared to the control group.
[b] Positive values shown are interpreted as an improvement compared to the control group.

group and 479 (SD, 408) in the control group. The parameter estimates from the ANCOVA analysis for differences in total days of absence from work (sick leave + disability pension) over 3-years are given in Table 2. In the PP analysis, a significant difference was found in favour of the females in the BM group. No significant differences were found in ITT analysis.

Cox regression was used to analyse the return to work rate during the 3-year follow-up period. Fig. 2 show the proportion still on sick leave in the PP analyses for the BM and Control treatment. In the ITT analyses, the proportions were similar. The results showed that women in the BM condition returned to work faster compared to the CG. A significantly faster rate of return to work was found in the Per Protocol analyses ($P=0.05$, hazard ratio 1.9, 95% CI 1.1–3.5)). No significant result was found for men. The results for PT and CBT were intermediate between the BM and Control groups.

The risk of being granted full-time early retirement during the follow-up period was evaluated by logistic regression. The control group constituted the reference category. No significant differences were found between the groups, either in the PP or the ITT analyses (Table 3).

3.2. Health-related quality of life

No statistical testing on the SF-36 was performed on the male sample due to the low response rate (control group 50% non-responders). A moderate to strong effect size (Cohen et al., 1996) was found in the female group participating in the BM programme (ITT = 0.74, PP = 0.79).After adjustment for multiple comparisons (Bonferroni) the PP analyses showed that women in the BM-group reported significantly better health than women in the control group (Table 2). No differences were found in the ITT analyses.

3.3. Health-care utilisation

The proportions of health-care utilisation reported during the 3-year follow-up are as follows: rehabilitation programme BM 6%, PT 7%, CBT 8%, CG 4%; Physician BM 27%, PT 34%, CBT 35%, CG 31%; Physiotherapist BM 29%, PT 37%, CBT 43%, CG 37%; Emergency ward BM 4%, PT 3%, CBT 4%, CG 3%; Social services BM 8%, PT 9%, CBT 7%, CG 3%; complementary medicine BM 13%, PT 17%, CBT 11%, CG 11%.

The results show few significant differences between groups in health-care utilisation. The BM group consulted physiotherapists less than the others ($P=0.05$), and the control group consulted the social services less often than the subjects in the intervention programmes ($P=0.05$).

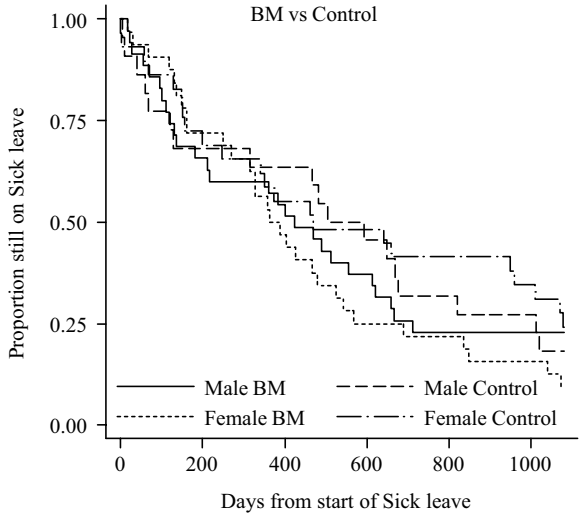

Fig. 2. The proportion of subjects still on sick leave, BM treatment versus Control Treatment. Per protocol analysis. A significantly faster rate of return to work was found in the behavioural medicine group compared to the control group but only for females ($P=0.05$, hazard ratio 1.9, 95% CI 1.1–3.5). Males had no significant difference.

