

# Rehabilitation in primary care

For patients with neck and back pain focusing on work ability

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CHARLOTTE POST SENNEHED  
ORTHOPEDICS | FACULTY OF MEDICINE | LUND UNIVERSITY





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<p>People of all ages suffer from musculoskeletal pain causing reduced functioning in daily life. The impact of work disability includes societal and economic consequences for the individual and the society including significant loss of health quality of life as well as loss of productivity.</p> <p>The overall aim of this thesis was to obtain deeper knowledge on assessment, referrals and rehabilitation of patients with musculoskeletal pain in a primary care setting, focusing on work ability.</p> <p>Methods: Study I was a methodological study testing the validity of a new short questionnaire, focusing on work-related psychosocial risk factors at the workplace. We analysed content (n=111 experts), structural and concurrent validity (n=75 patients). Study II was a prospective randomised controlled trial in primary care with one year follow-up and included 352 patients (intervention group, n=146 and reference group, n=206). The intervention was a workplace dialogue with the patient and the employer in addition to structured physiotherapy. The main outcome was work ability assessed by a weekly text message during one year after baseline. Study III was a prospective register study focusing on health care provider and community related factors on referral rates to multimodal rehabilitation (referrals/1000 registered patients at the primary care center), 153 primary care centers were included. Study IV was a feasibility study based on a register cohort in primary care with two years follow-up for patients undergoing multimodal rehabilitation (n=3831) and a reference cohort (n=101 877) with the same diagnosis. Main outcome was work ability two years after baseline.</p> <p>Results: The overall validity of the new short "Blue flags" questionnaire was acceptable. An early workplace dialogue in addition to structural physiotherapy improved work ability significantly compared to the reference group. Referral rates to multimodal rehabilitation were positively associated with primary care centers located in medium and large sized communities with higher socioeconomic status among the registered population, private primary care centers and primary care centers providing their own multimodal rehabilitation. We found limited feasibility of identifying two comparable groups for evaluation of the multimodal rehabilitation programme in primary care. Exclusion was mainly due to the sick leave criterion and due to low illness burden in the reference cohort.</p> <p>This thesis has deepened the knowledge on musculoskeletal pain rehabilitation in primary care by focusing on the patients work ability. A new assessment tool has been validated and an early intervention with workplace dialogue was found effective. Furthermore, knowledge has deepened about the impact of organisational and community factors on referral rates to rehabilitation in primary care. Finally, this thesis highlights the difficulties with evaluating effect of multimodal rehabilitation using register based data.</p>			
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# Abstract

People of all ages suffer from musculoskeletal pain, causing reduced daily life capacity. The impact of work disability includes societal and economic consequences for the individual and the society including significant loss of health quality of life as well as decreased work ability.

The overall aim of this thesis was to obtain deeper knowledge on assessment, referrals and rehabilitation of patients with musculoskeletal pain in a primary care setting, focusing on work ability.

Methods: Study I was a methodological study testing the validity of a new short questionnaire, focusing work-related psychosocial risk factors at the workplace. We analysed content (n=111 experts), structural and concurrent validity (n=75 patients). Study II was a prospective randomised controlled trial in primary care with one year follow-up and included 352 patients (intervention group, n=146 and reference group, n=206). The intervention was a workplace dialogue with the patient and the employer in addition to structured physiotherapy. Main outcome was work ability assessed by a weekly text message during one year after baseline. Study III was a prospective register study focusing health care provider and community related factors on referrals to multimodal rehabilitation (referrals/1000 registered patients at the primary care center), 153 primary care centers were included. Study IV was a feasibility study based on a register cohort in primary care with two years follow-up for patients undergoing multimodal rehabilitation (MMR) (n=3831) and a reference cohort (n=101 877) with the same diagnosis during 2010-2012. Main outcome was work ability two years after baseline.

Results: The overall validity in the new short “Blue flags” questionnaire was acceptable. An early workplace dialogue in addition to structural physiotherapy improved work ability significantly compared to the reference group. Referral rates to MMR were positively associated with primary care centers located in larger sized communities with higher socioeconomic status among the registered population, private primary care centers and primary care centers providing their own multimodal rehabilitation. We found limited feasibility of identifying two comparable groups for evaluation of the multimodal rehabilitation programme in primary care. Exclusion was mainly due to the sick leave criterion and due to low illness burden in the reference cohort.

This thesis has deepened the knowledge on musculoskeletal pain rehabilitation in primary care focusing the patients work ability. A new assessment tool has been validated and an early intervention with workplace dialogue was found effective. Furthermore, knowledge has deepened about the impact of organisational and community factors on referral rates to rehabilitation in primary care. Finally this thesis highlights the difficulties with evaluating effect of multimodal rehabilitation using register based data.

