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# Pain Rehabilitation in Sweden

## *A quality registry study*

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**To Sofia and Samuel**



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# ABSTRACT

**Background:** Chronic pain, defined as non-malignant pain emanating from the musculoskeletal system, may limit everyday activities, social functioning and the quality of social and working life for individuals, creating disability as well as incurring high economic and public costs for society. Controlled studies show that cognitive-behavioural interdisciplinary rehabilitation has a positive effect on functioning in patients who have been disabled by chronic non-malignant pain conditions. Positive outcomes described include lower pain intensity, less preoccupation with pain, greater independence and lower consumption of healthcare. On the other hand, the return to work rate varies.

To facilitate comparisons on the national level and to enable audit spirals for single programmes as part of the ongoing quality assurance in healthcare the Swedish Quality Registry for Pain Rehabilitation (SQRP) has aggregated data since 1998 on all patients referred to the majority of Swedish rehabilitation units.

The aim of this dissertation was to improve the knowledge base of pain rehabilitation in Sweden using the validated self-reported instruments of pain and its consequences included in the SQRP.

**Methods:** The SQRP data were collected before, at the end and 1 year after the intervention for all individuals included, and concerns self-reported demographic variables, pain intensity, activities, thought patterns, impact of pain on daily life and life satisfaction. Individual sick leave data were collected from the Swedish Social Insurance after 1 year. Data collected from 19833 patients (6002 men and 13831 women) of which 7289 participate in work ability improving programmes, were used.

**Results:** The results of four studies included in this thesis showed that the SQRP provided a basis for scientific works since it use the validated self-report instruments of pain and its consequences and contain a large amount of patient's data. However, a lack of follow-up data from some units influenced the opportunity of to analyse long-term outcomes. Nevertheless, the SQRP was a useful tool to audit and evaluate as well as to propose optimising of pain rehabilitation. It seemed that contextual factors such as patients' own beliefs and expectations, education, gender, actual sick leave and employment situation had more importance for the effect of rehabilitation programme than pain characteristics, depression or activity limitation.

The Multidimensional Pain Inventory (MPI) scale scores and MPI coping profiles might be used for assessing the outcomes of treatment

interventions. A reduction of MPI scale scores for Pain severity and Interference decreased the risk of being on full-time sick leave. On the other hand, the MPI coping profiles Dysfunctional, among both men and women, and Interpersonally distressed, among women, were associated with higher odds of being on full-time sick leave.

**Conclusions:** Attending cognitive-behavioural interdisciplinary pain rehabilitation programmes in Sweden resulted in improvements of the MPI scales after completing a pain rehabilitation programme and this improvement was sustained after 1 year. Moreover, these programmes decreased the levels of full-time sick leave 1 year after completed programme. The findings suggest also the need to tailor rehabilitative strategies differently for men and women as well as for different pain coping profiles.

**Key words:** chronic pain, pain-related disability, pain rehabilitation, registry study, sick leave benefits, audit

# SAMMANFATTNING PÅ SVENSKA

**Bakgrund:** Kronisk smärta, definierad som icke-malign smärta från rörelseapparaten, kan begränsa vardagliga aktiviteter, social funktion och det sociala livets och arbetslivets kvalitet för enskilda personer samt medföra stora samhällsekonomiska kostnader. Kontrollerade studier visar att kognitiv beteendeorienterad interdisciplinär rehabilitering har en positiv effekt på funktion hos patienter drabbade av kronisk icke malign smärta. Lägre smärtintensitet, mindre upptagenhet med smärta, större självständighet och lägre sjukvårdskonsumtion är beskrivna som positiva effekter. Å andra sidan varierar resultaten när det gäller återgång till arbetslivet.

För att underlätta jämförelser på nationell nivå och för att möjliggöra granskning av enstaka program, som en del av pågående kvalitetssäkring inom hälso- och sjukvården, har det Nationella Registret över Smärtrehabilitering (NRS) sedan 1998 samlat data på alla patienter som remitterats till rehabiliteringsenheterna i Sverige.

Syftet med denna avhandling var att förbättra kunskapsbasen om smärtrehabilitering i Sverige med hjälp av validerade självrapporterade instrument om smärta och dess konsekvenser som ingår i NRS.

**Metoder:** NRS data samlades in före, vid avslut och 1 år efter rehabiliteringsprogram och inkluderade självrapporterade demografiska uppgifter, smärtintensitet, aktiviteter, tankemönster, smärtans påverkan på dagligt liv och livstillfredsställelse. Individuella sjukfrånvarouppgifter samlades in från den Försäkringskassans databas ett år efter deltagande i rehabiliteringsprogram. Uppgifter insamlade för 19 833 patienter (6 002 män och 13 831 kvinnor) varav 7 289 deltog i arbetsförmågehöjande program har använts.

**Resultat:** Resultaten av fyra studier som ingår i denna avhandling visade att NRS kunde ge en grund för vetenskapligt arbete, eftersom det använde validerade självrapporterade instrument om smärta och dess konsekvenser och att registret innehöll en stor mängd patientdata. Bortfallet av uppföljningsdata från vissa enheter påverkade negativt möjligheten att analysera långsiktiga resultat. Trots detta var NRS ett användbart verktyg för att granska och utvärdera samt föreslå optimering av smärtarehabiliteringen. Det verkade som att kontextuella faktorer, som patienternas egna förväntningar om framtiden, utbildning, kön, faktisk sjukfrånvaro och sysselsättningssituationen hade större betydelse för effekten av rehabiliteringsprogrammet än smärtans egenskaper, depression eller aktivitetsbegränsning.

Multidimensional Pain Inventory (MPI) användes för att bedöma resultaten av behandlingsinsatser. En minskning av smärtans svårighetsgrad och inverkan på aktiviteter minskade risken av att vara heltidssjukskriven. Å andra sidan var MPI-profilerna Dysfunktionell, bland både män och kvinnor, och Interpersonell, bland kvinnor, associerade med högre odds av att vara på heltid sjukskriven.

**Konklusion:** Den kognitivt beteendeorienterad interdisciplinära smärtrehabiliteringen som genomfördes i de enheter som ingår i NRS visade förbättringar enligt MPI efter avslutat smärtrehabiliteringsprogram och denna förbättring kvarstod även efter ett år. Dessutom minskade dessa program nivåerna av heltidssjukskrivning ett år efter avslutat program. Resultaten tyder också på behovet av att skraddarsy rehabiliterande strategier på olika sätt för män och för kvinnor samt för olika coping profiler.

# ABBREVIATIONS

95% CI 95% Confidence Interval

AC Adaptive coping profile (MPI)

DYS Dysfunctional coping profile (MPI)

FSL Full-time sick leave benefits

ICF The International Classification of Functioning, Disability and Health

ID ID coping profile (MPI)

MPI (West Haven-Yale) Multidimensional Pain Inventory.

NBHW National Board of Health and Welfare

NSL Not full-time sick leave benefits

OR Odds ratio

SALAR The Swedish Association of Local Authorities and Regions

SFRM Swedish Association of Rehabilitation Medicine

SQRP Swedish Quality Registry for Pain Rehabilitation

SSIA Swedish Social Insurance Agency

VAS Visual analogue scale

# ORIGINAL PAPERS

This thesis is based on following papers, which will be referred to in the text by their Roman numerals.

**I.** Nyberg V, Sanne H, Sjölund BH. The Swedish Quality Registry for Pain Rehabilitation: Purpose, design, implementation and characteristics of referred patients. *J Rehabil Med* 2011; 43: 50–57

**II.** Nyberg VE, Novo M, Sjölund BH. Can register data be used as predictive factors for effective pain rehabilitation? In manuscript

**III.** Nyberg VE, Novo M, Sjölund BH. Do Multidimensional Pain Inventory Scale score changes indicate risk of receiving sick leave benefits 1 year after a pain rehabilitation programme? *Disability and Rehabilitation*, 2010; Early Online, 1–9.

**IV.** Nyberg VE, Novo M, Sjölund BH. MPI profile changes indicate risk of receiving sick leave benefits 1 year after a pain rehabilitation programme. (Submitted)

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# INTRODUCTION

## PAIN

The established definition of pain according to the International Association of the Study of Pain (IASP) is: 'An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage'. Pain is always a subjective experience. It is a sensation in a part or parts of the body, but it is always unpleasant and therefore as well an emotional experience (1).

### *Chronic pain*

IASP defines chronic pain as pain that has persisted beyond the normal tissue healing time (usually taken to be 3 months). In the literature chronic pain is, sometimes, pragmatically defined as pain persisting for 6 months. Chronic pain is influenced by physical, psychological, emotional and social factors and it also implies human suffering.

Studies of the prevalence of chronic pain in the population show that chronic pain is a very common condition in Sweden and in other European countries (2-5). According to Breivik et al (6) the prevalence of moderate to severe chronic pain in Sweden was 18%, in Norway 30 % and in the UK 13 % in the adult population.

Disability due to chronic pain has negative social consequences in the form of increased sick leave (approximately 30% of all sick leave in Sweden) (7) activity limitations and reduced participation in society(8). The economic costs of chronic pain in Sweden is estimated at around 87.5 billion SEK (7). There is a substantial suffering in the form of other symptoms such as depression, anxiety, fatigue, and difficulties in maintaining relationships (9)

Women seek more care for musculoskeletal pain than men (3, 10-12), and more women than men are on sick leave (13). In most studies included in the systematic review of rehabilitation in chronic pain, made by the Swedish Council on Health Technology Assessment (7) the majority of patients were women and it is rare that the results are reported separately for women and men. However, the difference in prevalence of care seeking behaviour between men and women is largely unexplained. Several studies have reported gender differences with respect to various pain-related items in patients with chronic pain (14-16). Gender differences have also been reported to have a major influence on the results of treatment of patients with chronic musculoskeletal pain (17-21) although others have found no gender difference in treatment outcome (22). Pain is the primary symptom that motivates people to seek medical treatment and individuals with pain,

often those who are on sick leave, are those who generally seen in primary health care and especially in the physiotherapy units (23).

