Different outcomes in subgroups of patients with long-term musculoskeletal pain

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ABSTRACT

Former studies have questioned the effectiveness of multidisciplinary rehabilitation for working-age adults with musculoskeletal pain problems. The lack of analysis within subgroups may explain why an effect of treatment of long-term musculoskeletal pain was not documented in former studies. In this article three later studies on long-term musculoskeletal pain patients are presented. The challenge of these studies was to identify subgroups of patients who benefit from different types of treatments. This article present the main findings of a large RCT with up till 54 months of follow-up among 664 persons sicklisted for musculoskeletal pain. It was hypothesised that different categories of patients need different treatment programs in order to get back to work. Patients with different prognoses for return to work were identified by means of a screening instrument, and it was tested whether those with poor prognosis need more extensive multidisciplinary treatment, compared to patients with less psychosocial and physical problems. Also, the effect of different treatment programs among patients with different diagnoses (ICD-9, low back pain and chronic widespread pain) and among men and women was examined. The results of the three studies support the authors' hypothesis that different categories of patients need different treatment programs. A higher percentage of return to work was demonstrated when the right treatment was given to the right patient, and considerable cost effectiveness was demonstrated.

INTRODUCTION

Musculoskeletal pain is a major cause of morbidity, disability, and economic loss (Nachemson 1992, Brage et al. 1998). Patients with musculoskeletal pain are a heterogeneous group. Cognitive-behavioural treatments are effective concerning pain experience, pain behaviour, cognitive coping and appraisal (Morley et al. 1999, van Tulder et al. 2001). Exercise therapy and manual therapy combined with exercises have shown effect in low back pain (LBP) patients on function and pain (Torstensen et al. 1998, Moseley 2002, Niemistö et al. 2003). However, randomised control trials have often failed to demonstrate significant effects of treatment on return to work for patients on long-term sickleave with musculoskeletal pain (Alaranta et al. 1994, Haldorsen et al. 1998). Problems of identifying effective treatments for musculoskeletal pain may be aggravated by the fact that health and economic evaluation studies include patients with very different prognoses to return to work. It is for example reasonable to expect that extensive treatment has little importance to patients with good prognoses of returning to work, therefore classifying patients seems reasonable. In a former extensive Norwegian randomised controlled study on a heterogeneous group of long-term musculo-

skeletal pain patients, where an extensive multidisciplinary cognitive behavioural treatment program was compared to treatment-as-usual, no significant effect on return to work was shown (Haldorsen et al. 1998). The lack of analysis within subgroups may explain why an effect of treatment of long-term musculoskeletal pain was not documented.

In this article we will present *three* later studies (Haldorsen et al. 2002, Skouen et al. 2002, Skouen et al. 2006) on long-term musculoskeletal pain patients from the same area of Norway, as in the study of Haldorsen and co-workers (1998). Based on the experience from this former study it was hypothesised that patients with a high degree of psychosocial and physical problems have a poorer prognosis and need more extensive treatment and that patients with good prognosis may not need any special treatment. The challenge of these studies was to identify subgroups of patients who benefit from different types of treatments.

Design

The three studies were part of a randomised controlled trial that took place in Bergen, Norway, between January 1996 and March 1997. The participants were recruited from the sickness insurance records of the municipality of Bergen and five surrounding munici-

palities. Inclusion criteria were holding a permanent job and being sick-listed more than 50% the last eight weeks, or having been sick-listed at least two month per year for the last two years for musculoskeletal pain. The medical exclusion criteria were active rheumatologic disease, progressive neurological disease, serious cardiac or other internal medical condition, or decreased lung capacity, cancer, acute traumas, infections, acute vascular catastrophes, or pregnancy.