# Svensk sammanfattning

Människor i alla åldrar lider av muskuloskeletal smärta som kan orsaka nedsatt funktion och aktivitetsförmåga. Detta innebär ofta betydande förlust av livskvaliteten samt ekonomiska konsekvenser för individen och samhället. Under 2012 bestod nästan en tredjedel av det totala antalet besök i primärvården i Sverige av patienter med muskuloskeletal smärta. Patienter med ryggsmärta utnyttjade dubbelt så mycket vårdresurser jämfört med den totala befolkningen. Återkommande muskuloskeletal smärta samt utveckling av kroniska besvär är hög, cirka en tredjedel av patienterna med tidigare akut ryggsmärta beräknas att få återkommande smärtproblem inom ett år. Det finns olika behandlingsalternativ för att stärka arbetsförmåga för dem med muskuloskeletal smärta, från unimodal till multimodal rehabilitering.

Det övergripande syftet med denna avhandling var:

- pröva ett frågeformulär med fokus på psykosociala riskfaktorer på arbetsplatsen
- studera primärvårdens remittering till multimodal rehabilitering
- utvärdera effekten av rehabilitering för patienter med muskuloskeletal smärta och nedsatt arbetsförmåga.

Studie I var en metodologisk studie som testade validiteten av ett nytt kort frågeformulär med fokus på arbetsrelaterade psykosociala riskfaktorer på arbetsplatsen. Vi analyserade innehåll (n=111 experter), strukturell och samtidig validitet (n=75 patienter). Resultatet var att den övergripande validiteten i det nya korta frågeformuläret "Blå flaggor" var acceptabel.

Studie II var en prospektiv randomiserad kontrollerad studie i primärvården med ett års uppföljning och inkluderade 352 patienter med akut/subakut smärta i nacke och/eller rygg (interventionsgrupp, n=146 och referensgrupp, n=206). Interventionen var Arbetsplats Dialog för Arbetsåtergång (ADA) där den behandlande fysioterapeuten hade dialog/samtal i flera steg med patienten och arbetsgivaren som komplement till strukturerad fysioterapi. Huvudutfall var egenrapporterad arbetsförmåga vid ettårsuppföljningen. Att ha arbetsförmåga definierades i denna studie som att inte vara sjukskriven under fyra veckor i sträck. Patienterna rapporterade med veckovisa SMS under ett år efter behandlingens start antal dagar med sjukskrivning den föregående veckan. Resultatet visade att en tidig arbetsplatsdialog som komplement till strukturerad fysioterapi förbättrade

arbetsförmågan jämfört med referensgruppen som fick enbart strukturerad fysioterapi.

Studie III var en prospektiv registerbaserad observationsstudie med fokus på vårdgivarfaktorer och samhällsrelaterade faktorer för remittering till multimodal rehabilitering (antal remisser/1000 registrerade patienter på vårdcentralen) där 153 vårdcentraler inkluderades i studien. Resultatet visade att antalet remisser till multimodal rehabilitering var positivt associerat med vårdcentraler i medelstora och stora samhällen med högre socioekonomisk status hos de registrerade patienterna på vårdcentralen, privata vårdcentraler samt vårdcentraler som tillhandahöll egen multimodal rehabilitering.

Studie IV var en registerbaserad observationsstudie inom primärvården. Syftet var att studera genomförbarheten för att mäta effekt av multimodal rehabilitering jämfört med en referensgrupp. Patienter med muskuloskeletal smärta (främst smärta i nacke och rygg) som genomgått multimodal rehabilitering, under åren 2010-2012 (n=3831) jämfördes med en referensgrupp, med samma diagnos under samma tid (n=101 877). Huvudutfallet var arbetsförmåga två år efter baslinjen, som mättes med antal sjukskrivningsdagar under fyra veckor i sträck. Resultatet visade att genomförbarheten att identifiera två jämförbara grupper för utvärdering av effekt av multimodal rehabilitering i primärvården var begränsad. Detta berodde främst på lägre sjukdomsbörda i referensgruppen samt att vi selekterade de med sjukskrivning 91-180 dagar i båda grupperna året innan.

Denna avhandling har fördjupat kunskapen om rehabilitering för patienter med muskuloskeletal smärta inom primärvården med fokus på patientens arbetsförmåga. Ett nytt frågeformulär har validerats och en tidig kontakt med arbetsplatsen har visat sig vara effektiv. Vidare har kunskapen fördjupats om hur organisatoriska faktorer och samhälls faktorer påverkar remitteringsfrekvens till rehabilitering i primärvården. Slutligen belyser denna avhandling svårigheterna med att utvärdera effekten av multimodal rehabilitering med hjälp av registerbaserade data.