Thus, the magnitude of the impact of disability of chronic pain is serious, and it is a great need to provide effective and evidence-based rehabilitation for these conditions. Obviously there is also a need of gender research of the impact of chronic pain.

## **BIOPSYCHOSOCIAL MODEL OF PAIN AND DISABILITY**

The biopsychosocial model incorporates the notions that at the biological level (e.g. nociception and neuropathy) changes are initiated by trauma or pathology; psychological are reflected in the attention and appraisal of internal sensations, and these appraisal and behaviour respondents are in turn influenced by social or environmental variables (9, 24)

The biopsychosocial approach is now widely accepted as a heuristic perspective to the understanding and treatment of chronic pain disorders.

The biopsychosocial model of pain and disability views the maintenance of chronic pain as a dynamic interaction among physiological, psychological, behavioural, and social-contextual factors, which perpetuates and may even worsen the clinical presentations. Each individual experiences pain uniquely and a range of psychological and socio-economic factors can interact with physical pathology to modulate a patient's report of symptoms and subsequent disability (22, 25).

## **COGNITIVE – BEHAVIOURAL TREATMENT**

The biopsychosocial model has been instrumental in the development of cognitive –behavioural treatment approaches for chronic pain (9). In the 1960s, multidisciplinary rehabilitation programmes emerged that included behavioural (26) and later cognitive components (27) in the treatment approaches to patients disabled with chronic pain.

Controlled studies show that cognitive-behavioural-oriented multidisciplinary rehabilitation has a positive impact particularly in terms of functioning and activity level, but the effect on working capacity varies (28-30).A meta-analysis based on 5 studies from Scandinavia verified the scientific evidence for a clinically relevant effect of multidisciplinary interventions on return to work (31).

Cognitive behavioural treatment does not refer to a specific intervention but rather to a class of intervention strategies under the heading of cognitive-

behavioural treatment (32). In Sweden, the secondary and tertiary (medical) pain rehabilitation units are working according to the multidisciplinary cognitive-behavioural oriented method. A standard interdisciplinary rehabilitation team includes a physician, who is usually a specialist in rehabilitation medicine or pain management, a cognitive-behaviourally oriented psychologist, a physiotherapist, a social counsellor and an occupational therapist. However, due to tradition and lack of resources/availability, the psychologist is often missing or works only consultatively. The rehabilitation is focused on education about pain mechanisms and their consequences on different life domains, pain psychology and self-management of pain problems. The programmes lasts approximately 90–120 h over a 3- to 6-week period and are delivered in a group format to normalise the pain experience and to maximise the possibilities of learning from other group members, and as guided practice on setting individual goals and working towards them.

## **ICF**

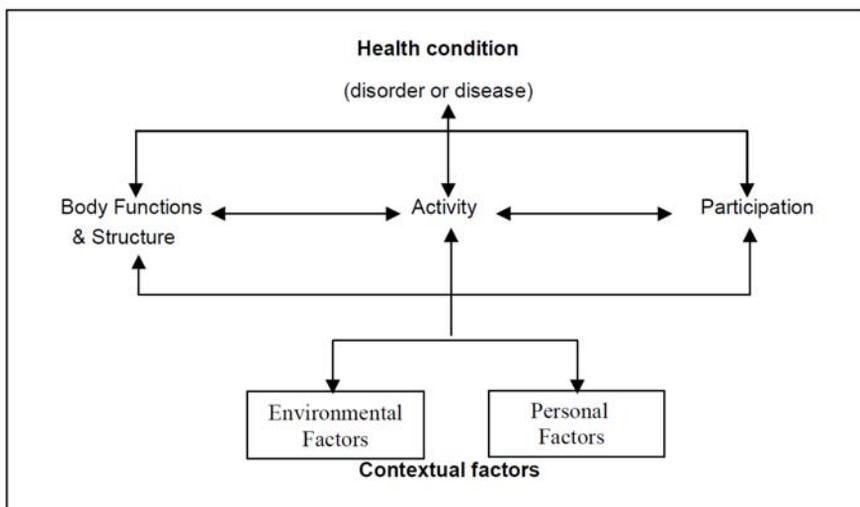
The International Classification of Functioning, Disability and Health – ICF (33) provides the ability to describe a person's functioning, disability and health from a biopsychosocial model perspective. The ICF enables us to set chronic pain and persons suffering and being disabled by chronic pain in a wider context than the individual perspective.

The structure of ICF contains of two parts, each with two components:

1. *Functioning and Disability*. One component of the term *functioning* in this part is body function and structure. If body functions or structure are affected, this is referred to as impairment. The other component in this part is activity and participation. The ICF term *functioning* refers to all body functions, activities and participation, while *disability* is similarly an umbrella term for impairment, activity limitations and participation restrictions.

2. *Contextual factors*. The two components of contextual factors are the environmental and the personal factors.

As Figure 1 indicates, in the ICF functioning and disability are viewed as outcomes of interaction between health conditions and contextual factors.



**Figure 1.** Interactions between the components of ICF.

The formal definitions of the components of ICF are provided below.

**Body Functions** are physiological functions of body systems (including psychological functions).

**Body Structures** are anatomical parts of the body such as organs, limbs and their components.

**Impairments** are problems in body function or structure such as a significant deviation or loss.

**Activity** is the execution of a task or action by an individual.

**Participation** is involvement in a life situation.

**Activity Limitations** are difficulties an individual may have in executing activities.

**Participation Restrictions** are problems an individual may experience in involvement in life situations.

**Environmental Factors** make up the physical, social and attitudinal environment in which people live and conduct their lives.

**Personal factors** Age, sex, education, experiences, coping style, self-efficacy, fear, pain-behaviour.

The ICF has been proven as suitable within the rehabilitation medicine (34) and chronic pain research (35, 36), particularly with regard to body structures and functions as well as activity and participation.

Contextual factors, including environmental factors and personal factors are currently not classified in ICF. It is a weakness of the ICF since those factors are essential components of medical rehabilitation aimed to improve working ability. In a mixed-method (qualitative-quantitative), multicenter

study has been found that 18% of the ICF concept was assigned to the ICF component personal factors (37). Personal factors identified in this study include important aspects related to psychosocial factors, management of resources and development of coping strategies. On the other hand, many of environmental factors occur in the workplace and around the worker. They have an impact on the work ability as facilitators, but they may also be perceived to be barriers (37). One of the challenges of future research on the ICF and work ability is investigating the role of contextual factors (personal and environment) in capturing important aspects of work functioning (38).

## **HEALTHCARE QUALITY REGISTRIES IN SWEDEN**

A system of national quality registries has been established in the Swedish health and medical services in the last decades. The Swedish Association of Local Authorities and Regions (SALAR) and the National Board of Health and Welfare (NBHW) have collaborated to support the development and use of National Quality Registries (39). This collaboration is looked after by the Executive Committee for National Quality Registries. This committee also includes representatives from the Swedish Society of Medicine and the Swedish Society of Nursing. Until 2007, the quality registries were under the auspices of the NBHW. From 2007, SALAR has taken on the primary responsibility for the development and financing of the registries.

Development of the registries has been done by representatives of the professional groups that use them. In year 2010, 89 health quality registries in Sweden received financial support from the SALAR. National Quality Registries contain data on patients' problems/diagnosis, treatment interventions, and treatment outcomes. These are monitored annually and approved for financial support by the Executive Committee.

The main aim of the health quality registries in Sweden is a quality control and improvement of the quality of healthcare in the Swedish health services. The secondary aim of the registries is to be used for research on health and medical services in accordance with SFS 2008:335, capture 7, 5§. (40)

## **SWEDISH QUALITY REGISTRY FOR PAIN REHABILITATION**

To facilitate comparisons of pain rehabilitation programmes in Sweden and to enable audit spirals for single programmes as well as outcome studies, the Swedish Association for Rehabilitation Medicine (SFRM) initiated a national quality registry in 1995. This registry, the Swedish Quality Registry for Pain

rehabilitation (SQRP) has aggregated data since 1998 and compares all patients referred to the majority of Swedish rehabilitation units, firstly at a multidisciplinary assessment and secondly, if considered indicated at the assessment, after the participation in a rehabilitation programme.

Inclusion criteria for the registry: Patients of working age (16 – 64 years) with non-malign persistent (lasting more than 3 months) and complex musculoskeletal pain, which are referred to the participating units for multi-professional assessment and / or multimodal rehabilitation on functional impairments, activity / participation limitations in work and leisure. One limitation of some of the participating units is the lack of rehabilitation resources – i.e. they primarily provide an assessment service for the Swedish Social Insurance Agency regarding the possibility of a person returning to work (see further below).