Table 3
Data on early retirement at 3-year follow-up

	Per protocol				Intention to treat			
	Full-time early retirement n (%)		OR (CI)		Full-time early retirement n (%)		OR (CI)	
	Females	Males	Females	Males	Females	Males	Females	Males
BM	5 (20)	6 (25)	0.3 (0.1–1.1)	0.7 (0.2–2.6)	9 (30)	10 (31)	0.6 (0.2–1.7)	0.9 (0.3–3.1)
PT	11 (33)	5 (38)	0.7 (0.2–1.9)	1.3 (0.3–5.5)	12 (33)	5 (31)	0.7 (0.2–1.9)	0.9 (0.2–3.8)
CBT	5 (26)	7 (33)	0.5 (0.1–1.7)	1.0 (0.3–3.8)	5 (23)	7 (27)	0.4 (0.1–1.4)	0.7 (0.2–2.7)
CG	12 (43)	6 (33)			12 (43)	6 (33)		

Odds Ratio (OR) with 95% confidence interval (CI). Estimation with logistic regression model. No significant differences between groups in the intention to treat analyses. The differences between BM and CG in the per protocol analyses of early retirement in females approach significance ($P=0.081$).

4. Cost-effectiveness

In the economic part of this study, the focus is on costs and differences in costs between different intervention programmes (BM, PT and CBT).

4.1. Intervention costs

Intervention costs were calculated based on the standardised written rehabilitation programme used in this study. Each intervention group consisted of on average 6 patients. The cost for each professional category was calculated based on existing tariffs (incl taxes). The cost in Euro per hour was for physician 138, PT 55, psychologist 11, fitness trainer 55 and secretary 41. The total cost per patient and program was for BM 1862 €, PT 1000 € and the CBT 1179 €. Per protocol analyses was applied in the economic analyses.

4.2. Disability pension

From information on the subject's date of birth (year-month-day) and date when disability pension was granted in relation to the statutory retirement age in Sweden (65 years), a calculation of production years lost was made for each individual on disability pension and for each study group. By assuming that everyone who has been granted disability pension is of the same age as the total study sample (42.8) an age-adjusted calculation of production years lost can be made. This was done to control for differences in mean–age between conditions. Cost per subject is calculated by multiplying total years lost per subject with annual costs for production losses (26,422 €). Mean years lost and cost for females were BM 4.44 years and 117,314 €, PT 7.40 years and 195,523 €, CBT 5.84 year and 154,360 €, CG 9.51 year and 251,386 €. Mean years lost and cost for males were BM 5.55 years and 146,642 €, PT 8.54 years and 225,603 €, CBT 7.40 year and 195,523 €, CG 7.40 year and 195,523.

The result reveals that the most effective programme, the BM programme, decreased costs for disability pensions by about 134,072 € per woman compared to the control group, and for men the BM programme reduced costs by 48,881 €.

4.3. Sick leave

To calculate production losses due to sick leave a recalculation was made to include only working days (5 working days/week on average). With 220 working days per year the average cost per day will be about 120 € (26,422 € per year). The annual cost for sick leave 1-year pre-intervention, and per year post-intervention, is shown in Table 4. In 3-years post-intervention, the mean cost for sick leave per subject has decreased by 18,489 € for males (3×6163) and by 11,473 € for females in the BM programme. In the PT and the control group, the decrease is of a lesser magnitude for both males and females. For the CBT programmes, the cost increased post-intervention.

Table 4
Cost for sick leave per subject 1-year pre-intervention and mean cost per year post-intervention

	Working days lost per year post-intervention		Sick leave cost post-intervention per year and subject (€)		Working days lost per year pre-intervention		Sick leave cost 1 year pre-intervention per subject (€)		Incremental cost per year and subject post-intervention (€)	
	Females	Males	Females	Males	Females	Males	Females	Males	Females	Males
BM	67	72	8074	8583	99	123	11,898	14,746	−3824	−6163
PT	76	92	9098	11,040	95	110	11,352	13,152	−2254	−2112
CBT	115	109	13,750	13,114	108	101	12,996	12,073	754	1041
CG	65	80	7804	9583	82	86	9863	10,345	−2058	−761

Calculations of cost are made on mean working days lost per year due to sick leave. Per protocol $n=181$. Note that the figures above are based on sick leave only, not total absences (sick leave and disability pension) as used earlier in the ANCOVA analysis of effects on absences from work.

