Pain 84 (2000) 203–211

PAIN

www.elsevier.nl/locate/pain

Treatment outcome of chronic non-malignant pain patients managed in a Danish multidisciplinary pain centre compared to general practice: a randomised controlled trial

Niels Becker[a,*], Per Sjøgren[a], Per Bech[b], Alf Kornelius Olsen[a], Jørgen Eriksen[a]

[a]*H:S Multidisciplinary Pain Centre, Danish National Hospital, Copenhagen University Hospital, Tagensvej 18B, 7122, DK-2200 Copenhagen N, Denmark*
[b]*Psychiatric Department, Frederiksborg General Hospital, Hillerød, Denmark*

Received 28 September 1998; received in revised form 2 June 1999; accepted 3 August 1999

Abstract

This randomised controlled study investigated the effect of outpatient multidisciplinary pain centre treatment (MPT) compared with treatment by a general practitioner after initial supervision by a pain specialist (GP-group) and with a group of patients waiting for 6 months before treatment was initiated (WL-group). One-hundred-and-eighty-nine chronic non-malignant pain patients were studied. At referral, and after 3 and 6 months patients filled in questionnaires evaluating pain intensity, health related quality of life (HRQL) and use of analgesics. HRQL was evaluated using the Medical Outcome Study-Short Form (SF-36), the Hospital Anxiety and Depression scale (HAD) and the Psychological General Well-being Scale (PGWB). After 6 months patients allocated to MPT ($n = 63$) reported statistically significant reduction in pain intensity (VAS-score, $P < 0.001$), improvement in psychological well-being (PGWB, $P < 0.001$), quality of sleep ($P < 0.05$) and physical functioning (SF-36-Phycical Functioning, $P < 0.05$). No improvements were seen in the GP-group ($n = 63$). In the WL-group ($n = 63$) a statistically significant deterioration was observed in PGWB-scores, HAD-scores and in 6 of 8 SF-36-subscores ($P \leq 0.05$). A reduction in use of opioids administered on demand was obtained in the group receiving MPT ($P < 0.001$). In the MPT- and GP-groups a decrease in the use of short acting opioids was observed ($P < 0.01$). No change in use of analgesics was seen in the WL-group. The study showed that (i) in the MPT-group there was a significant reduction in pain intensity and improvement of HRQL compared to the WL-group, and (ii) the mere establishment of a pain diagnosis and a pain management plan by a pain specialist was not sufficient to enable the referring GP to manage severely chronic pain patients. © 2000 International Association for the Study of Pain. Published by Elsevier Science B.V.

Keywords: Pain center; Chronic pain; Treatment outcome; Outpatient; Primary care

1. Introduction

Chronic non-malignant pain represents a major challenge to the Western medical communities. Multidisciplinary pain treatment (MPT) is generally considered to be the most effective treatment of chronic pain, and during the past decades there has been a rapid growth in the number of pain clinics and centres. However, the long term effect of MPT has not yet been firmly established. Although several studies and a number of meta-analysis (Malone et al., 1988; Flor et al., 1992) have supported the efficacy of MPT, methodological problems limit the strength of the conclusions which may be drawn from these studies. In the meta-analysis made by Flor et al. (1992) two-thirds of the studies had no control group, and when control groups were included they often consisted of patients who, because of lack of economical funding or motivation, did not enter the treatment programmes (Roberts and Reinhardt, 1980; Sturgis et al., 1984; Guck et al., 1985; Cassisi et al., 1989; Deardorff et al., 1991). Some studies have indicated that treatment effects found in non-randomised studies may in fact represent spontaneous fluctuations or regression towards the mean (Whitney and Von Korff, 1992). Relatively few randomised studies have compared MPT programmes with no treatment or conventional medical treatment. The majority of these studies have used patients allocated to a waiting list for 2–3 months as controls (Turner, 1982; Moore and Chaney, 1985; Nicholas et al., 1992; Spence, 1989; Turner and Jensen, 1993; Williams et al., 1996; Basler et al., 1997). The studies evaluating inpatient management programmes have generally demonstrated statistically significant short-term treatment effects. The result of outpatient treatment

* Corresponding author. Tel.: +45-3545-7136; fax: +45-3545-7349.
E-mail address: nielsbecker@dadlnet.dk (N. Becker)

0304-3959/00/$20.00
PII: S0304-3959(99)00209-2

programmes are more equivocal (Peters and Large, 1990; Bendix et al., 1995; Williams et al., 1996). To our knowledge no randomised studies comparing outpatient pain management programs with a control group have demonstrated a significant effect for more than 3 months.

A number of studies indicate that even for MPT-programmes which have a pronounced initial effect a gradual loss of treatment effect may take place (Swanson et al., 1979; Wang et al., 1980; Painter et al., 1980; Härkäpää et al., 1990; Maruta et al., 1990).

Another problem is that even if MPT is superior to other treatments, the number of chronic pain patients far exceeds the limited treatment capacity of the existing multidisciplinary pain centres in most countries (Ekter-Andersen et al., 1993). Considering the often life-long nature of chronic pain conditions it therefore seems relevant to continue the search for alternative and less resource demanding long-term treatment models. Although most of the patients referred to our centre were severely chronified, many of the patients had undiagnosed and untreated neuropathic pain conditions or other pain problems, which not necessarily required multidisciplinary intervention (Becker et al., 1997). We therefore hypothesised that the mere establishment of a pain diagnosis and a pain management plan by a pain specialist might enable the referring general practitioner (GP) to manage many of the chronic pain patients and to obtain improvements which might be comparable to results obtained with resource demanding MPT.

The aim of this randomised controlled study on chronic non-malignant pain patients was to compare the effect of outpatient MPT with treatment by a GP after initial supervision by a pain specialist. For comparison of treatment effects the study included a six months control group which received no specific pain treatment and continued to be managed by their GP.