The main purposes of the national quality registry for pain rehabilitation are:

- To compare patient populations in different types of rehabilitation programmes to initiate a fact-based discussion of patient referral, selection and prioritization, i.e. resource utilization.
- To study the influence of patient characteristics on the outcome of functioning in different domains, including life satisfaction and return to work, i.e. the rehabilitation potential of the patient.
- To compare the effects of the rehabilitation process between differently designed rehabilitation programmes by adjusting for the influence of differences in patient profile, i.e. the effectiveness of the rehabilitation programme.
- To analyse which outcome variables are used for the prospective assessment of work ability.
- To assess outcomes regarding the ability to support one by using data from the Swedish Social Insurance on sick leave benefits and analyse predictive factors, i.e. clinical predictors.
- The registry can also provide a basis for scientific analysis of the above and of the relevance of the biopsychosocial model for pain rehabilitation.

The Board of SQRP consists of a manager, three specialists in rehabilitation medicine, three members representing the participating units, and a Board secretary/coordinator. The registry was started with Västra Götaland County, later with Västerbotten and since 2011, Region Skåne as the authority responsible for the SQRP. Financiers for the registry ongoing development and improvement, and the registry administration are SALAR

and the participating units. Since 2007, annual reports from the registry are transparent (open) at the unit level.

## **SWEDISH SOCIAL INSURANCE**

Social protection in Sweden aims at providing financial security at various stages of a person's life; for families and children, during working life, in case of unemployment, occupational injuries, sickness, handicap and similar situations as well as for the elderly (41). Financial security in case of sickness, work injury, handicap and unemployment is provided partly as payment for loss of income and partly as allowances to certain groups of people.

To be eligible for sickness benefits from the Swedish social insurance, a person must have a medical condition that contributes to work disability. Sickness cash benefit is payable in cases of illness that reduces working capacity by at least 25 per cent. The benefit can be paid in full or three-quarters, half or one quarter of the full rate, depending on the extent of the loss of working capacity. Sickness cash benefit is also paid during medical treatment or rehabilitation for preventive purposes, in order to prevent or shorten the consequences of an illness. Before and until 1 July 2008 (the study time of this thesis), sickness cash benefit was payable for an unlimited period.

Persons between 16 and 64 who suffer from reduced working capacity due to illness or physical or mental disorders can be granted temporary or permanent disability pension. The disability pension is payable in full or three quarters, half or one quarter of the full rate pension. In January 2003, the disability pension was replaced for individuals between 19-29 with "activity compensation", while for individuals between 30-64 years old it is called "sickness compensation". Sickness compensation and activity compensation were maximized to three years, after which it was to be reconsidered impartially again. Activity compensation is to include a continuing rehabilitation plan for the individual. The persons with long-term incapacity to work caused by illness, which assesses to last until the person is eligible for an old age pension, can be granted permanent disability pension.

In 2008, the government introduced several changes to the sickness insurance system. The most prominent feature of the reform involve a fixed time schedule for work ability assessments (the Rehabilitation Chain) which describes how work ability should be assessed in increasingly broader terms as time passes, which affect eligibility for sickness benefits. An ending-point to sickness benefits was also introduced, where benefits after 365 days are only to be granted in cases of severe illness. Further, a system of temporary

disability pension for people with more long-term diseases was abolished to direct the sickness insurance system more towards labour market reintegration.

### ***The incapacity rate***

The Swedish Social Insurance Agency use to report the statistics on sickness benefits as the incapacity rate, which is the mean number of days with sickness benefit days and days with sickness or activity compensation for every person over a one-year period in Sweden. This measure seems to be very broad since it does not pay attention to more detailed measures that also have a large importance when sickness benefits and medical rehabilitation is studied such as persons with full-time and part-time sickness benefits, those who granted temporary or permanent disability pension and so on. However, reduction of the incapacity rate was the publicly declared aim for rehabilitation programmes aimed at the return to work of sick-listed individuals with musculoskeletal disorders.

# AIMS OF THE STUDY

The general aim of this thesis is to improve the knowledge base on assessment and rehabilitation of persons with disability from chronic musculoskeletal pain, using the validated self-report instruments of pain and its consequences included in the SQRP.

The specific aims were:

- **Paper I.** To describe the design and implementation of the SQRP. Furthermore, it aimed to clarify whether there are major variations between patient cohorts with disabilities due to chronic pain, referred to different rehabilitation centres in a country with a homogenous social security and healthcare system.
- **Paper II.** The aim of this study were: a) to analyse which patients with chronic pain were offered participation in rehabilitation programme after assessment in interdisciplinary team with regard to demographical and different pain features, and b) to analyse if there were features in the SQRP which could already before the program predict a positive outcome – on sick leave, after a completed programme.
- **Paper III.** The aim of this study was to explore whether the Multidimensional Pain Inventory (MPI) scale scores changes immediately after a pain rehabilitation programme might indicate which persons disabled by chronic pain that would be on sick leave benefits 1 year later.
- **Paper IV.** This study was carried out to analyse if changes in coping profiles derived from Multidimensional Pain Inventory (MPI) during the rehabilitation programme were associated with changes of the sick leave situation 1 year later.

# **METHODS**

## **DESIGN**

All four studies included in this thesis were retrospective observational registry studies carried out on data collected for auditing purposes. In three of the studies, however, actual sick leave data from the Swedish Social Insurance Agency 1 year after going through a pain rehabilitation programme was used as an independent outcome variable.

## **SETTINGS**

During the 2000's when this study was carried out almost 80 percent of all pain rehabilitation units in Sweden, both public and private, were included in the SQRP. As Table 1 shows most of the SQRP data were collected at the units attached to large university hospitals – Umeå, Linköping and Lund. There was a large disparity between units included in this study as regard referral source as well as regarding the proportion of patients who participate in programme.

The data about the referral source were taken from the form completed by the staff. Most units received their referrals from health care in general and primary care in particular. However, some units had the Social insurance agency as the main referral source. Some of these referrals from the Social Insurance Agency were only about the assessment of working capacity without requesting medical rehabilitation. In some cases, the request for pain rehabilitation programme was included in the referrals, since the programme was a step to the planned job training placement already arranged by the Agency. The units with many referrals from "Else" sources, e.g. Ramlösa, Mösseberg and Stockholm, checked off just the option "Others" in the staff completed form.

Moreover, some of the units had own routines owing to their tasks and working practices. For example, the Högbo unit did not use to register the SQRP questionnaire completed at the assessment if patients did not participate in the programme. Therefore, they reported to SQRP that all 100% of patients were offered and participate in the WAIP.

Some of the units were closed down or had changed organization during the period. The Göteborg unit did not carry out the WAIP but it referred the patients assessed being able to benefit from pain rehabilitation programme to another rehabilitation unit not participating in the SQRP.

**Table 1.** *The SQRP units included in this study.*

Unit	Percent	Referral source			
		Health care <sup>b</sup>	SSIA	Else <sup>c</sup>	WAIP <sup>d</sup>
Ramlösa	3.7	0.3	63.0	36.7	18.2
Huddinge	4.9	17.9	80.9	1.2	25.8
Helsingborg	7.7	79.0	16.8	4.2	21.4
Härnösand	3.0	97.7	1.1	1.1	50.8
Jönköping	4.0	94.0	0.6	5.4	31.4
Karlshamn	1.2	90.7	0.0	9.3	55.6
Hässleholm	2.0	97.2	0.6	2.3	31.3
Linköping	13.3	91.4	0.2	8.4	17.0
Lund	11.3	88.3	0.2	11.5	39.1
Mösseberg	2.0	6.4	39.2	54.4	45.6
Sandviken	2.9	100.0	0.0	0.0	60.0
Stockholm <sup>e</sup>	7.3	36.6	13.4	50.0	35.2
Säter	4.1	66.5	29.6	3.9	50.8
Umeå	12.6	94.2	3.6	2.3	25.8
Uppsala	2.9	96.8	0.0	3.2	40.3
Örebro	6.6	98.6	0.2	1.2	19.9
Göteborg	1.9	0.0	88.3	11.7	50.0
Högbo	2.2	96.3	3.2	0.5	100.0
Sunderbyn	3.8	99.4	0.0	0.6	31.7
Växjö	2.6	96.5	0.0	3.5	48.0
Total	100.0	76.9	12.9	10.2	33.0

<sup>a</sup> – Proportion of each unit's contribution to the collected data.

<sup>b</sup> – Primary health care units (public and private), hospitals and Occupational Medicine units.

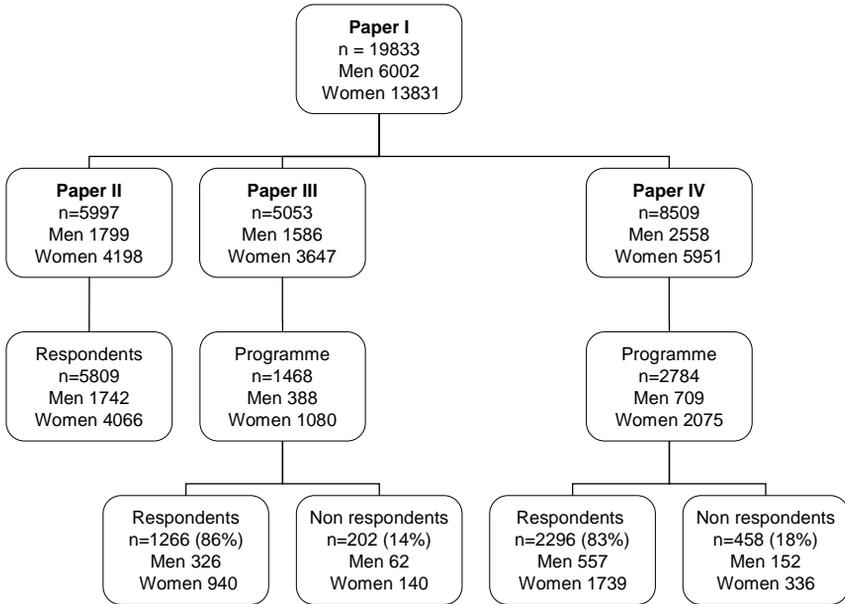
<sup>c</sup> – Employment office, employer, authority, patient self or otherwise.