Table 5
Total cost per subject in Euros for intervention, sick leave, and pension[a] for 3-year period

Group	Total cost per subject	
	Females	Males
BM	107,703	130,015
PT	189,760	220,268
CBT	157,800	199,824
CG	245,212	193,239

[a] Pension counted up to 65 years.

4.4. Total cost

The total cost for society is calculated as the sum of changes in the cost of sick leave during the 3-year period and costs for granted disability pension; finally, intervention costs are added. This is done in order to obtain an overall cost, since a decrease in sick leave can be due to disability pension instead of return to work. The total cost is shown in Table 5. As shown above, the 'usual care' control group and the different intervention groups had similar health-care utilisation post-intervention and, therefore, the estimated costs should be about equal. Thus, no calculation of those costs has been conducted, but the assumption is that the relative costs between groups are not affected.

The results reveal that compared to the control group the full-time programme (BM) is the most cost-effective programme, since it decreased the costs by about 137,509 € per subject in the female group during the first 3-years after rehabilitation. Overall for women the costs were reduced with treatment, the least reduction being in PT (54,452 €). However, caution is needed when interpreting the results. The only significant difference established regarding change in sick leave was in the female BM group, and difference in disability pension approached significance in the same group.

5. Discussion

The result of this study shows that a full-time behavioural medicine programme is effective in increasing health and decreasing costs for women suffering from spinal pain. Further, we could not show that rehabilitation efforts of the type evaluated in this study is cost-effective for men. Only the per-protocol results were statistically significant, but the intention to treat results revealed a consistent trend supporting the per protocol results. The wide confidence interval in the analyses of sick leave and health-related quality of life indicates a low statistical power, which increases the risk of type II errors. This study suffers from a small study sample and thus a lack of power due to difficulties in collecting enough subjects during the time limits set on financial grounds. The strength of the study is that for absences from work (sick leave and disability pensions) and the economic analysis, data were available on all subjects, thus increasing the power. Results are, furthermore, so consistent that, even though there are few significant findings in the intention to treat analysis, conclusions can be drawn.

Our economic calculations reveal that an investment in an effective measure reduces production losses considerably. Production losses are an important factor that affects growth negatively. The result of the cost-effectiveness analysis is based on some fundamental assumptions. The annual cost for production losses per subject is set to a minimum wage level with the purpose of minimising the risk of overestimating the cost and revenues. The approach of Goossens (1999) to include time spent by spouses and friends in helping the patient manage daily life, i.e. household work, has not been applied in this study. The net cost of this type of activity is the same regardless of who is performing it: the patient or the spouse. If, for example, the patient is relieved from cleaning the house he/she might be able to engage in a productive life to a greater extent and thus produce more. At the same time, the spouse might be less able to engage in productive life due to more time spent at home. Thus, the costs will balance each other and will not affect the relative costs/benefits. Yet there is a need to further investigate the incentives of the firm and economic effects of health, measured both on the individual and the firm levels (Färe and Grosskopf, 2003). By presenting good examples, more firms could be influenced to invest more or differently in the health of their employees.

One question that needs to be studied further is why women benefit from rehabilitation and not men? Rehabilitating women has a substantial impact on costs for society, whereas rehabilitating men seems to be effortless or even costly, with no effect on either health or the economy. Therefore, it is of vital importance to ask what was lacking or what can be improved in the rehabilitation programmes studied with regard to their ability to facilitate return to work among the men. From the descriptive information revealed in Table 1, it is evident that there are no major differences between men and women with regard to the demographic, psychosocial and biomedical variables assessed. But factors beyond the demographics such as adherence to treatment plans, coping ability or psychosocial factors at work may influence the effect of treatment (Grossi et al., 1999; Jensen et al., 1994a,b; Keefe et al., 2000). Adherence to treatment plans was reported at the 18 months follow-up (Jensen et al., 2001). The results revealed that compared to men females in the behavioural medicine group had a higher degree of compliance with lifestyle changes post-treatment. In a cognitive behavioural perspective a higher compliance rate is associated with favourable outcome. Thus, this may be one explanation of the less favourable outcome in the male group. Coping strategies have been shown to differ between the genders and to be of importance in the development of the pain problem (Grossi et al., 2000; Jensen et al., 1994a; Nachemson