2. Methods

2.1. Subjects

During the study period from August 1994 to October 1996 all patients suffering from chronic non-malignant pain conditions who were referred to the Multidisciplinary pain centre from the Copenhagen area were consecutively considered for inclusion in the study. Criteria for inclusion were: age above 18 years, no psychiatric diseases present, no illegal use of opioids, all relevant medical or surgical investigations and/or treatments should be completed prior to referral and informed consent obtained from the patients' own GP. Patients who were unable to fill in questionnaires were not included. Patients not included in the study received the usual treatment in the pain centre but entered a quality control study in which the same questionnaires as the randomised study were used.

Patients found eligible were asked to participate in the study. They were informed that the purpose of the study was to investigate whether a thorough examination and establishing of a management plan by a pain specialist in the GP's consultation room would be equally effective as MPT. Furthermore, they were informed, that the current waiting period was more than 6 months and that participation in the study, regardless of the randomisation, would result in earlier treatment. Patients who gave written informed consent were randomly assigned to one of three groups: MPT, $n = 63$; treatment by their general practitioner after initial supervision (GP), $n = 63$; or waiting list control (WL), $n = 63$. Randomisation was performed in blocks of nine. Randomisation within each block was performed using the sealed envelope method. Ethically, the investigation was in accordance with the Helsinki Declaration III, and approved consent was given by the Ethical Committee of Copenhagen.

2.2. Treatment

The MPT-group received outpatient treatment at the Multidisciplinary Pain Centre. The treatment programme was carried out on an individual basis and when considered necessary planned and initiated after a multidisciplinary evaluation. The treatment was of primarily cognitive-behavioural nature and included one or several of the following components: (1) education on the physiology and psychology of pain; (2) teaching of pain management strategies (e.g. relaxation training); (3) analgesic treatment; (4) socio-economic counselling and (5) physiotherapy. The physiotherapy focused primarily on teaching of exercise programs and education in biomechanics. The staff consisted of anaesthesiologists, psychologists, physiotherapists, nurses and a social worker. Throughout the treatment period all patients were seen regularly by the pain specialists. Between consultations patients received telephone counselling from nurses at the pain centre.

In the GP-group the intervention consisted of a single initial consultation during which the pain specialist evaluated the patient together with the GP in his/her consultation room. The pain specialist made a medical record and a pain analysis. Based on this the pain specialist and the GP established a treatment plan. Treatment consisted primarily of analgesic tailoring, however, during the consultation the importance of education on the physiology and psychology of pain and behavioural pain management strategies were also emphasized. The protocol allowed patients access to additional monospeciality treatment if needed.

The WL-group continued to be managed as usual by their GPs for 6 months. They received no specific pain treatment except for continuation of already ongoing pain medication. Ethically this was considered acceptable because the waiting list for patients not included in the study was more than 6 months. Immediately after the 6 months the patients in the control group were offered treatment in the pain centre.

2.3. Assessment and outcome measures

Immediately before start of treatment and after 3 and 6 months the MPT-patients and the GP-patients filled in questionnaires concerning pain intensity, physical, psychological and socio-economic conditions, and the use of analgesics. Patients allocated to the WL-group received the questionnaires at inclusion and after 3 and 6 months. At the first consultation at the pain centre or in the GPs' consultation the pain specialists made a medical record, a pain analysis including classification according to the IASP-coding system, and filled in a questionnaire concerning sociodemographic data. Data on the mean number of in-hospital days during a five year period prior to referral were achieved from the Danish National Board of Health.

The patient questionnaire dealt with four main subjects: Pain, sleep, HRQL and use of analgesics. Measurements of pain intensity were performed using a visual analogue scale (VAS) and a five-point Likert scale (1 = no pain, 2 = mild, 3 = moderate, 4 = severe, and 5 = unbearable pain). Quality of sleep during the last week was evaluated as good, fair or poor.

HRQL instruments were selected to cover three dimensions: physical function (disability), psychological well-being and social well-being (Bech, 1993). They included the Hospital Anxiety and Depression Scale (HAD) (Zigmond and Snaith, 1983), the Psychological General Well-Being Scale (PGWB) (Dupuy, 1984), and the MOS 36-Item Short Form Health Survey (SF-36) (Stewart et al., 1988).

HAD identifies milder cases of depression and anxiety in medically ill patients. It is developed and validated on non-psychiatric medical patients. Items relating to both mood disorder and physical illness have been eliminated. HAD consists of a depression and a anxiety-subscale. Scores on each subscale range from 0–21. Scores above 8 indicate that a depressive or anxiety disorder is likely to be present (Zigmond and Snaith, 1983).

PGWB is a 22-item inventory originally designed to measure subjective psychological well-being in population based studies. It is extensively validated and has been proven to posses good psychometric properties in several clinical studies within indications such as hypertension (Omvik et al., 1993) and gastrointestinal symptoms (Dimenäs et al., 1993). PGWB is comprised of six subscales providing evaluations of anxiety, depression, vitality, positive well-being, self-control and general health. Each subscale has three to five items. The subscales range from 0 to 15, 20 and 25, respectively. The overall PGWB-index score range from 0–110. The norm for the American normal population is 82 ± 15, the higher the better (Dupuy, 1984). The norm value for the Danish version has been confirmed on well-controlled diabetes patients (Naylor, 1996). Validation has been performed by comparing with the Beck Depression Inventory and the Hopkins SCL-90. Correlation coefficients about 0.7 (Dupuy, 1984) have been demonstrated.

SF-36 is a general health questionnaire evaluating the physical, social and mental aspects of HRQL. SF-36 includes 8 subscales: Physical Functioning (PF), Role Functioning-Physical (RF), Bodily Pain (BP), Social Functioning (SFA), Mental Health (MH), Role Functioning-Emotional (RE), Vitality (VIT) and General Health Perceptions (GH). The range for each subscale is 0–100. SF-36 has been validated extensively on general populations and different diseases demonstrating high reliability and good construct validity (McHorney et al., 1994). Calculation of scores were performed according to Ware et al. (1993).