<sup>d</sup> – WAIP – Proportion of patients who participate in Working Ability Improving Programme.

<sup>e</sup> – Included the SQRP data from the Karolinska University Hospital and Danderyd University Hospital.

## PARTICIPANTS

As of 2007, data from the multidisciplinary assessment of 19 833 patients had been collected. Of these patients, 12 594 were assessed once only, usually for determining vocational ability. Furthermore, 7289 patients were assessed and had participated in rehabilitation programmes. These data were analysed in paper I.



**Figure 2.** Data collection path.

In paper II we used data from 5997 patients who were assessed in during the period 2003 – 2007. One unit, with 188 patients, was omitted did not used to register the SQRP questionnaire completed at the assessment if patients did not participate in its programme.

In paper III we used data from 5053 patients from which 1468 attended pain rehabilitation programme. After the programme, data from 86% of patients were collected. In paper IV, data from 2784 patients, who attended pain rehabilitation programmes, were collected. One unit with 81 patients (37 men and 44 women) was omitted from the analysis since it did not carry out the WAIP but referred the patients to another rehabilitation unit not included in the SQRP. After the programme 2296 (83%) patients responded to the SPQR questionnaire.

## **INSTRUMENTS**

*Demographic data.* The patient's age, sex and education (none/primary/secondary/university level) were collected initially, as was current vocational status and dependence on benefits.

*Pain intensity* was assessed in a self-administered form, where the patient indicated his or her experienced level of pain on a continuous 100-mm horizontal visual analogue scale (VAS) (42, 43). The anchor points were "no pain" = 0 and "worst pain imaginable" = 100. VAS has proven to be user-friendly and reliable (44) has been validity-tested for both chronic and experimentally induced pain (45) and has shown reproducibility for both experimental and chronic pain (46).

*Pain characteristics* in the form of the number of months since the pain started and of the distribution of pain, number of regions in pain defined as 10 different regions ("neck", "arm", "low back", etc.) and an 11th alternative, "varying main localization".

*Patient's beliefs concerning recovery and return to work.* Simple 5 category scales were constructed for this purpose. All patients were asked before the programme to indicate on a self-administered form how convinced they were about their recovery. The anchor points were 1 = 'entirely convinced to recover'; 5 = 'not at all convinced to recover'. Categories 2-4 were not specified. They were also asked how easy they thought it would be to resume work (anchor points 1 = 'very easy'; 5 = 'very difficult') and when this would happen (1 = 'immediately; 5 = 'never').

*Diagnoses relevant to rehabilitation* (pain condition first; up to 4), according ICD-10 (47) was registered at assessment (by the team physician).

*Pain mechanism.* Nociceptive, neuropathic, psychogenic or unknown, classified by the team physician according to the criteria by the International Association for the Study of Pain (48).

*The Hospital Anxiety and Depression scale (HAD)* is a self-screening questionnaire for depression and anxiety (49) It consists of 14 questions, 7 for anxiety and 7 for depression. Each group of questions is given 0–3 points and > 10 points on either set of questions indicates anxiety or depression. Based on data from a large population, the basic psychometric properties of the HAD scale as a self-rating instrument should be considered as quite good in terms of factor structure, inter-correlation, homogeneity and internal consistency (50, 51).

*The Modified Somatic Perception Questionnaire (MSPQ)* was derived for use with chronic backache patients, although it is used with other chronic

pain problems as well. The 13 item scale (each given 0-3 points with a maximum (worst) sum score of 39) was designed to measure heightened somatic awareness among patients with chronic pain from a study of 102 chronic backache patients and its construct validity confirmed on a further study of 200 backache patients. The scale has been shown to be of importance in the understanding of functional disability and the simple self-report design is easy to administer and has high patient compliance (52). The MSPQ appears to be reliable and valid but was only weakly associated with pain outcomes in a study by Deyo et al in 1989 (53). However, we did not employ this instrument in our analyses included in this thesis because of methodological issues as well as large intern non response.

*The Disability Rating Index (DRI)* is a 12 item self-administered tool, where the patients mark on a 100 mm VAS in accordance with their perceived ability to perform daily physical activities in question (0 representing without any difficulty and 100 representing cannot perform at all). The items are divided into three categories: common daily activities, more demanding daily activities and work related or more vigorous activities. The DRI items can be analysed as a total mean index score (all item scores added together and divided by 12) or separately for each of the 12 items (54). The DRI has proven to be both reliable and valid for patients with chronic neck, shoulder and low back pain (54, 55).

*Life Satisfaction Scale. (LiSat-11)* (56) consists estimations of satisfaction with life as a whole as satisfaction in ten specific domains ; vocation, economy, leisure, contact with friends and acquaintances, sexual life, ability to self care (ADL), family life, partner relationship, physical health, and psychological health. Each item has six possible answers 1= very dissatisfying, 2 = dissatisfying, 3 = rather dissatisfying, 4 = rather satisfying, 5 = satisfying and 6 = very satisfying. For comparison purposes, the LiSat-11 scale can be dichotomized into either satisfied (5–6) or not satisfied (1–4) (56).

*The Multidimensional Pain Inventory (MPI)* (57) was developed as a multidimensional assessment instrument for use in patients with chronic pain. Its purpose was to be psychometrically sound and theoretically based on the cognitive-behavioural perspective of chronic pain. The instrument is an integral part of the Multiaxial Assessment of Pain and enables individuals with pain to be classified according to psychosocial and behavioural factors rather than factors related to their physical disease or injury (57, 58).

The MPI (version 2) is a 61 item self-report questionnaire in which recipients are asked to respond on a 7-point numerical scale (range 0–6), with higher scores indicating a greater frequency of occurrence. The MPI is divided into one psychosocial (Part 1) and two behavioural (Parts 2 and 3) sections

making a total of nine empirically derived scales. The first section addresses the impact of pain on an individual's life and contains five subscales: (1) Pain Severity, (2) Interference of daily living, (3) Life Control, and (4) Affective Distress, and (5) Support from significant others. The second section measures the types of responses made by significant others when there is an expression of pain and contains the subscales: (1) Negative Responses, (2) Solicitous Responses, and (3) Distracting Responses. The final section (part 3) assesses the frequency that an individual engages in common activities of daily life. These activities together form the index of General activity.

According to Bergstrom et al 1998 (59), the MPI scale 'General Activity' has been shown not to be applicable in the Swedish context. Therefore, they suggested that the MPI section 3 may only be used for assessing general activity.

The SQRP management decided nevertheless to continue to use the original version of the MPI as a lot of data had already been collected and the MPI-S (59, 60) was not broadly applied within pain rehabilitation units in Sweden. The SQRP registry stores answers to all 61 questions from each patient. Thus, the exclusion of section 3 can be done during analysis.

From a cluster analysis, the MPI yields three prototypic (primary) psychosocial coping clusters: Dysfunctional profile (DYS) profile patients with high pain impact, affective distress, and severe functional limitations; ID (ID) profile patients with poor perception of social support by their significant others in response to pain and Adaptive coper (AC) patients with low pain impact and high levels of functional activity. There are also non-prototypic profiles: the hybrid profile patients are those that share features with more than one prototypic subtype, Anomalous profiles are those that are significantly different from all three prototypic MPI profiles. Unanalyzable, are those that miss more than two of the scale scores used to assign them to a cluster, mostly those who are living alone and therefore do not complete part 2 of the MPI.

The MPI has been widely used to assess the adjustment of chronic patients and the outcomes of treatment interventions. The strength of MPI is its factor structure with three empirically established clusters (58, 61) and its psychometric properties have been replicated in the United States (62) Germany (63), Sweden (60), the Netherlands (64), Finland (65) and Italy (66). There are also validated versions of the MPI in French (67) and in Chinese (68). The MPI has also been validated for other pain conditions such as temporomandibular disorder (69), spinal cord injury (70) and cancer (71).

## **STATISTICS**

Data analysis was conducted using the Statistical Package for Social Sciences (SPSS) for Windows, version 14.0 in Paper III and version 18.0 in Paper II and IV.

In Paper IV we used the algorithm for classification provided in the commercially available computer program for analysis of the MPI data (MPI Software Version 3.0) developed by Rudy (72). The algorithm was calculated according to the multivariate discriminate model developed and validated by Kerns et al (57). and Turk & Rudy (58).

In all papers Pearson's chi-squared test for categorical variables and *t*-test for parametric data were used to estimate a p-value between the groups. A confidence interval of 95% for odds ratio and a p-value < 0.05 for frequency were chosen as statistically significant. With a large data source, even small associations will give statistically significant results (73). Relating the size of the data source to the clinical relevance of any differences is therefore more important in such cases than simply looking at the p-values. A method used to address the problem with multiple comparisons is the Holm-Bonferroni correction (74) which was used in Paper II and III.

A logistic regressions analysis was used in to analyse whether changes of MPI scale scores (Paper III) or changes of MPI profiles (Paper IV) might predict sick leave benefits 1 year after completing a pain rehabilitation programme.