A total of 1988 sick-listed employees were invited to participate, 813 accepted the invitation by signing a consent form, 510 wrote back explaining that they did not wish to be considered for the program and 665 did not respond to the invitation. Further, 97 patients dropped out before randomisation and 52 patients were excluded before randomisation for medical and administrative reasons. Finally, 10 patients who assigned to receive one of the two clinical treatments withdrew from the study before treatment was completed. Due to different classification systems 10 patients could not be accounted for in Study I. The final experimental sample included 654 patients for Study I, and 664 for Study II and III (Figure 1). For each group of 60 patients of the total of 664, 25 were randomly assigned to treatment-as-usual, 20 to a light multidisciplinary treatment program and 15 to an extensive program (block randomisation due to limited capacity at the clinic). Follow-up information on sick-leave status was available from the National Insurance Scheme Registry from the first 56 months after enrolment, corresponding to 54 months after treatment (in average 2 months went from invitation until end of treatment).

Multidisciplinary treatment

At the Outpatient Spine Clinic, Haukeland University Hospital in Bergen, Norway, patients were offered a light or extensive multidisciplinary program.

The light program: In the light program the patients were given a 1-hour lecture about topics such as exercise, lifestyle and fear-avoidance advice. After this session the patients were given individual information and feedback by the team. The patients were encouraged to gradually improve their activity level even if the pain got worse. Great emphasis was put on the effort to reduce fear and uncertainties about musculoskeletal pain and avoid sickness behaviour (Vlaeyen and Linton 2000, Waddell 2004). Some patients were referred to external physiotherapists and psychologists. All patients were followed up to one year with individual pain management given by the team members and occasional work place interventions. On an average, each patient received three individual follow-ups as required by one of the team members. The follow-ups could be related to further help in performing their exercise program, or it could be for medical or psychosocial support. In addition all patients were offered individual appointments with the team at 3, 6 and 10 months.

The extensive program: This program lasted for four weeks with 6-hour sessions 5 days per week. The program included cognitive behavioural modification, education, exercises and occasional work place interventions. Cognitive behavioural modification was given in group sessions (2-h sessions per week). The education sessions involved different topics such as anatomy, pain, physical and mental coping strategies, work, and lifestyle. The lectures were followed by small group sessions where the patients discussed the issues raised in class. The physical exercise program was to a large extent based on body awareness strategies (Bunkan and Thornquist 1990, Kvåle and Ljunggren 2006), although increase of physical endurance was also emphasised. At the end of the four week program, the patients developed their own rehabilitation plan and they were followed up to one year with individual pain management given by different team members as required. Patients in the treatment group received the same follow-ups as patients in the light multidisciplinary program. The control group received treatment as usual in general practise.
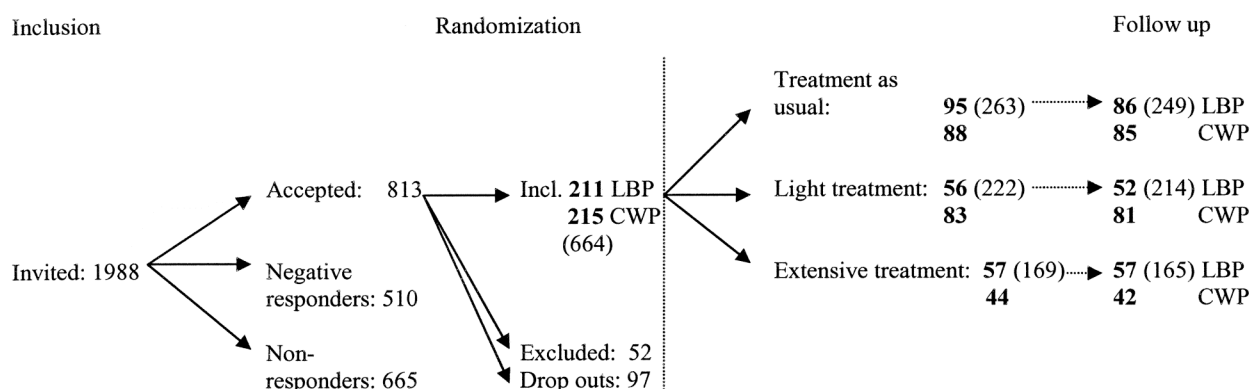

Figure 1. Flow of participants in Study I, II and III. Patients with low back pain (LBP) and chronic widespread pain (CWP) are highlighted (total number of participants in parentheses).