Information concerning the use of medications, i.e. types of analgesics, daily doses, administration routes and temporal aspects of drug intake during the last week were registered. All opioid doses are given as milligrams of oral morphine. For opioids other than morphine the equipotency table published by Clausen et al. (1995) was used for conversion.

2.4. Statistical methods

One-way-ANOVA and chi-square tests for contingency tables were used to test for differences at referral in demographic and pain epidemiological characteristics, pain severity and HRQL.

Each of the outcome variables were entered in a separate 3×3 (treatment × assessment period) repeated-measures analysis (MANOVA) using the General Linear Models procedure in SAS. Statistically significant interactions were explored further using tests of simple effects: One-way ANOVA and Bonferroni *t*-tests were used to analyse between-group differences. Improvements obtained within groups were analysed using *t*-tests for repeated measures. $P \leq 0.05$ was chosen as the limit of significance.

Bias due to dropout was estimated by performing the statistical analysis with and without data from patients who dropped out after the initial evaluation. In the analysis which included patients who dropped out after the initial evaluation, missing data were substituted using the last observation method.

3. Results

Out of 391 patients consecutively referred to the Pain Centre, 100 patients did not fulfil the inclusion criteria. Consent from the referring GP was not obtained in 97 patients. Five patients did not want to participate in the investigation. Consequently, 189 patients were scheduled for inclusion in the study and randomised. However, 22 patients (11.6%) had to be excluded at the initial consultation. The reasons for exclusion did not differ significantly between the three groups. Six patients withdrew their consent, six patients were unable to fill in questionnaires because of age, impaired cognition or inadequate mastering of the Danish language, five patients had symptoms indicating major psychiatric disease, four patients had illegal use of

opioids, and one patient did not need treatment. This left 167 patients who were included in the study: MPT-group, 56 patients; GP-group, 58 patients; WL-group, 53 patients. Thirty-three of the 167 patients (19.8%) were excluded or dropped out after the initial consultation and before the 6 months evaluation: Two patients in the MPT-group were excluded because of manic-depressive disorders, and five patients did not return questionnaires. In the GP-group four patients were excluded for ethical reasons and given MPT, and 12 patients did not return questionnaires. In the WL-group one patient was excluded for ethical reasons and given MPT, and nine patients did not return questionnaires. Patients who were excluded or dropped out of the study did not differ from patients included in the study with respect to demographic data, pain epidemiology or HRQL at referral.

Ninety-two (90.2%) of the 102 patients who were not included in the study because of lack of consent filled out questionnaires as part of a quality control study. At referral these patients did not differ from patients included in the study in any measure.

3.1. Treatment

3.1.1. Treatment received by the MPT-group

All patients were seen by a physician. The mean number of medical consultations was 5.1 (SD 2.7). Mean number of telephone counsellings from nurses at the pain centre was 10.8 (SD 6.1). Thirty-nine percent of the patients were treated by psychologists, mean number of treatment sessions was 3.6 (SD 2.8). Fifty-three percent were seen by physiotherapists. Forty-seven percent received socio-economic counselling. Mean duration of treatment was 10.5 months (SD 7.1).

3.1.2. Treatment received by the GP-group

During the 6 months after inclusion in the study the patients were seen 4.3 (SD 2.4) times by their GP. Twenty-eight percent of the patients were treated by a physiotherapist, 11.1% received counselling by a social worker, and 5.6% were treated by a psychologist.

3.1.3. Treatment received by the WL-group

The WL-group patients continued to be managed as usual by their GPs for 6 months. They received no specific pain treatment except for continuation of already ongoing pain medication.

3.2. Demographic data, pain epidemiology and HRQL at inclusion

Table 1 presents sociodemographic data, duration, localisation and pathophysiology of the pain condition for the 167 patients included in each of the three groups. Table 2 shows pain and HRQL at inclusion for the 134 patients, who returned questionnaires after 6 months. At inclusion no statistically significant differences were found between the three groups.

3.3. Treatment outcome: pain and HRQL

Table 2 shows pain intensity and HRQL scores at inclusion and after 3 and 6 months. Fig. 1 presents a graphic illustration of the changes in pain intensity (VAS-scores) and PGWB-scores obtained in the three groups. A MANOVA for repeated measures design demonstrated a statistically significant time × treatment group interaction for all outcome measures except quality of sleep and the role physical-subscale of the SF-36 questionnaire (Table 3).

An intent-to-treat MANOVA which included patients who returned questionnaires after 6 months ($n = 134$) and patients who dropped out after the initial evaluation ($n = 26$) resulted in almost identical mean scores and levels of significance.

3.3.1. Within-group changes

An analysis of the within-group changes using *t*-tests for repeated measures design showed, that the MPT-group obtained reduced pain intensity, improved psychological general well-being measured with the PGWB, improved quality of sleep, and improvements in 5 of 8 SF-36-subscales (Table 3 and Fig. 1). Concerning anxiety and depression no statistically significant changes were seen in the HAD-scores, but after 6 months improvements were observed in the PGWB-anxiety- and the PGWB-depression-subscales (ΔPGWB-Anx: 1.9 (SD 4.9), $t = 2.62$, $P < 0.01$; ΔPGWB-Dep: 1.5 (SD 3.4), $t = 3.03$, $P < 0.004$). The GP-group did not improve in any of the outcome measures. In the WL-group pain intensity remained stable during the 6 months observation period, but a statistically significant deterioration was observed in PGWB-scores (Fig. 1), HAD-scores, and in 5 of 8 SF-36-subscores (Table 3).