A probability calculus based on the association between individual assessment variables included in the SQRP questionnaire and the register data on dependence on benefits from the Swedish Insurance Agency was carried out by 3 steps forward logistics analysis in Paper II (75).

## **ETHICAL CONSIDERATIONS**

The legislation of using registry data for research purposes has become more elaborate in the last decade due to issues regarding integrity of the individual (76). A definite requirement is that subjects should not be identifiable throughout the research process. In accordance with the regulations of the management of National Health Quality Registers, patients had received written information on the registry and they had an opportunity to decline participation in it. Most of the units apply a written consent from the patients. Patients have the right to demand that their personal information be erased from the registry. In addition, they have the right to demand a registry record and to request that incorrect information should be corrected (76). All data extracted from the registry database for analysis were coded and individual patients could not be identified. Information on individual patients is protected according to 13 § of the Swedish Personal Particulars Law (PuL) (76).

This study was approved by the Regional Ethical Review Board in Umeå (Dnr 2010-168-31 M)

# RESULTS

## PATIENT CHARACTERISTICS

These aims were studied in Papers I and II. Table 2 shows some of demographic characteristic at assessment among the patients included in the SQRP. Compared to the average Swedish population in time when data were collected (77), there were more women among the patients than in the population (51%), more those with secondary school (48%) and less with university education (24%). Many more were unemployed than in the Swedish population (7%).

**Table 2.** Demographic characteristics at assessment.

	Mean (SD)
Age, years	42 (10,1)
	Percent
Women	70
Education	
None	1
Primary school	24
Secondary school	54
University	17
Missing data	4
Occupation	
Employed	59
Unemployed	27
Students	4
Other	7
Missing data	3

When we compared different SQRP units we found considerable variations in demographic profile of the patients between units, as regards educational level (6–38%), as well as concerning the proportion of unemployed (10–67%).

As regards pain characteristics, there was little variation between mean VAS pain intensities and the overall mean pain intensity was high (68 mm). On the other hand, there were apparent differences between patients referred to different units as regards pain duration (29 – 154 months). No of the units reported a mean number of pain locations of less than 10 in a single patient.

Regarding emotional problems, several of the units reported that the patients referred had a mean depression score (HAD) above 8, i.e. the cut-off for “possible depression” (8 – 10) as well as “probable depression” (11 or more). Moreover, the patients included in the registry perceived pronounced activity limitations with a mean DRI sum-score of no less than 54 mm and with little variation between units.

Thus, data indicating that contextual factors, but not pain characteristics, depression or activity limitations vary between patients referred to different units, making comparisons of rehabilitation results difficult. The high response rate in the first data-set made it possible to provide the assessment profiles for the team assessment. On the other hand, a lack of follow-up data from some units influences the possibility of the SQRP as a whole to analyse the relationship between various factors of importance for long-term outcomes of the rehabilitation performed.

## **CLINICAL PREDICTORS OF WORK ABILITY**

Prediction, using the variables in the registry, was studied in Paper II. We analysed which patients with chronic pain were offered participation in rehabilitation programme after assessment in interdisciplinary team with regard to demographical and other pain features, as well as if there were features which could already before program predict a positive outcome – sick leave, after completed programme.

The left column presents the variables predicting that assessment team will offer programme and which were significant in the 3rd step of logistic regression analysis (with exception for “Hard to resume work”). OR and 95% CI are not presented for this analysis. The right column presents results of 3rd step for probability of having NSL 1 year after completed programme among those who participate in programme.

The results showed that, based on registry data, there was a discrepancy in prediction of which person would benefit between the team assessment for which persons that were considered to benefit from a rehabilitation programme and the actual outcomes. Moreover, it seemed that variables that measured pain and its health consequences were of less importance for future sick leave situation than the actual contextual situation and the patients’ own beliefs about the future work situation.

**Table 3.** Results of the 3-step logistic regression analysis for probability of being offered programme by assessment team (OR and 95% CI do not presented in the table) and OR and 95% CI for probability of having NSL, among those who participate in the programme, 1 year after completed programme.

Variables predicting that assessment team will offer programme (with exception for *)	Probability of having NSL 1 year after programme among programme participants			
	Sig.	OR	95% C.I.	
Low age	–	–	–	–
Woman	–	–	–	–
Higher education level	–	–	–	–
Not Employed	0.001	0.79	0.68 - 0.91	
Not Swedish origin	–	–	–	–
Full-time sick leave	<0.001	0.36	0.29 - 0.45	
Years outside work	<0.001	0.81	0.74 - 0.88	
Hard to resume work*	0.003	0.89	0.83 - 0.96	
Later to resume work	–	–	–	–
Not convinced to recover	–	–	–	–
Years with continuous pain	–	–	–	–
MPI Interference	–	–	–	–
MPI Activity index	–	–	–	–
DRI Sitting for a longer time	–	–	–	–
DRI Light work	0.001	0.994	0.991 - 0.998	
Satisfied LiSat - 11 Vocational	0.001	1.11	1.04 - 1.18	
Satisfied LiSat - 11 Physical health	–	–	–	–

NSL – not full-time sick leave benefits.

(–) The variable concerned was not statistically significant at the 3rd step for respectively analysis.

## **PREDICTION OF EFFECTS OF THE REHABILITATION PROGRAMMES**

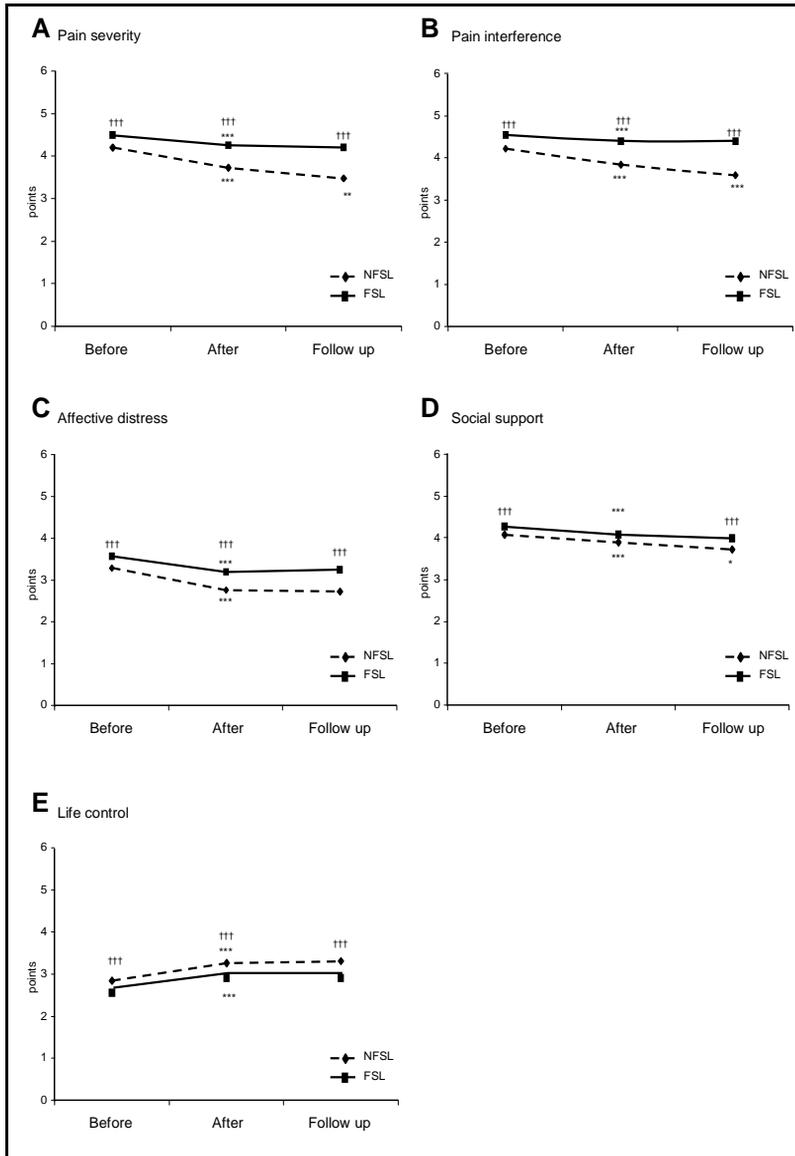
A prediction of the effects of the rehabilitation programmes carried out at the units included in the SQRP was studied in Papers III and IV. As the outcome variable we chose data on sick leave benefits obtained from the SSIA's register. According to Swedish social security regulations the participation in rehabilitation programmes have the aims to improve or to maintain existing working ability. Therefore we compared two groups of patients: those who had 100% sick leave benefits (FSL) and those with no or part-time sick leave benefit (NSL).

We also chose the MPI as the predictor since it describe chronic pain problems and their consequences from several perspectives, and it is useful to explore the various dimensions involved in the experience of chronic pain. Moreover, it has been widely used in a several studies to assess the adjustment of chronic patients and the outcomes of treatment interventions.

By measuring the changes of the MPI scales and the distribution of the profiles respectively and relate these data to the outcome of the programmes carried out at the units included in the SQRP we might spot the factors that should be in focus of the pain rehabilitation. We carried out two different studies: the first on the MPI scales and the second on the MPI coping profiles. A reason for this was that we would offer valuable results also to those who did not had possibility to estimate the MPI profiles in clinical work. The aim of both studies was to explore whether MPI scale scores (paper III) and profile changes ( paper IV) immediately after a pain rehabilitation programme might indicate which persons disabled by chronic pain would be on sick leave benefits 1 year later.