Ethics

All participants were thoroughly informed by personal instruction and a written consent was then obtained prior to inclusion. The regional ethic committee accepted the study and it was performed according to the Helsinki declaration. The project was endorsed by the Norwegian Data Inspectorate.

STUDY I

Based on the experience from former studies on the same patient group, the underlying hypothesis was that patients with a high degree of psychosocial and physical problems have a poor prognosis and need more extensive treatment and that patients with good prognosis may not need any special treatment (Haldorsen et al. 2002).

The aims of study I were:

- To develop a screening instrument that could differentiate between musculoskeletal patients with good, medium and poor prognoses for return to work.
- Is there a right treatment for a particular patient group?
- Does right treatment for a particular patient group yield positive net returns for the society?

Material and methods

A screening instrument vas developed and based on previous prognostic studies by Haldorsen and co-workers (1998a,b,c), and consisted of one part with 15 questions related to psychosocial and motivational factors, which the patient filled in before coming to the first visit to the clinic. The other part of the screening instrument consisted of four standardised physiotherapy examinations performed at the first visit: 1) Examination of movement: seven separate movement tests examining flexibility and ability to relax, taken from the Global Physiotherapeutic Examination (Sundsvold et al. 1982, Kvåle et al. 2003); 2) Presence and number of 18 tender points, using the American College of Rheumatology test procedure for fibromyalgia (Wolfe et al. 1990); 3) The Sock Test, which reflects a functional ability in sitting (Strand and Wie 1999); 4) Performance on a lifting test, called PILE (progressive isoinertial lifting evaluation) (Mayer et al. 1998, 1990). The final score for return to work was based on both parts of the screening instrument, each part counting equally. Patients with good prognoses were given score 1, medium prognoses score 2 and poor prognoses score 3. The final scoring of the forms was left to the medical doctors who also diagnosed and classified the patients after a physical examination. After the screening and physical examination, randomisation was performed by means of a sequence of pre-label cards contained in sealed envelopes. The 654 patients were randomised to either treatment-as-usual initiated by the general practitioner (n=263; 97 men,

166 females; mean age 44, SD 10.9), to light multidisciplinary treatment (n=222; 72 men, 150 females; mean age 43, SD 10.3) or to extensive multidisciplinary treatment (n=169; 53 men, 116 females; mean age 43, SD 10.5).

Outcome measures

In the study we used full return to work as outcome measure. Study I is based upon follow-up data for the first 14 months after testing. Follow-up data were collected from the National Health Insurance Register. Absence of sick pay or related benefits in a given month was interpreted as having returned to work. The economic benefits were calculated by the costs of treating patients with the light multidisciplinary program or with the extensive multidisciplinary treatment instead of treatment-as-usual by a standard cost-benefit formula (Haveman et al. 1984, Berkowitz 1988, Risa 1997).

Statistics

The data were analysed according to intention-to-treat principals. Significant differences between groups were evaluated by analyses of variance (ANOVA) with Bonferroni correction for overall error rate, and with chi-square tests. Return to work data was not available for government employed workers, therefore return to work data was based on 654 minus 27 patients.

Results of study I

The screening instrument differentiated between patients with different prognoses for return to work, independent of the type of treatment. Among patients classified to have poor prognoses only 44% returned to work after 14 months, compared to 61% among patients with good prognoses (X^2=8.5, d.f.=1, p>0.004), and 57% among patients with medium prognosis (X^2=7.6, d.f.=1, p>0.006).

Extensive multidisciplinary treatment for patients with good prognosis did not result in higher return to work rate than treatment-as-usual. Most patients returned to work if they were given treatment that corresponded with their screening category. Between 55 and 64% of the patients in the different prognostic categories had returned to work after 14 months when given what was assumed to be the right treatment. Among patients classified to have poor prognoses (n=178), those who received extensive multidisciplinary treatment returned more often to work compared to patients who had light multidisciplinary treatment or treatment-as-usual (Figure 2). Gender and age influenced the prognostic score, and return to work. Women were classified to have a more moderate or poor prognosis, as compared to men. Older patients with poor prognoses returned less to work compared to younger patients with poor prognoses.