3.3.2. Between-group differences at 6 months

Table 3 shows the results of a series of ANOVAs and Bonferroni *t*-tests exploring the between-group differences at 6 months. Compared with the WL-group, the MPT-group reported statistically significant lower pain intensity, lower anxiety-score (HAD), higher psychological well-being-scores (PGWB), better social functioning (SF-36-SFA) and higher general health perception (SF-36-GH). Treatment results in the MPT-group were also superior to those obtained in the GP-group on measures of pain relief and general psychological general well-being (PGWB). Concerning the other SF-36-subscores and HAD-scores no statistically significant differences could be demonstrated between the MPT-group and the GP-group.

At 6 months pain intensity and HRQL of the patients in the GP-group did not differ statistically significant from the WL-group.

3.4. Use of analgesics

Table 4 shows the use of analgesics at inclusion and after

Table 1
Sociodemographic and pain epidemiological data of patients in the MPT-group, GP-group and WL-group

	MPT ($n = 56$)	GP ($n = 58$)	WL ($n = 53$)	Statistics
Age: mean (SD)	57.7 (15.8)	55.1 (14.6)	57.2 (15.5)	$F_{2,164} = 0.46$, NS
Sex (% female)	60.7	69.0	64.2	$\chi^2 = 0.86$, NS
Civil status (n,%)				$\chi^2 = 7.87$, NS
Married	32 (57.1)	33 (56.9)	30 (52.0)	
Single	2 (3.6)	5 (8.6)	4 (7.5)	
Divorced/widow	22 (39.3)	19 (32.8)	15 (28.3)	
Other	–	1 (1.7)	4 (7.5)	
Education $>$ 10 years (n,%)	12 (21.4)	5 (8.6)	8 (15.1)	$\chi^2 = 6.28$, NS
Employment status ($<$ 68 years, n,%)				$\chi^2 = 8.27$, NS
Working	8 (22.9)	5 (11.4)	5 (12.8)	
Unemployed/sick leave	9 (25.7)	12 (27.3)	13 (33.3)	
Disability pension	16 (45.7)	23 (52.3)	16 (41.0)	
Other	2 (5.7)	4 (9.1)	5 (13.9)	
Applying for disability pension (*n*,%)	3 (5.5)	5 (9.3)	7 (13.2)	$\chi^2 = 2.03$, NS
Hospitalised, days/year, mean (SD)	4.8 (7.2)	7.4 (8.2)	6.6 (9.0)	$F_{2,164} = 1.04$, NS
Pain				
Duration, years, mean (SD)	10.2 (9.1)	7.8 (8.1)	9.7 (8.0)	$F_{2,164} = 0.90$, NS
Localisation (*n*,%)				$\chi^2 = 5.87$, NS
Extremity	20 (35.7)	17 (29.3)	16 (30.2)	
Low back	14 (25.0)	15 (25.9)	13 (24.5)	
Head or facial	0	1 (1.7)	1 (1.8)	
Abdominal	12 (21.4)	11 (19.0)	9 (17.0)	
Thoracic	3 (5.4)	6 (10.3)	2 (3.8)	
Rectal	1 (1.7)	1 (1.7)	2 (3.8)	
More than three locations	6 (10.7)	7 (12.1)	10 (18.9)	
Primary pathophysiology (n,%)				$\chi^2 = 5.72$, NS
Somatic	25 (44.6)	21 (36.2)	27 (50.9)	
Neuropathic	20 (35.7)	27 (46.6)	16 (30.2)	
Visceral	7 (12.5)	4 (6.9)	6 (11.3)	
Psychogenic	2 (3.6)	4 (6.9)	1 (1.9)	
Unknown	2 (3.6)	2 (3.4)	3 (5.7)	

Table 2
Pain intensity and HRQL scores at inclusion and after 3 and 6 months[a]

Measure	MPT-group ($n = 49$)			GP-group ($n = 42$)			WL-group ($n = 43$)		
	Pre-treatment	3 months	6 months	Pretreatment	3 months	6 months	Pretreatment	3 months	6 months
Pain, VAS	67 (15)	52 (24)	52 (24)	65 (23)	63 (20)	65 (25)	64 (25)	65 (24)	67 (19)
Pain, verbal	3.7 (0.7)	3.3 (0.8)	3.2 (0.8)	3.7 (0.7)	3.6 (0.7)	3.7 (0.9)	3.9 (1.0)	3.8 (0.9)	3.8 (0.8)
PGWB	51 (17)	56 (18)	62 (17)	53 (19)	57 (20)	53 (19)	58 (21)	54 (22)	51 (20)
HAD-ANX	7.8 (4.0)	7.2 (4.2)	7.1 (4.5)	7.8 (4.2)	7.5 (4.3)	8.2 (4.0)	8.6 (5.6)	9.1 (5.7)	10 (5.9)
HAD-DEP	6.8 (4.9)	6.3 (5.2)	6.1 (5.4)	6.4 (4.2)	6.4 (4.4)	6.6 (4.3)	4.5 (4.6)	5.8 (5.6)	6.4 (5.0)
SF-36-RP	14 (25)	20 (28)	25 (33)	22 (32)	19 (27)	18 (33)	19 (31)	15 (30)	15 (28)
SF-36-PF	48 (26)	51 (26)	52 (27)	53 (28)	51 (27)	51 (28)	51 (25)	49 (24)	46 (24)
SF-36-BP	28 (16)	34 (21)	38 (21)	30 (18)	32 (17)	34 (22)	29 (19)	26 (18)	24 (17)
SF-36-GH	39 (20)	43 (20)	44 (23)	41 (22)	41 (19)	38 (18)	41 (20)	36 (14)	32 (20)
SF-36-VIT	34 (21)	37 (20)	43 (22)	37 (23)	39 (24)	39 (21)	45 (27)	43 (25)	36 (25)
SF-36-SFA	58 (28)	58 (30)	65 (30)	52 (30)	55 (29)	51 (26)	65 (35)	65 (34)	57 (32)
SF-36-RE	31 (15)	31 (15)	32 (16)	29 (16)	27 (16)	24 (15)	34 (15)	33 (15)	27 (15)
SF-36-MH	56 (21)	61 (22)	63 (23)	56 (24)	59 (21)	57 (21)	60 (25)	56 (28)	56 (25)
Sleep	2.1 (0.8)	1.9 (0.8)	1.9 (0.8)	2.3 (0.7)	2.0 (0.7)	2.2 (0.7)	2.1 (0.8)	2.2 (0.8)	2.1 (0.7)

[a] Values are mean (SD).