### ***MPI scales***

As figure 3 shows most MPI scale scores showed improvements after completing a pain rehabilitation programme and this improvement was sustained after 1 year. Although both NSL and FSL showed significant improvements in the MPI scale scores it was true particularly for those who had NSL 1 year later. Moreover, those on FSL 1 year after the pain rehabilitation programme reported significantly more disadvantageous MPI scale scores than those on NSL both before entering the pain rehabilitation programme, after the programme as well as 1 year later.



p-value within the sickness benefits groups (i.e. within NFSL and FSL respectively): \*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$ ,  
 p-value between the sickness benefits groups (i.e. between NFSL and FSL):  
 †  $p < 0.001$ .

**Figure 3.** Changes of MPI scales before and after pain management program as well as at 1 year follow up among those with no full time sickness benefits – NFSL (diamonds) and those with full time sickness benefits – FSL (cubes).  $N=872$ . Advantageous changes are: decrease of A, B, C and D; increase of E.

The multiple logistic regression analysis showed that a reduced scale score in Pain severity [OR 0.85, (95% CI 0.73–0.99)] and in Interference [OR 0.73, (95% CI 0.61–0.87)], were negatively associated with being part of the FSL group. Neither gender, age nor any of the other scale score changes on the MPI scales showed any significant association with the outcome variable.

### ***MPI profiles***

After the pain rehabilitation programmes, there was a significantly decreased share of DYS profiles among both men (44 % before compared to 31% after), and women (39% to 26%) as well as an increased share of AC profiles (men 15% to 24% and women 14% to 24%). There were no changes in the shares of other MPI profiles. Significantly more women than men showed a DYS profile both before as well as after rehabilitation programme. An opposite distribution was noted among those with Unanalyzable profiles.

Both men and women with DYS profiles had higher levels of sick-leave compared to AC and ID, before as well as after a completed rehabilitation programme. The DYS profile was underrepresented after the programme among those with NSL while it was correspondingly overrepresented among those with FSL, in particular as compared to those with AC profiles. Among women a similar trend was found. However, after going through a programme significantly fewer women had a DYS profile among those with NSL and PSL. On the other hand, more women displayed a DYS profile among those with FSL in comparison to those with ID and AC profiles. Among men there were no significant changes in the MPI profiles distribution in the different sick leave groups.

Moreover, those who had a DYS profile before the programme showed a stronger tendency to move to other profiles during the programme than those with other profiles, in particular among women who moved mainly to the AC profile. AC profiles among men and ID profiles among women were relatively stable.

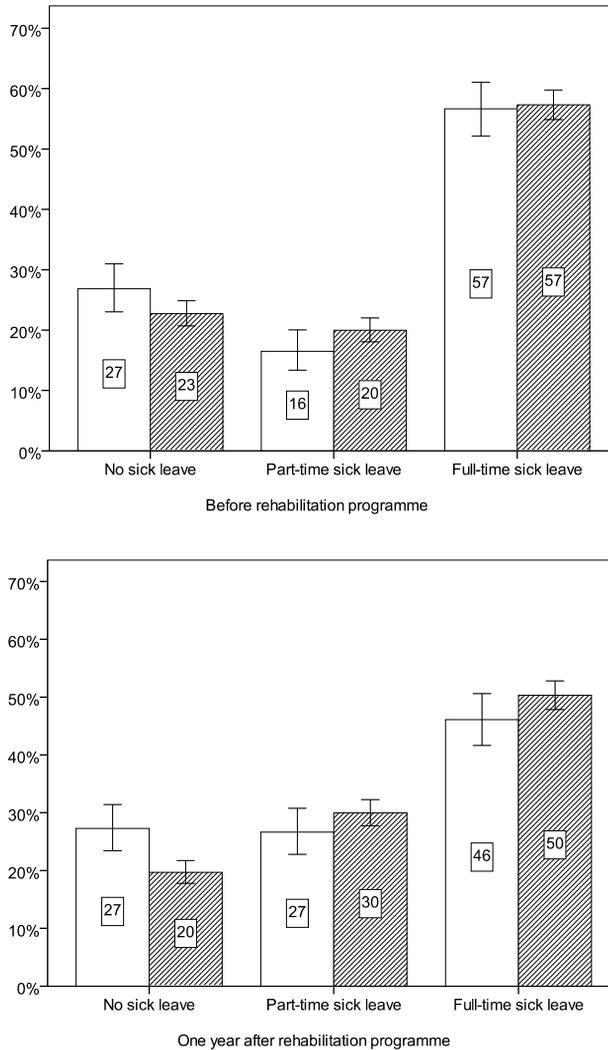
**Table 4.** Results of logistic regression analysis presented as OR and 95% CI for having NSL (not full-time sick leave) after work capacity improving pain rehabilitation programme among men and women. Those who were AC before and remained AC after programme were used as a reference with OR set at 1.

	Men n=398				Women n=1320			
	n	%	OR	95 %CI	n	%	OR	95 %CI
AC-AC	51	13	1.00		135	10	1.00	
AC-DYS	12	3	1.04	0.24 – 4.48	35	3	0.33	0.16 – 0.72
AC-ID	7	2	0.97	0.17 – 5.61	46	3	0.82	0.41 – 1.66
DYS -DYS	128	32	0.24	0.12 – 0.48	316	24	0.27	0.18 – 0.41
DYS-ID	37	9	0.17	0.06 – 0.42	116	9	0.49	0.30 – 0.82
DYS-AC	47	12	0.69	0.29 – 1.62	170	13	0.66	0.41 – 1.05
ID-ID	78	20	0.60	0.28 – 1.29	374	28	0.53	0.35 – 0.80
ID-DYS	14	4	0.39	0.12 – 1.31	57	4	0.29	0.15 – 0.56
ID-AC	24	6	1.40	0.44 – 4.50	71	5	0.90	0.49 – 1.65

AC – Adaptive copier, DYS – Dysfunctional, ID – Interpersonally disturbed

The results of multivariate logistic regression with sick leave 1 year after rehabilitation as the independent variable is presented in Table 4. Among men, those who remained with a DYS profile or moved from a DYS profile to an ID profile were associated with a significantly lower possibility (OR 0.35 – 0.27) for an improved sick leave situation. Among women, each combination where moving into a DYS profile was involved after a completed pain rehabilitation programme, was associated with a considerably lower possibility for an improved sick leave situation. On the contrary those with a DYS profile who changed into an AC profile after the programme had an odds ratio close to 1. Also those with an ID profile who remained in the same profile had a lower possibility for an improved sick leave situation, although this association was of lower magnitude than that with a DYS profile. Thus, there were clear gender differences regarding MPI profile changes after going through a rehabilitation programme with respect to the possibility of getting an improved sick leave situation, i.e. no or a decreased level of sick leave.

## Rehabilitation programme and sick leave



**Figure 4.** Levels of sick leave before and 1 year after pain rehabilitation programme. Men – white bar, Women – dashed bar. Percents, n=2296. (From Paper IV).

Observationally, in paper IV, the presently used cognitive behavioural pain rehabilitation programmes in Sweden, seemed to decrease the levels of full-time sick leave 1 year later (Figure 3), even if this decrease was paralleled by an increase of part-time sick leave rather than an increase of having no sick leave.

The only gender difference was found among those with no sick leave 1 year after programme – women were significantly fewer in this group compared to men.

# **DISCUSSION**

## **PATIENT CHARACTERISTICS**

There were major differences in some characteristics of chronic pain patients referred to Swedish pain rehabilitation programmes, e.g. in education level, pain duration as well concerning the proportion of unemployed. These differences are mainly contextual, which is remarkable considering that Sweden has uniform public social security. One explanation to this is that the units reporting to SQRP have different tasks and agreements with different prescribers – health care, Social insurance agency and employment office. These differences in the characteristics must be taken into account when attempting to compare outcomes from different programmes.

On the other hand, none of the units reported a mean number of pain locations of less than 10 in a single patient, which means that most of the patients had chronic widespread pain or fibromyalgia. Patients with chronic widespread pain have been found to present with more severe impairment of health status than those with no chronic pain or with chronic regional pain (78).

Several psychosocial factors, such as belonging to a lower socio-economic group, being an immigrant, living in a compromised housing area, having a lower educational level, experiencing lower social support and having a family history of chronic pain, were associated with the populations with chronic widespread pain or fibromyalgia (78-80). Even if there is moderately strong scientific evidence that multimodal rehabilitation efforts will lead to overall positive effects in fibromyalgia (7, 81), the results from studies on rehabilitation of these patients are contradictory and there appears to be little scientific evidence for the effectiveness of multidisciplinary rehabilitation. This might influence the results from the SQRP units, i.e. the results in this study. A study carried out on a different diagnosis might contribute to more realistic results of effects of pain rehabilitation in the SQRP units.

This study showed that there were more women than men who were referred to rehabilitation units as well as participated in rehabilitation programmes. Consequently, there were also more women who were on sick leave. Women are over-represented in seeking care for many painful musculoskeletal disorders (10). Moreover, it seems to be a special vulnerability for persistence of pain in females (3). The explanation for this over-representation of women is largely unexplained. Women have been shown to have increased sensitivity to pain in experimental and clinical situations (82). It has also been proposed that there are sex differences in family factors, affective

disorders, reaction to distress, hormones, cognitive factors, social responsibilities and coping strategies that may promote disability from chronic pain in women (83).