Cost-benefit analysis of the economic returns showed that if treatment was given according to the prognostic category, productivity gains would have amounted to NoK 7,332,278. When subtracting costs, the net social value for the first 14 months was NoK 1,875,100.

Discussion of study I

When one extensive multidisciplinary treatment program was compared with treatment-as-usual in a heterogeneous group of patients with long-term musculoskeletal pain, no effects on return to work rate was found (Haldorsen et al. 1998). On the other hand, this multidisciplinary cognitive behavioural treatment model resulted in better physical and psychological health than treatment-as-usual. When the same category of patients were subgrouped according to a screening battery dividing patients into poor, medium and good prognoses and the treatment programs were differentiated into extensive multidisciplinary treatment and light multidisciplinary treatment, positive results were found concerning return to work (Haldorsen et al. 2002). Patients with poor prognoses who had been randomised to extensive multidisciplinary treatment, returned fully back to work significantly more often than patients with poor prognoses that had been randomised to treatment-as-usual. Patients with good prognoses who were randomised to either of the two multidisciplinary treatment programs, did not return more often to work compared to the treatment-as-usual group.

The screening instrument with its combination of psychosocial questions and physical tests seems to be a useful way to classify patient into subgroups, and with the use of this instrument different treatment outcome could be demonstrated in percentage of return to work in the different groups. The questions have been validated in former prognostic studies by Haldorsen and co-workers (1998a,b,c). The physical tests consist of four different types of physiotherapy examinations that seem suitable for a wide range of musculoskeletal problems. The different tests have individually been tested for reliability and validity (Sundsvold et al. 1982, Wolfe et al. 1990, Strand and Wie 1999, Mayer et al. 1998, 1990, Kvåle et al. 2003). When the right patient gets appropriate treatment, large sums of money can be saved.

When generalizing the results of this study, some cautions should be considered. Only 33% of those who were invited to participate entered the study (n=664). Questionnaires explaining why some did not want to participate were, however, filled in by one third of the non-participants, and work status data was available for almost all. It seemed that the non-participants responded that they were expecting to soon return to work and they also did return to work at a higher rate compared to the participants. It can be inferred that the non-participants were healthier than those who volunteered to participate. The aim of this study was to investigate whether it was possible to get an effect on return to work if treatment was given in a differentiated way, depending upon their prognosis for return to work. This was documented.
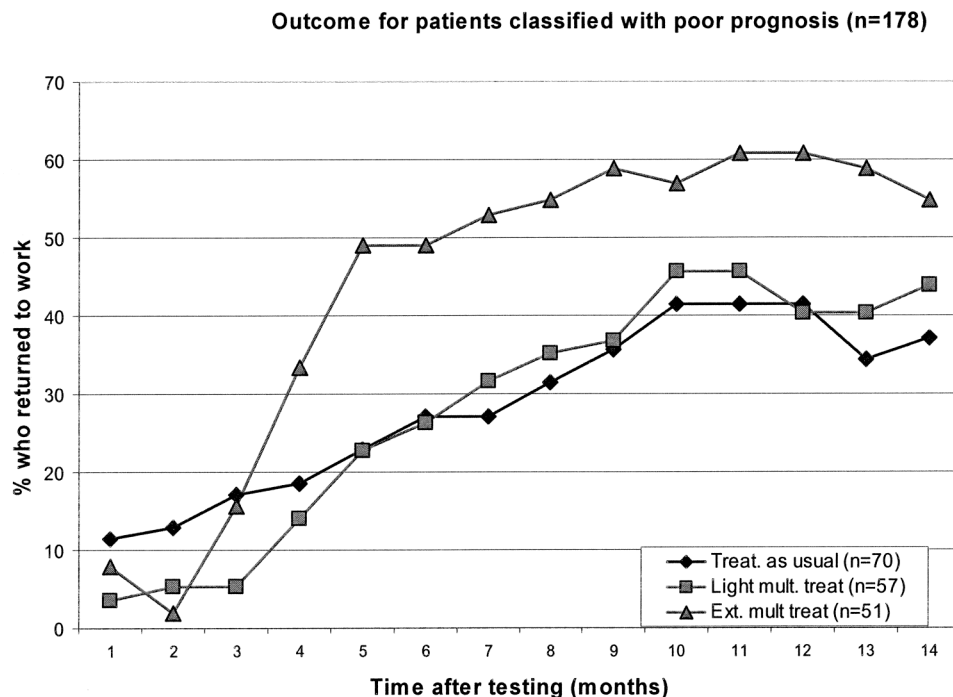