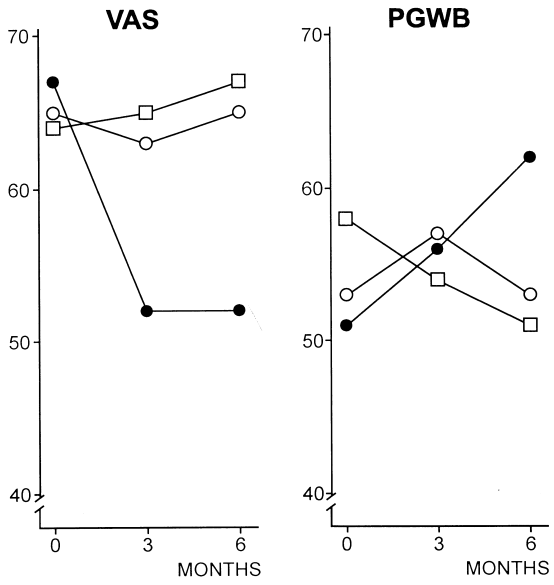

Fig. 1. Pain intensity (VAS score) and Psychological well-being (PGWB-score) at inclusion and after 3 and 6 months in the MPT-group (●), GP-group (○) and WL-group(□). Higher PGWB-scores signify improvement. After 6 months the MPT-group had improved statistically significant compared to both pretreatment scores and to the other groups. See Table 3 for statistical analysis.

6 months. There were no statistically significant pretreatment differences between groups.

During the six months study period no statistically significant changes were seen in the amount of opioids used ($F_{2,2,182} = 0.51$, NS) or the number of patients treated with opioids (MPT-group: $\chi^2 = 1.27$, NS; GP-group: $\chi^2 = 1.62$, NS; GP-group: $\chi^2 = 0.10$, NS).

A reduction of opioids used on demand was obtained in the MPT-group ($\chi^2 = 14.5$, $P < 0.001$). In the GP-group the reduction in opioids used on demand was not statistically significant. After 6 months an increase in the number of patients treated solely with long acting opioids was observed both in the MPT-group and the GP-group (MPT-group: $\chi^2 = 20.1$, $P < 0.001$; GP-group: $\chi^2 = 7.6$, $P < 0.006$) (Table 4).

A statistically significant increase in the number of patients treated with anticonvulsants and antidepressants was seen in the MPT-group ($\chi^2 = 9.66$, $P < 0.002$). No change in the use of medication was seen in the WL-group.

4. Discussion

The main purpose of our study was to compare the effect of outpatient MPT with the effect of a primary care based minimal intervention model in which patients were treated by the GP after initial supervision from a pain specialist. By including a 6 months waiting list group and using a randomised study design, the study aimed at providing a more solid evidence concerning the duration of the treatment effects, which can be obtained by outpatient MPT. The patients investigated in the present study did not differ from the other patients seen at our pain centre. However, a previous study indicated, that patients seen at our pain centre were comparable only to the most chronified subpopulation of pain patients seen at other pain centres (Becker et al., 1997).

In our study patients receiving outpatient MPT obtained reduced pain intensity, improved psychological general well-being and improvements in most of the subscales of

Table 3
Statistical analysis of changes in pain intensity and HRQL from inclusion to 6 months

Measure	Interaction of timextreatment group (MANOVA)	Between-group differences at 6 months (ANOVA)	Post hoc comparisons at 6 months (Bonferroni)	Change from admission to 6 months (*t*-test)		
				MPT	GP	WLC
Pain, VAS	$F_{(2,2,123)} = 4.55^{a}$	$F_{(2,125)} = 5.35^{a}$	MPT > GP, MPT > WL	4.87^{b}	0.06, NS	0.80, NS
Pain, verbal	$F_{(2,2,125)} = 2.85^{c}$	$F_{(2,127)} = 6.48^{a}$	MPT > GP, MPT > WL	4.24^{b}	0.52, NS	0.57, NS
PGWB	$F_{(2,2,123)} = 11.9^{b}$	$F_{(2,125)} = 5.47^{a}$	MPT > GP, MPT > WL	6.14^{b}	0.02, NS	3.06^{cd}
HAD-ANX	$F_{(2,2,122)} = 3.5^{c}$	$F_{(2,124)} = 4.89^{a}$	MPT > WL	1.64, NS	0.65, NS	2.31^{cd}
HAD-DEP	$F_{(2,2,122)} = 2.97^{c}$	$F_{(2,124)} = 0.16$, NS		1.22, NS	0.39, NS	3.46^{ad}
SF-36-RP	$F_{(2,2,117)} = 1.47$, NS	$F_{(2,129)} = 1.36$, NS		2.05^{c}	0.11, NS	0.87, NS
SF-36-PF	$F_{(2,2,119)} = 3.04^{c}$	$F_{(2,121)} = 0.82$, NS		1.99^{c}	0.26, NS	1.97^{cd}
SF-36-BP	$F_{(2,2,122)} = 4.97^{b}$	$F_{(2,124)} = 7.50^{a}$	MPT > WL	4.18^{a}	1.61, NS	1.70, NS
SF-36-GH	$F_{(2,2,122)} = 4.85^{a}$	$F_{(2,124)} = 6.43^{a}$	MPT > WL	1.83, NS	0.94, NS	2.75^{cd}
SF-36-VIT	$F_{(2,2,122)} = 5.38^{b}$	$F_{(2,124)} = 1.10$, NS		4.00^{b}	1.07, NS	2.76^{cd}
SF-36-SFA	$F_{(2,2,120)} = 3.92^{a}$	$F_{(2,122)} = 3.05^{c}$	MPT > WL	1.80, NS	0.17, NS	3.32^{ad}
SF-36-RE	$F_{(2,2,117)} = 3.07^{c}$	$F_{(2,119)} = 2.92^{c}$		0.39, NS	2.20^{cd}	2.69^{cd}
SF-36-MH	$F_{(2,2,120)} = 2.65^{c}$	$F_{(2,124)} = 1.45$, NS		3.29^{a}	0.32, NS	1.54, NS
Sleep	$F_{(2,2,120)} = 1.73$, NS	$F_{(2,122)} = 2.91^{c}$		2.04^{c}	0.10, NS	0.18, NS