## **SELECTION TO REHABILITATION PROGRAMME**

In Paper II we analysed which patients disabled with chronic pain that were offered participation in the rehabilitation programme after assessment in interdisciplinary teams with regard to demographical and pain features as well as activity and life satisfaction measures from the registry data. Although, there was a comparatively small explanatory power of the registry data, being a woman, having higher education, being employed and being of Swedish origin as well as not having full-time sick leave were proven to increase the chances of being selected for rehabilitation. It was remarkable that the variables which were directly connected to pain and its consequences, e.g. MPI and DRI had little influence. However, it seemed that the assessment teams took into account other (latent or clinical) variables in consideration when they offered the participation in rehabilitation programmes aimed to improve or maintain working ability.

## **CLINICAL PREDICTORS OF WORK ABILITY**

Our results presented in Paper II show that there was a comparatively small explanatory power of the registry data, regarding features which could already before the programme predict a positive outcome, i.e. less sick leave. The strongest predictive factors for a return to work were the having full time sick leave and disadvantageous employment, which can be understandable. We found also that patients' own beliefs and expectations about future working ability had a strong predictive factor for a return to work. Thus, we confirmed the results from previous studies that have been shown individual the individuals' expectations as a strong predictive factor for a return to work (84, 85). Moreover, it has also been found that patients' pre-treatment beliefs about recovery influenced the long-term decrease of pain intensity (86).

## **EFFECTS OF THE REHABILITATION PROGRAMMES**

The effects of the rehabilitation programmes aimed at improving or to maintain existing working ability carried out at the units included in the SQRP was studied in Papers III and IV. As the outcome variable we chose data on sick leave benefits obtained from the SSIA registry. The aim of both

studies was to explore whether MPI scale score (paper III) and profile changes (paper IV) immediately after a pain rehabilitation programme might indicate which persons disabled by chronic pain would be on sick leave benefits 1 year later.

Predicting the effects of rehabilitation programmes aimed at improving working ability carried out at the units included in the SQRP was studied in Papers III and IV. As the outcome variable we chose data on sick leave benefits obtained from the SSIA's register and the aim of both studies was to explore whether MPI scale score (paper III) and profile changes (paper IV) immediately after a pain rehabilitation programme might indicate which persons disabled by chronic pain would be on sick leave benefits 1 year later.

We also chose the MPI since it was developed for patients with chronic pain and is thus condition specific. MPI describe chronic pain problems and their consequences from several perspectives, and it is a useful tool to explore the various dimensions involved in the experience of chronic pain. Moreover, it has been widely used in a numerous of studies assessing the adjustment of chronic patients and the outcomes of treatment interventions.

The most important outcome from study III and IV was that the presently applied cognitive-behavioural pain rehabilitation programmes in Sweden, decreased the levels of full-time sick leave 1 year later. Even if this decrease resulted in an increase of part-time sick leave rather than an increase of having no sick leave, we consider this result as very encouraging. Patients, health care staff, as well as social insurance officials, but not by employers consider part-time sick leave is considered as an appropriate transition from a period of sickness to work (87).

It should be underlined that the present data are observational, without any control group. Nevertheless, the changes in the presently used independent outcome variable sick leave 1 year after rehabilitation indicate an improvement, whether specific from the intervention or due to the time factor. Many of these patients had had their pain and their sick leave for several years (paper I), making the time factor less credible.

In addition, there has recently been an upgrade of the validity of observational studies in the literature. Observational studies are usually considered to be of lower scientific value than randomised controlled trials (RCTs), since there is no true control and they are commonly considered to overestimate treatment effects. However, it has been shown that the results of observational studies carried out on large patient data neither overestimate the magnitude of the effects of treatment nor differ qualitatively from those obtained in RCTs on the same topic (88). As Black

(89) suggests, a randomised trial may be inappropriate when the effectiveness of the intervention depends on the subject's active participation, which, in turn, depends on the subject's beliefs and preferences. It is widely recognised that a clinical audit is successful in improving the quality of healthcare only if the participating clinicians have a sense of ownership of the process. The same may be true for many interventions for which clinicians, or patients, or both, have a preference (despite agreeing to random allocation), and where patients need to participate in the intervention. However, observational studies often lack details of treatment, outcome assessment, patient characteristics, and confounding assessment, which make them inadequate to compare study designs or allow other meaningful interpretation of results (90). These issues were at least partly avoided in this study by using very detailed registry data.

### ***MPI scales***

The main result in paper III is that reductions in the Interference as well as in the Pain Severity scale scores at the end of the rehabilitation programme predicted a high probability of having no or part-time sick leave benefits 1 year later. Thus, positive changes in the MPI scale scores for Pain Severity and Interference were strong predictors of future work ability. In some other studies of separate MPI scales, the Interference scale has been shown to predict chronicity after acute symptom onset (91, 92)

We also found that MPI scale scores showed improvements after completing a pain rehabilitation programme and this improvement was sustained after 1 year. Although both NSL and FSL showed significant improvements in the MPI scale scores it was true particularly for those who were NSL 1 year later. Moreover, those on FSL 1 year after the pain rehabilitation programme reported significantly more disadvantageous MPI scale scores than those on NSL both before entering the pain rehabilitation programme, after the programme as well as 1 year later. This positive and long-lasting effect of cognitive behavioural rehabilitation programmes is in accordance with other studies (28, 93-98)

We found that a decrease in MPI scales scores for Interference immediately after the pain rehabilitation programme decreased the risk of being on full-time sick leave 1 year later. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) now recommends the MPI pain interference scale as a core outcome measure for (perceived) physical functioning in clinical trials for efficacy and effectiveness of chronic pain treatment (99).

The Interference scale, which may be considered to include ICF components of both activities and participation, might represent the core of suffering among persons disabled with pain.

The Interference scale consists of 11 items concerning how pain interferes with a person's life, including interference with family and marital functioning, work, social recreational activities and satisfaction with current level of functioning. These items cover almost all aspects of the consequences of pain, which might explain why the Interference scale had such a strong association with full-time sick leave in the present study population. Moreover, the Interference scale might be considered to include the ICF component of activity limitations: influence on daily activity, on working capacity, on leisure time, on household and work activities. It may also signal participation restrictions: less pleasure from leisure time, and from family/friends, inability to share work experiences, change in relations to relatives and friends and inability to plan for the future.

### ***MPI profiles***

In study IV we present the outcome of profile changes pre- and post treatment separately for men and women. The result of this study was that persons staying with or moving into a DYS profile after a rehabilitation programme had a low probability of having no or part-time sick leave. Our study confirmed previous research (100, 101), that persons with DYS profiles have higher levels of sick-leave compared to AC and ID. This profile is characterized by high pain severity, high interference, high affective distress, low life control as well as low activity level. Moreover, those persons appear to have sub-optimal coping strategies compared to AC (58).

An ID profile was also associated with less chance to improve the sick leave situation, in particular among women. The ID profile is characterised by low levels of perceived support from significant others. Some studies (102) indicate that the difference between patients with ID and DYS profile is vague and there are no differences between these two profiles on a global measure of psychological distress.

The results suggested that rehabilitation programmes that were performed in units included in the SQRP seemed to have insufficient effect on women with DYS profile as well on men who failed to become adaptive copers. One explanation for this seemed to be that dysfunctional patients engage in more catastrophizing and overt pain behaviour (102). It has been suggested that both solicitous and punishing responses from significant others were negatively associated with acceptance of pain (103) as well as the empirical

evidence demonstrates a strong and consistent relationship between marital satisfaction and psychological distress in pain samples (83). Thus, some changes in rehabilitation programmes are needed. The patients with DYS profile may benefit from interventions that guide them toward decreasing pain catastrophizing by learning more adaptive means of communicating their pain experience and desire for support. On the other hand, the rehabilitation of ID patients should perhaps have more focus on improving the coping of both patient and family.

Moreover, we found gender differences regarding MPI profile changes after rehabilitation programme with respect to the possibility of having no full-sick leave 1 year after completed programme. Gender differences have also been reported to have a major influence on the results of treatment of patients with chronic musculoskeletal pain (25, 26), although others have found no gender difference in treatment outcome (22). An explanation offered for this may be the pre-treatment expectations of rehabilitation outcome between men and women (104). While men are more likely to expect that the treatment would enable them to cope better with being a spouse and that the cause of their pain would be found, women are more likely to expect that the treatment would enable them to better accept the fact that they could no longer do what they were able to do in the past, and that they would have fewer problems with household activities. We discussed that these differences might lead among women to insight that sick leave is necessary, albeit in part-time and temporary, to maintain full-time working ability. On the other hand, men's expectations of being a better spouse and women's expectations of having fewer problems with household activities could be explained by the distribution of domestic work between spouses – women who do most of domestic work and men who try to fulfil the demands of contemporary family life of equal distribution duties in the family.

The MPI is widely used for assessing the adjustment of chronic patients, the outcomes of treatment interventions and has the potential for matching treatments to patient subgroups (105). However, the MPI has limitations. Patients living alone can not be classified into clusters, because they do not complete part 2 of the MPI (72). Another weakness is about the possible instability of the classification (102, 106) and it has been recommended that the MPI classification should preferably be used with other clinical data when attempting to match treatment to patients needs. Furthermore, it has been shown in a Swedish study that about 30% of these patients are unclassifiable(107).

## ICF

It has been recommended the use of the MPI Interference scale as a core outcome measure for physical functioning in clinical trials of the efficacy and effectiveness of chronic pain treatment (99). We found that this scale may be considered to include ICF components of both activities and participation and might represent the core of suffering among persons disabled with pain. Moreover, we ponder that even other MPI scales can be linked to the ICF components, as shown in Table 5.