Outcome for patients classified with poor prognosis (n=178)

Figure 2. Study I: Full return to work in patients with long-term musculoskeletal pain categorised as having poor prognosis, comparing light multidisciplinary treatment, extensive multidisciplinary treatment and treatment-as-usual, 14 months after enrolment, testing and treatment.

STUDY II

The aim of study II was to compare return to work in the three treatment groups only in patients with long-term LBP.

Material and methods

Out of 664 patients, 211 were patients with LBP according to ICD-9 diagnosis (WHO 1977), (Skouen et al. 2002). Work status data was available in 195 of these patients. The LBP patients were randomised to treatment-as-usual initiated by the general practitioner (n=86; 31 men, 55 females; mean age 44, SD 11.7), light multidisciplinary treatment (n=52; 21 men, 31 females; mean age 43.7, SD 11.5) or extensive multidisciplinary treatment (n=57; 17 men, 40 females; mean age 42.9, SD 10.5) (Figure 1). The content of treatment is mentioned in the introduction.

Outcome measures

Study II is based on follow-up data with information about sick-leave status from the National Health Insurance Register for the first 26 months after the end of treatment. The zero-point is 2 months after enrolment, which is the end of the defined treatment period. As outcome variable we used the proportion of patients being back at fulltime work, recorded every month during the 26-month follow-up period. Economic returns for society from treatment at the clinic versus treatment-as-usual, were calculated using standard cost benefit formula (Haveman, 1984, Bercowitz 1988, Risa 1997).

Statistics

Significant differences between the three treatment groups were evaluated by analyses of variance comparing the mean values of number of months at work from after the end of treatment to 12, 18, and 24 months of follow-up. Least significant difference (LSD) post hoc test was used for pair-wise comparison.

Results of study II

Figure 3 show full return to work in men from 0 to 26 months after treatment. The figure illustrates that the *light* multidisciplinary treatment program increased full return to work in men compared with treatment-as-usual, and the difference between the two groups was significant at 12, 18, and 24 months after the end of treatment. Statistical analyses showed no significant treatment effect between the groups in women. No significant differences were found between the extensive multidisciplinary treatment program and treatment-as-usual, either in men or in women. Treating the 57 male patients with LBP with light multidisciplinary treatment instead of subjecting them to treatment-as-usual, yields productivity gains for the society amounting to NOK 7,858,100. When subtracting costs, the net productivity gains for society accumulated during the first two years after enrolment was NOK 7,240,900.

Discussion of study II

Men with LBP according to ICD-9 who were randomised to the light multidisciplinary treatment program,