[a] $P < 0.005$.
[b] $P < 0.0005$.
[c] $P < 0.05$.
[d] Deterioration.

Table 4
Use of analgesics at inclusion and after 6 months

Measure	MPT-group		GP-group		WL-group	
	Pre-treatment ($n = 53$)	6 months ($n = 49$)	Pretreatment ($n = 54$)	6 months ($n = 42$)	Pretreatment ($n = 50$)	6 months ($n = 43$)
Opioid use, *n* (%)	36 (67.9)	28 (57.1)	34 (63.0)	21 (50.0)	31 (62.0)	28 (65.1)
Opioid dose in mg of morphine, mean (SD)	47.6 (75.9)	69.3 (97.5)	45.3 (76.4)	52.3 (113.4)	39.6 (85.6)	37.7 (80.9)
Opioid administration pattern, n (%)						
On demand	25 (47.1)	6 (12.2)[a]	21 (38.9)	8 (19.0)	19 (38.0)	12 (27.9)
Not on demand	11 (20.7)	22 (44.9)[a]	13 (24.1)	13 (31.0)	12 (24.0)	16 (37.2)
Only long-acting	3 (5.7)	17 (34.7)[a]	3 (5.5)	9 (21.4)[a]	6 (12.0)	5 (11.6)
Antidepressants or anticonvulsants, *n* (%)	10 (18.9)	23 (47.9%)[a]	10 (18.5)	15 (36.6)	10 (20.0)	10 (23.3)
Acetylsalicylic acid, paracetamol or, NSAIDs, *n* (%)	34 (64.2)	20 (40.8)	35 (64.8)	17 (40.5)	33 (66.0)	25 (59.5)

[a] Statistically significant pretreatment to 6 months change (see text), $P < 0.002$.

the SF-36 general health questionnaire. After 6 months patients treated at the pain centre still reported statistically significant less pain and higher general psychological well-being than the GP-patients and the WL-group. To our knowledge our study is the first randomised controlled study which in a convincing way has documented effect of an outpatient MPT programme for as long as 6 months. A number of randomised studies comparing MPT with patients placed on a waiting list of 2–3 months duration have shown that patients immediately after completion of MPT-programmes had less severe pain and/or higher HRQL than non-treated patients (Linton and Gotestam, 1984; Moore and Chaney, 1985; Spence, 1989; Peters and Large, 1990; Turner and Jensen, 1993; Vlaeyen et al., 1995; Williams et al., 1996; Basler et al., 1997). However, results of the few randomised studies which have compared outpatient MPT with non-treated control groups for more than 3 months have been less convincing. In the study by Härkäpää et al., 1989 outpatient treatment was superior to standard medical treatment immediately after completion of the treatment programme, but in the 8 months to 2.5 years follow up study the scores of the outpatients did not differ from controls (Härkäpää et al., 1990). A similar loss of treatment effect was seen for most of the outcome measures in the 12 months follow-up study by Peters et al. (1992). Patients who had received MPT still reported less pain intensity than the non-treated control group, but a 52% drop-out in the control group severely limited the validity of the study. These studies have added to the concern, that the long-term treatment effect demonstrated in a number of uncontrolled studies may represent regression towards the mean (Whitney and Von Korff, 1992). In the present study improvements were observed only in the MPT-group and the WL-group deteriorated. This seems to indicate that spontaneous improvements did not play any significant role in our study. Furthermore, no loss of treatment effect was observed between 3 and 6 months. This suggests a lasting effect of our treatment programme, but a follow-up assessment of our patients will be necessary in order to evaluate the long-term effects.

The reduction in pain intensity and improvement in HRQL obtained among patients treated at the pain centre was not accompanied by a reduction in the use of opioids. The majority of patients in our study were treated with opioids already at referral. Probably due to the liberal opioid prescription policy in Denmark (Clausen et al., 1995). In these patients the primary goal was to eliminate the often uncontrolled and irrelevant 'on demand' use of short acting opioids. Only in two occasions was opioid treatment initiated by the pain centre. However, stabilising uncontrolled opioid use often involved an increase in the total opioid dose. After 6 months the majority of patients treated at the pain centre were stabilised on an opioid treatment using solely long acting opioids.