and Jonsson, 2000). Psychosocial factors at work and in private life have been shown to be of importance and may even be stronger than biomedical ones in preventing long-term dysfunction and sick leave (Hoogendoorn et al., 2000; Kivimaki et al., 1997, 2001; Linton, 2002; Main and Spanswick, 2000; Main et al., 2000; SBU, 2003; Voss, 2002). All these factors may have influenced the results on men and women differently.

An observation from our clinical work is that men are less prone to stay on sick leave part-time. Data from the National Health Service lend support to this, showing a difference of on average 9% in proportion of men and women on part-time sick leave (RFV, 2003a). The reluctance to be at work only part-time could lead to men preferring to either stay on full-time sick leave or seek full-time disability pension.

The hypothesis that the BM programme would be consistently superior to the PT and CBT conditions in comparison with the control group was supported among females. The non-significant effects in the part-time programmes generate several hypotheses. The time factor could have influenced the results in the full-time behavioural medicine programme positively. Since participants spend 6–9 h a day together, this may create a positive group climate which functions as a support during the intervention and afterwards. However, some studies refute that hypothesis and instead point to the content and timing of treatment as crucial factors (Kivimaki et al., 1997; Linton et al., 1993, 1997).

During recent decades the concepts of 'fear of pain' and 'fear of movements' have evolved, and evidence of the existence and effects of interventions directed towards those behaviours have been shown (Vlaeyen and Linton, 2000). Our hypothesis about the full-time programme being superior was based on the assumption that by combining the cognitive behavioural intervention with a physical intervention, the patient would be able to practise behaviours aiming to increase activity and eliminate fear of pain and movement at the clinic. Our results support this hypothesis and evidence of multidisciplinary rehabilitation programmes for back pain with a cognitive behavioural approach is comprehensive (Bergström and Jensen, 2002; Karjalainen et al., 2001, 2003b; Nachemson and Jonsson, 2000; Schonstein et al., 2003),

Why the cognitive behavioural intervention alone compared to the 'treatment-as-usual' group is non-effective and maybe even produces an increase in sick leave and disability pensions is puzzling and is a question that remains to be answered. One hypothesis is that the patients' expectations (which were lowest in the cognitive behavioural group) (Jensen et al., 2001) have influenced the outcome negatively (Kalauokalani et al., 2001). In the combined behavioural medicine programme, a much more comprehensive basis for understanding the complex system working in the development of back pain and dysfunction is present by merely combining the skills of the different professionals involved.

The diagnosis on the sick leave certificate was not of major concern in this study. It has been shown in other studies that irrespective of the primary diagnosis the cause on the certificate varies over time (Bauer et al., 2003; Nathell, 2002; SBU, 2003). Consequently, the aim in this study was to assess the effect on sick leave overall, independent of the cause on the certificate. When using sick leave as an outcome measure it is also essential to include disability pension, since it is only people who are working (or unemployed) that can be on sick leave. Thus, a spurious effect can be established as a decrease in sick leave when it is only due to an increase in individuals receiving disability pension.

The participants in this study were gathered from a well-defined source population, the AGS insurance scheme. This means that the results can be generalised to a majority of employed individuals in Sweden (blue-collar and service/care sector) suffering from similar problems involving long-term, non-specific spinal pain. In conclusion, a full-time behavioural medicine programme is a cost-effective method for improving health and increasing return to work in women working in blue-collar or service/care occupations suffering from spinal pain.

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