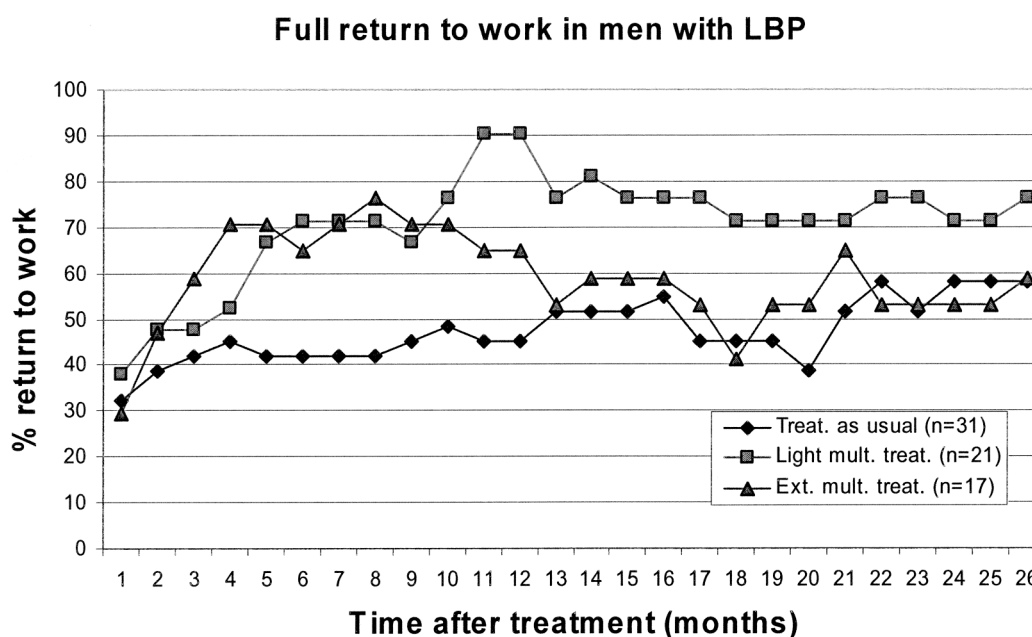**Full return to work in men with LBP**

Figure 3. Study II: Full return to work in men with low back pain (LBP), comparing light multidisciplinary treatment, extensive multidisciplinary treatment and treatment-as-usual, 26 months follow-up after treatment.

returned more often to work than men who were ran-
domised to the extensive multidisciplinary treatment
program or treatment-as-usual (Skouen et al. 2002).
When a more localized pain develops in the spine
because of an acute injury or degenerative process,
patients with LBP seem to need a simple message con-
taining coping strategies to reduce anxiety and uncer-
tainty about LBP. Men seem to be mainly concerned
about concrete practical solutions to their problem.
The positive difference in favour of the light multi-
disciplinary treatment program for men at the end of
the observation period indicates that a cost-benefit
analysis based on a longer follow-up period will yield
an even higher estimate of the economic benefits of
treatment. Interestingly, no differences between the
groups were found among women with LBP. It is pos-
sible that women do more domestic work, which can
lead to role conflict and mental and physical overload.
Again, this may have a negative impact on career
orientation and motivation concerning return to work.
This may be an explanation of why several women
returned partially, rather than fully, to work in our
study. In women, the emphasis on illness behaviour,
family situation, and job factors, such as control over
work and job satisfaction, may be important elements
in future LBP programs.

STUDY III

The aim of study III was to consider the treatment
effects only among patients with chronic widespread
pain (CWP) participating in the large randomised
controlled trial. Return to work in the three treatment
groups was compared during the first 54 months after
treatment (Skouen et al. 2006).

Material and methods

Of the 664 patients, 215 had CWP according to ICD-9
diagnoses. Work status data was available in 208 of
them. The patients had had widespread muscle pain for
at least three months and no sign of muscle and/or
joint disease. Pain was defined as widespread if
patients on a pain drawing had marked their pain as
being both above and below a horizontal line in the
thoracolumbar region (Kvåle et al. 2001). Pain in the
left and right sides of the body and above and below
the waist was not always present. Pain was present on
digital palpation in at least 11 of 18 tender points
according to the American College of Rheumatology
criteria (Wolfe 1990). Each patient was given a prog-
nosis based on the screening instrument comprising
the 15-item questionnaire related to psychosocial fac-
tors and four physical tests (Haldorsen et al. 2002). At
the end of the examination performed by a physio-
therapist and a doctor, the patients were randomised to
three different treatment groups: treatment-as-usual
(n=85; 26 men, 59 females; mean age 43.1, SD 10.7),
light multidisciplinary treatment (n=81; 25 men, 56
females; mean age 43.2, SD 10.9) or extensive multi-

disciplinary treatment ((n=42; 12 men, 30 females;
mean age 42.6, SD 11.0) (Figure 1).