In the GP-group the only significant effect of treatment was the stabilisation of opioid use. No reduction in pain intensity or improvement of HRQL was observed. This may not be surprising in view of the minimal treatment intervention received by this group. Less than 6% of the patients received psychological intervention, and the number of patients given physical therapy was only half of that in the MPT-group. A more intensive and comprehensive primary sector management model might have been more effective, but our study does not allow for any conclusions regarding the reason for the inefficacy of the primary sector management model. The negative results obtained in the GP-group do not exclude the possibility that a primary care based minimal intervention model may be effective for many of the less chronified patients seen by GPs. Furthermore, the collaboration initiated between the pain specialists and the GPs may have long-term beneficial effects by improving the GPs' general knowledge on chronic pain management. This in turn may lead to improved management of chronic pain patients in the primary sector and to earlier referral of complicated cases needing MPT.

Few studies have investigated the effect of chronic pain

management models in primary care. Basler and Rehfisch, 1990 compared the effect of behavioural treatment in a primary care setting with a waiting list condition. Holroyd et al. (1991) compared a home based cognitive-behavioural treatment for tension headache with amitriptyline therapy, and Richardson and McGrath (1989) investigated minimal therapist-contact interventions applied in a primary care setting. These studies showed that primary care intervention programmes may be effective for some pain patients. However, no studies have investigated the effects of minimal intervention programmes on a patient population comparable to ours. The present study indicates, that primary care management models are insufficient for managing the often severely chronic pain patients referred to a pain centre. This is in accordance with the views expressed by other authors (Turner, 1996).

The WL-group reported no change in pain intensity but a significant worsening of their psychological well-being was observed. A trend towards better HRQL-scores in the WL-group compared to the other groups at inclusion raise the suspicion that the observed deterioration may be the result of regression towards the mean. However, deterioration of HRQL among WL-patients has also been reported in studies where no initial differences existed (Moore and Chaney, 1985; Spence, 1989). In our opinion it is more likely that the deterioration in HRQL scores reflects the 'natural course' of an exacerbation in pain intensity, which then leads to the referral of the patient and, subsequently, when the pain condition is not treated, there is a gradual impairment of HRQL. This supports the notion that chronic pain precedes the deterioration in HRQL - and not visa versa. It also illustrates that long waiting lists which are a problem for many pain units, including ours, is unacceptable.

A number of methodological problems in our study demand some comments. Due to practical problems, the decision to include patients were based on information contained in the referral letters. At the first evaluation which was performed after randomisation, 11.6% of the patients were found not to fulfil the inclusion criteria. We might have chosen to deal with these patients according to the intent-to-treat principles. However, for the primarily excluded patients no questionnaire data could be obtained. The fact that the reasons for primary exclusion did not differ between treatment groups, makes it unlikely that a randomisation bias was introduced. The MANOVA including all patients who dropped out after inclusion showed no drop-out bias.

The study relied on self-report measures. The use of objective measures of improvement in for example physical performance would have strengthened the study. However, HRQL as well as pain are by definition subjective phenomena, and the questionnaires used in the study are extensively validated and designed for use in patients with a diversity of medical conditions (Dupuy, 1984; McHorney et al., 1994). Return to work is often used as a measure of treatment success. Obviously, return to work is a major goal in the treatment of chronic pain patients within the working age. However, in our study it would not be very sensitive as an indicator of treatment success. The majority of the patients referred to the pain centre were permanently non-employed and living on social welfare benefits, disability pension or retirement pension. A long-term follow-up study is presently being conducted. This study will include an evaluation of the socio-economic effects of our MPT.

The present 6 months randomised controlled study on chronic, non-malignant pain patients referred to a Danish pain centre showed: (i) patients receiving outpatient MPT obtain a significant reduction in pain intensity and improvement of HRQL compared to non-treated patients, and (ii) the mere establishing of a pain diagnosis and a pain management plan by a pain specialist was not sufficient to enable the referring GP to manage and improve severely chronified pain patients.

Acknowledgements

The authors would like to thank Karis Hagild, head of the primary sector department of the Board of Health in Copenhagen who financed the majority of the project. The authors would also like to thank the GPs of Copenhagen who participated in the collaboration project, Keld Mulvad at the Department of Health Care in Copenhagen and Dr Med. Prof. Allan Krasnik at the Department of Social Medicine, Copenhagen University for valuable comments on the manuscript.

References

Basler HD, Rehfisch HP. Followup results of a cognitive-behavioural treatment for chronic pain in a primary care setting. Psychol Health 1990;4:293–304.

Basler HD, Jakle C, Kroner Herwig B. Incorporation of cognitive-behavioural treatment into the medical care of chronic low back patients: a controlled randomised study in German pain treatment centres. Patient Educ Couns 1997;31:113–124.

Bech P. Rating scales for psychopathology, health status and quality of life. In: Bech P, editor. Berlin: Springer, 1993. pp. 395–424.

Becker N, Thomsen AM, Olsen AK, Sjøgren P, Eriksen J. Pain epidemiology and health related quality of life in chronic nonmalignant pain patients referred to a Danish multidisciplinary pain centre. Pain 1997;73:393–400.

Bendix AF, Bendix T, Ostenfeld S, Bush E, Andersen A. Active treatment programs for patients with chronic low back pain: a prospective, randomised, observerblinded study. Eur Spine J 1995;4:148–152.

Cassisi JE, Sypert GW, Salamon A, Kapel L. Independent evaluation of a multidisciplinary rehabilitation program for chronic low back pain. Neurosurgery 1989;25:877–883.

Clausen TG, Eriksen J, Borgbjerg FM. Legal opioid consumption in Denmark 1981–1993. Eur J Clin Pharmacol 1995;48:321–325.

Deardorff WW, Rubin HS, Scott DW. Comprehensive multidisciplinary treatment of chronic pain: a follow-up study of treated and nontreated groups. Pain 1991;45:35–43.

Dimenäs E, Gliese H, Hallerbäck B, Hernqvist H, Svedlund, J, H.,Svedlund, J. and Wiklund, I., I. Quality of life in patients with

upper gastrointestinal symptoms. Scand J Gastroenterol 1993;28:681–687.