**Table 5.** *Tentative classification of MPI scales as ICF components.*

Multidimensional Pain Inventory scale	ICF components
Pain severity	Body structures and functions
Interference	Activity/Participation
Life Control	Participation
Affective Distress	Body structures and functions
Social Support	Environmental factors
Punishing, Solicitous, Distraction	Environmental factors
Activity Index	Activity

The Pain severity scale consists of items concerning level, severity and frequency of pain a person experiences. The scale Affective distress includes ratings of mood, irritability and anxiety. Thus these two scales describe physiological and psychological body functions respectively.

The Interference scale consists of 11 items concerning how pain interferes with a person's life, including interference with family and marital functioning, work, social recreational activities and satisfaction with current level of functioning. These items cover almost all aspects of the consequences of pain, which might explain why the Interference scale had such a strong association with full-time sick leave in the present study population. Moreover, the Interference scale might be considered to include the ICF component of activity limitations: influence on daily activity, on working capacity, on leisure time, on household and work activities. It may also signal participation restrictions: less pleasure from leisure time, and from family/friends, inability to share work experiences, change in relations to relatives and friends and inability to plan for the future.

The MPI scale Activity Index concerning the how often an individual perform a task or action, without taking the individual's involvement in the task or action into account. The scale Life Control measures patients' perceived control over pain and life events, which can be considered rather as the ICF component participation.

The MPI scale Social support appraises of the amount of support received from a spouse or significant other while the Punishing, Solicitous and Distraction response scales deal about a person's experience of how different reactions from the significant others affects one's pain. Thus, it would be considered as environmental factors.

Although this classification can be disputed since some of the MPI scales can included different ICF components, there was no doubt that the scales Social support Punishing, Solicitous and Distraction responses represented environmental factors. Moreover, the MPI coping profile ID is entirely defined by responses from the persons' environment. Moreover, the supposed environmental ICF component Social Support is included in other two prototypic profiles. This also enhances importance of contextual factors, at least the environmental ones, in capturing important aspects of work functioning (38).

## **METHODOLOGICAL CONSIDERATIONS**

In this section, some methodological considerations are discussed regarding the use of registry data. The discussion is based on a framework for evaluation of secondary data sources for research proposed by Sørensen et al (73).

Development in technology has led to a considerable increase in the number of individual-based data sources, registries, data bases, and information systems that may be of value in epidemiological research, and the number of studies that are based on secondary data may be expected to increase.

Secondary data in research are data which have not been collected with a specific research purpose, e.g. individual-based data sources, registries, data bases, and information systems. Such data are often collected for management, administration and planning, evaluation of activities within health care and so on. The main advantage of using secondary data sources is that they already exist as well as that the costs of the project are reduced markedly. The disadvantages of secondary data are related to the fact that their selection and quality, and the methods of their collection, are not under the control of the researcher, and that they are sometimes impossible to validate.

Factors that can affect the research on data such as healthcare registry data are: the accuracy and degree of completeness of the data registered, completeness of registration of the individuals, the size of the data source, and the possibility of linkage to other data sources and registration period.

### ***The accuracy and degree of completeness of the data registered***

The accuracy of the data registered refers to validity and precision of questionnaire used in a registry. The questionnaires included in the SQRP are instruments vital to characterizing pain and its sequelae that were available in Swedish at the time when the SQRP started (1995–1997). Validity and reliability as well as sensitivity to changes that could be hypothesized to occur were also taken into account.

High response rates are usually considered to give a fair picture of the studied population, while low response rate poses a threat to the validity of quantitative research. The data within the SQRP were collected primarily for clinical audit rather than research purposes. It was not possible for the authors to influence how well the questionnaires were filled out at the various units, except by means of the general instructions given to all the participating units. However, the reports from the units indicated that more than 90% of the patients filled out the questionnaire at the first assessment. As presented in Paper I the second data-set (after rehabilitation) had a response rate of 83–88% for the instruments examined, the third data-set (the 1 year follow-up) had a rate of only 53–56%. When analysed further, this turned out to be due to severe lack of data from a limited number of participating rehabilitation units during extended time periods, whereas the majority of units did well. Moreover, in Paper III the attrition rate was 14% in the second data-set and 41% in the third data-set, which was the reason that the analysis of the association between the MPI scale changes 1 year after completed rehabilitation programme and sick leave situation at the same time could not be performed.

One explanation for the low non-response rate at the first two points might be that the initial and post-programme questionnaires were collected during the time when the participants were in a position of dependence on the programme staff, although it was stressed (according to ethical research norms), that filling in the questionnaire was voluntary and would not influence the therapy. The questionnaire at the follow-up 1 year later was mailed to the participants and if no answer was obtained within 1 month a reminder was mailed to the non-responders. This may still have been

ineffective and might have contributed to the high non-response rate at that time.

### ***Completeness of registration of the individuals***

By this means the proportion of individuals in the target population which is correctly classified in the data source. The SQRP includes approximately 80% of pain management care programmes in Sweden, from the public as well as the private sector. Thus, the results of this study can be generalised to a majority of employed individuals in Sweden who suffered chronic musculoskeletal pain and who participated in pain rehabilitation programmes aimed at improving work ability.

### ***The size of the data source***

The size of the data source, i.e. the number of people and the number of variables registered, may have an impact in the results. In a large data source, even small associations will give statistically significant results. Relating the size of the data source to the clinical relevance of any differences is therefore more important in such cases than simply looking at the p-values. In statistics, a method used to address the problem with multiple comparisons is the Holm-Bonferroni correction (74), which was used in papers II and III.

Statistical interpretation of the registry data can result in that even minor differences pre - vs. post-rehabilitation may be statistically significant at the group level. However, it is important to interpret such results in view of the clinical situation and to keep in mind or to determine what a minimum clinically important change is (108). There are few clinically relevant cut-off points, e.g. for VAS pain (109, 110), HAD (49) and for MPI Interference scale (99).

### ***Possibility of linkage to other data sources***

In Sweden, each person is assigned a unique civil registration number at birth, allowing linkage between several data systems. It makes it possible to link the SQRP data with the data concerning all financial benefits in the Swedish Security Insurance Agency Data base. Thus, we had the opportunity to use independent registry data on sick leave benefits for all study participants precisely 1 year after completing pain rehabilitation programme.

### ***Registration Period***

Often data sources only contain cross-sectional registrations, which reduce the possibility for analytical studies. With respect to longitudinal studies, information concerning the registration period(s) is essential for the design in order to relate exposure and effect to possible induction and latent periods. We used in this study the SQRP data from period 2003 – 2007. In January 2003, the disability pension was replaced for individuals between 19-29 with “activity compensation”, while for individuals between 30-64 years old it was called “sickness compensation”. Sickness compensation and activity compensation were maximized to three years, after which it was to be reconsidered impartially again. Moreover, the sick leave that lasted more the 12 months could be converted to temporary pension as above. In 2008, the government introduced a fixed time schedule for work ability assessments (the Rehabilitation Chain). An ending-point to sick leave benefits was introduced, where benefits after 365 days are only to be granted in cases of severe illness. Further, a system of temporary disability pension for people with more long-term diseases was abolished to direct the sickness insurance system more towards labour market reintegration. Therefore we included in this study the SQRP data collected in 2003 – 2007.

## CONCLUSIONS

- The SQRP provides a basis for scientific works since it use the validated self-report instruments of pain and its consequences and contain a large amount of patient's data. However, a lack of follow-up data from some units influences the opportunity of the SQRP to analyse long-term outcomes.
- It seemed that that contextual factors such as patients' own beliefs and expectations, education, gender, actual sick leave and employment situation as well as assessment team's latent or clinical variables have more importance for the effect of rehabilitation programme than pain characteristics, depression or activity limitation.
- The Multidimensional Pain Inventory (MPI) scale scores and MPI profiles can be used for assessing the outcomes of treatment interventions. Our observational data indicated that a reduction in MPI scales scores for Pain severity and Interference decreased the risk of being on full-time sick leave. On the other hand, the MPI Dysfunctional coping profile, among both men and women, and Interpersonally disturbed, among women, were associated with higher odds for being on full-time sick leave.
- Attending cognitive behavioural pain rehabilitation programmes in Sweden resulted in improvements of the MPI scales after completing a pain rehabilitation programme and this improvement was sustained after 1 year. Moreover, these programmes decreased the levels of full-time sick leave 1 year after completed programme.
- The findings suggest also the need to tailor rehabilitative strategies differently for men and women as well as for different coping profiles.

## **FUTURE RESEARCH**

This thesis analysed and answered only few of the SQRP's aims and research questions – above all that the cognitive-behavioural pain rehabilitation programmes decreased the levels of full-time sick leave 1 year after completed programme.

During the work many new questions raised, e.g. the importance of high attrition rate at the 1 year follow-up, gender differences among others. A lot of instrument included in the SQRP were outside the aims of this thesis and they might give more knowledge about chronic pain consequences. The registry has a large amount of aggregated data and these analyses would not be difficult to perform. One of the most important issues within chronic rehabilitation research is what kind of multimodal rehabilitation is best regarding improved work ability. However, this issue cannot be answered by the SQRP, since we do not have appropriate data.

The web-based SQRP, available since 2009, enables now the different units to get outcome reports directly on-line. They can also compare their own data with the national means. Moreover, the registry board has noticed that attrition rate has been significantly lower since introducing the web-based SQRP. Hopefully it will lead to increased interest in research, at least at the unit level.

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