Outcome measures

This study was based on following-up data including
sick leave status from the National Insurance Scheme
Register from the first 56 months after enrolment,
corresponding to 54 months after treatment. Outcome
variable was the proportion of patients who had
returned fully back to work for each month during the
follow-up period. For each calendar month after enrol-
ment it was registered whether the patients received
sickness benefits, rehabilitation benefits or disability
pension. Absence of benefits payments signifies full
return to work.

Statistics

Multiple regression analyses on the total number of
days absent from work was performed to determine the
mean effect of treatment on those treated in the
different groups, controlling for remaining random
differences in age and pre-treatment prognosis
between the treatment groups after randomization.
Reference groups for the regression model are
treatment-as-usual for the intervention groups, and
good prognosis for medium and poor prognosis. Men
and women were analysed separately.

Results of study III

Regression analyses showed that the mean effect of
extensive treatment versus treatment-as-usual for
women, on total number of days absent from work
(Table 1), was estimated to –206.95 days. Figure 4
shows that the extensive program among women was
more effective than treatment-as-usual at most time-
points up till about 40 months of follow-up. In the last
year of follow-up there is no difference in return to
work among the different treatment groups. Among
men, the light program was associated with signifi-
cantly more days absent from work, and the light
program was less effective than treatment-as-usual
during the whole follow-up period. Independent of
type of treatment, men and women with poor progno-
ses were absent from work more days compared to
those with good prognoses. In our sample, higher age
significantly increased the number of days absent from
work, but only for women.

Discussion of study III

Poor pretreatment prognosis means that patients have
problems with coping of pain, have low motivation
and low scores on physical variables, which is com-
mon for patients with chronic widespread pain (CWP)
(Andersson et al. 1996, Croft 1999). Women diagno-
sed with CWP according to ICD-9 returned more often
to work after treatment in the extensive multidiscip-
linary treatment program, compared to the treatment-

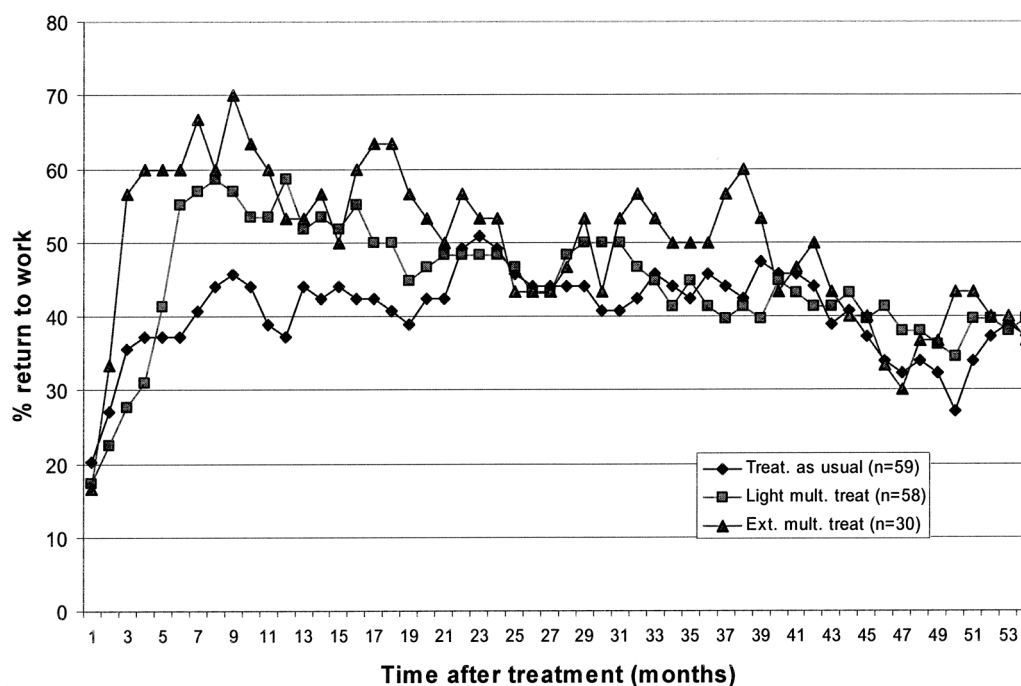**Outcome in women with CWP (n=147)**

Figure 4. Study III: Full return to work in women with chronic widespread pain (CWP), comparing light multidisciplinary treatment, extensive multidisciplinary treatment and treatment-as-usual, 54 months follow-up after treatment.