Dupuy HJ. The psychological general well-being (PGWB) index. In: Wenger NK, Mattson ME, Furberg JF, Elinson JA, editors. Assessment of quality of life in clinical trials of cardiovascular therapies, New York: LeJacq, 1984. pp. 170–183.

Ekter-Andersen J, Janzon L, Sjølund B. Chronic pain and the sociodemographic environment: Results from the pain clinic at Malmø General Hospital in Sweden. Clin J Pain 1993;9:183–188.

Flor H, Fydrich T, Turk DC. Efficacy of multidisciplinary pain treatment centres: a meta-analytic review. Pain 1992;49:221–230.

Guck TP, Skultety FM, Meilman PW, Dowd ET. Multidisciplinary pain centre follow-up study: evaluation with a no-treatment control group. Pain 1985;21:295–306.

Härkäpää K, Jarvikoski A, Mellin G, Hurri H. A controlled study on the outcome of inpatient and outpatient treatment of low back pain. Part I. Pain, disability, compliance, and reported treatment benefits three months after treatment. Scand J Rehabil Med 1989;21:81–89.

Härkäpää K, Mellin G, Järvikoski A, Hurri H. A controlled study on the outcome of inpatient and outpatient treatment of low back pain. Scand J Rehab Med 1990;22:181–188.

Holroyd KA, Nash JM, Pingel JD, Cordingley GE, Jerome A. A comparison of pharmacological (amitriptyline HCL) and nonpharmacological (cognitive-behavioural) therapies for chronic tension headaches. J Consult Clin Psychol 1991;59:387–393.

Linton SJ, Gotestam KG. A controlled study of the effects of applied relaxation and applied relaxation plus operant procedures in the regulation of chronic pain. Br J Clin Psychol 1984;23:291–299.

Malone MD, Strube MJ, Scogin FR. Meta-analysis of non-medical treatments for chronic pain. Pain 1988;34:231–244.

Maruta T, Swanson DW, McHardy MJ. Three year follow-up of patients with chronic pain who were treated in a multidisciplinary pain management centre. Pain 1990;41:47–53.

McHorney CA, Ware JE, Lu JF, Sherbourne CD. The MOS 36-item short-form health survey (SF36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care 1994;32:40–66.

Moore JE, Chaney EF. Outpatient group treatment of chronic pain: effects of spouse involvement. J Consult Clin Psychol 1985;53:326–334.

Naylor AS. Epilepsi and psychiatric disorder – a comorbidity study, Copenhagen: FADL, 1996 p. 108.

Nicholas MK, Wilson PH, Goyen J. Comparison of cognitive-behavioural group treatment and an alternative non-psychological treatment for chronic low back pain. Pain 1992;48:339–347.

Omvik P, Thaulow E, Herland OB, Eide I, Midha R, Turner RR. Double blind, parallel, comparative study on quality of life during treatment with amlodipine or enalapril in mild or moderate hypertensive patients: a multicenter study. J Hypertens 1993;11:103–113.

Painter JR, Seres JL, Newman RI. Assessing benefits of the pain centre: why some patients regress. Pain 1980;8:101–113.

Peters JL, Large RG. A randomised control trial evaluating in- and outpatient pain management programmes. Pain 1990;41:283–293.

Peters JL, Large RG, Elkind G. Follow-up results from a randomised controlled trial evaluating in- and outpatient pain management programmes. Pain 1992;50:41–50.

Richardson GM, McGrath PJ. Cognitivebehavioural therapy for migraine headaches: A minimal-therapistcontact approach versus a clinic-based approach. Headache 1989;29:352–357.

Roberts AH, Reinhardt L. The behavioural management of chronic pain: long-term follow-up with comparison groups. Pain 1980;8:151–162.

Spence SH. Cognitivebehavior therapy in the management of chronic, occupational pain of the upper limbs. Behav Res Ther 1989;27:435–446.

Stewart AL, Greefield S, Hays RD, Wells K, Rogers WH, Berry SD, McGlynn EA, Ware JE. The MOS short form general health survey. Med Care 1988;26:724–735.

Sturgis ET, Schaefer CA, Sikora TL. Pain centre follow-up study of treated and untreated patients. Arch Phys Med Rehabil 1984;65:301–303.

Swanson DW, Maruta T, Swenson WM. Results of behaviour modification in the treatment of chronic pain. Psychosom Med 1979;41:55–61.

Turner JA. Comparison of group progressive-relaxation training and cognitive-behavioural group therapy for chronic low back pain. J Consult Clin Psychol 1982;50:757–765.

Turner JA. Educational and behavioural interventions for back pain in primary care. Spine 1996;21:2851–2857.

Turner JA, Jensen MP. Efficacy of cognitive therapy for chronic low back pain. Pain 1993;52:169–177.

Vlaeyen JW, Haazen IW, Schuerman JA, Kole Snijders AM, van Eek H. Behavioural rehabilitation of chronic low back pain: comparison of an operant treatment, an operant-cognitive treatment and an operant-respondent treatment. Br J Clin Psychol 1995;34:95–118.

Wang JK, Ilstrup DM, Nauss LA, Nelson DO, Wilson PR. Outpatient pain clinic – a long-term follow-up study. Minn Med 1980;63:663–666.

Ware JE, Snow KK, Kosinski M, Gandek B. SF-36 Health survey manual and interpretation guide, Boston, MA: New England Medical Centre, The Health Institute, 1993.

Whitney CW, Von Korff M. Regression to the mean in treated versus untreated chronic pain. Pain 1992;50:281–285.

Williams AC, Richardson PH, Nicholas MK, Pither CE, Harding VR, Ridout KL, Ralphs JA, Richardson IH, Justins DM, Chamberlain JH. Inpatient vs. outpatient pain management: results of a randomised controlled trial. Pain 1996;66:13–22.

Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand 1983;67:361–370.