Table 1. Study III. Linear regression analysis of the effect of extensive multidisciplinary treatment and light multidisciplinary treatment versus treatment-as-usual in patients with chronic widespread pain, on total number of days absent from work controlled for differences in age and pre-treatment prognosis, 54 months of follow-up. Total compensation: number of days with sickness benefits, rehabilitation benefits or disability pension.

	Total compensation, females ($n = 145$)			Total compensation, males ($n = 63$)		
	Coefficient	Standard error	p	Coefficient	Standard error	p
Light multidisciplinary treatment	−72.54	71.41	0.31	182.47	90.60	0.05
Extensive multidisciplinary treatment	−206.95	86.29	0.02	142.71	112.06	0.21
Medium prognosis	68.72	101.98	0.50	−18.22	91.72	0.84
Poor prognosis	223.72	109.23	0.04	283.69	109.66	0.01
Age	7.98	3.17	0.01	0.55	3.34	0.87

as-usual (Skouen et al. 2006). Our experience was that women in the extensive multidisciplinary program seemed to appreciate group discussions of psychosocial problems. A key objective of the extensive treatment for the patients was to better understand muscular pain and to gain some self-control over the pain. It is important to discover through cognitive behavioural talks how environmental or personal factors exercise positive or negative influence of coping. These observations are an important basis for applying self-help strategies and stress management (Keel 1999). Men with CWP did not benefit from any of the multidisciplinary programs, and especially not the light model.

One explanation could be that men have more difficulty in recognizing the relationships between anxiety, pain coping and CWP.

Among CWP patients, higher age significantly increased the days absent from work, but only for women. It is hard to explain why higher age significantly increased the number of days absent from work only for women and not for men. One explanation could be that women with CWP are suffering more from CWP compared to men, and that this difference is more pronounced at higher age (Andersson et al. 1996, Croft 1999).

MAIN FINDINGS

Data from the latest Bergen study showed that the screening battery was an appropriate method of sub-classifying patients with long-term musculoskeletal pain. Furthermore, it has shown that it is important to offer patients with a high degree of problems extensive multidisciplinary treatment, whereas those with little psychosocial and physical problems can continue with treatment-as-usual (Haldorsen et al. 2002). The paper by Haldorsen and co-workers (1998) presented the same type of multidisciplinary treatment to different types of musculoskeletal pain problems. By sub-grouping the patients into different prognoses for return to work and at the same time offer different treatment programs, better results were achieved (Haldorsen et al. 2002). The papers from Skouen and co-workers (2002, 2006) did show that classifying patients with long-term musculoskeletal pain according to the diagnosis system ICD-9 at an outpatient spine clinic, revealed treatment effects depending on different types of treatment. It also seems clear that men and women respond differently on different kinds of multidisciplinary treatment and that the effect of treatment decrease with higher age in women with chronic widespread pain. The right treatments to the right patient depend on prognoses and diagnoses, sex and age.

Final remarks

Patients with different kinds of long term musculo-skeletal pain are the major cause of morbidity and disability in the working population, and in addition contribute to economic loss to the society. Much effort has been done over the last years to improve treatments for these patients. However, the quality of research in this field is mixed. The effect of intervention in many studies is most likely partly due to lack of sub-grouping of the patients. Further studies are needed to show if validated classification systems in patients with musculoskeletal pain can document better effect of interventions on fully return to work and cost effectiveness in these patients.

ACKNOWLEGDEMENTS

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