# Thesis at a glance

Aim	Main results	Conclusions
<p>Study I  <b>To test the validity of a short “Blue flags” questionnaire, which focuses on work-related psychosocial risk factors and any potential need for contacts and/or actions at the workplace.</b></p>	<p>The two panels considered the 14 psychosocial items to be relevant and all 14 items showed satisfactory loadings on all factors. The overall correlation was very strong <math>r_s=0.87</math> (<math>p&lt;0.001</math>). Correlations were moderately strong for factor one, <math>r_s = 0.62</math> (<math>p &lt; 0.001</math>) and factor two, <math>r_s = 0.74</math> (<math>p &lt; 0.001</math>). Factor three and factor four were weaker, but still fair and significant at <math>r_s = 0.53</math> (<math>p &lt; 0.001</math>) and <math>r_s = 0.41</math> (<math>p &lt; 0.001</math>) respectively. The internal consistency of the whole “Blue flags” was good with Cronbach’s alpha of 0.76.</p>	<p>The content, structural and concurrent validity were satisfactory in the short “Blue flags” questionnaire. Testing in clinical contexts and in other patient populations is recommended to ensure predictive validity and usefulness.</p>
<p>Study II  <b>To study the effect on work ability when adding a workplace dialogue in physiotherapy practice for pain patients in primary care.</b></p>	<p>Significantly more patients in the intervention group reached work ability (108/127, 85%) compared to the reference group (127/171, 74%) (<math>p=0.02</math>). Patients in the intervention group reported work ability to a higher extent at one-year compared to the reference group, also after adjustment for baseline health related quality of life (OR 1.85, CI 1.01-3.38).</p>	<p>An early workplace dialogue in addition to structured physiotherapy improved work ability significantly.</p>
<p>Study III  <b>To study the impact of health care provider and community related factors on referral rates to MMR in patients with MSP in primary care.</b></p>	<p>Factors related to more MMR referrals/1000 registered patients in the multiple regression analyses were PCCs located in medium and large communities and with above average socioeconomic status among the registered patients at the PCCs, private PCC and PCCs providing their own MMR.</p>	<p>Referral rates to MMR were positively associated with PCCs located in medium and large sized communities with higher socioeconomic status among the registered population, private PCCs and PCCs providing their own MMR.</p>
<p>Study IV  <b>To study the feasibility of identifying a defined treatment group and a comparable reference group for possible evaluation of a MMR programme in primary care for patients with MSP on short-term sick leave.</b></p>	<p>We were unable to identify big enough groups for comparisons. A minor part of the MMR cohort fulfilled all criteria at baseline and only 130 (3.4%) of the original 3831 patients were selected. By applying the set of criteria to the original reference cohort the reduction was even larger, from 101 877 to 213 patients (0.2%). The patients in the reference group had in general better health at baseline. The proportion of patients with full work ability increased over time and at the two year follow-up it reached 52% in the MMR group and 73% in the reference group.</p>	<p>We found limited feasibility of identifying two comparable groups for evaluation of the MMR programme in primary care. Exclusion was mainly due to the sick leave criterion and due to low illness burden in the reference cohort.</p>

# Abbreviations

CDM	Convergence Dialogue Meetings
HRQoL	Health Related Quality of Life
MMR	Multimodal Rehabilitation
MSD	Musculoskeletal Disorders
MSP	Musculoskeletal Pain
OR	Odds Ratio
PCC	Primary Care Center
QPS <sub>Nordic</sub>	The General Nordic Questionnaire for Psychological and Social Factors at Work
RCT	Randomised Controlled Trial
RTW	Return to Work

# Definitions

Content validity	The degree to which the content of a questionnaire is an adequate reflection of the construct [1].
Concurrent validity	The degree to which the scores of a questionnaire are an adequate reflection of a gold standard [1].
Cronbach's Alpha	A reliability index that estimates the internal consistency or homogeneity of a measure composed of several subparts to the degree to which the items that make up the scale "hang together".
Feasibility	An analysis of how successfully a project can be completed.
Intention-to-treat	"Gold standard" for analysis in clinical trials. In the analysis, data from all subjects initially enrolled are used for the analysis of efficacy and safety.
Musculoskeletal disorders	Different diseases and injuries within the musculoskeletal and soft-tissues organs.
Musculoskeletal pain	The main/major common symptom in most musculoskeletal disorders and can be caused by pathophysiological processes in bones, joints, cartilage tissue, muscles, tendons, ligaments, bursae or a combination.
Multimodal rehabilitation	In this thesis used to describe team-based biopsychosocial rehabilitation with different professions for patients in working age with musculoskeletal pain.
Pain	<i>"An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"</i> [2].
Structural validity	The degree to which the scores of a questionnaire are an adequate reflection of the dimensionality of the construct to be measured [1].

Reliability

The scores for the patients are the same for repeated measurement [1].

Validity

The degree to which the measurement measures what it is supposed to measure [3].

# List of papers

- I.** Sennehed CP, Gard G, Holmberg S, Stigmar K, Forsbrand M, Grahn B. "Blue flags", development of a short clinical questionnaire on work-related psychosocial risk factors – a validation study in primary care.  
BMC Musculoskeletal Disorders 2017;18:318.
- II.** Sennehed CP, Holmberg S, Axén I, Stigmar K, Forsbrand M, Petersson IF, Grahn B. Early workplace dialogue in physiotherapy practice improved work ability at one-year follow-up – WorkUp, a randomised controlled trial in primary care (NCT02609750).  
Submitted: 2017-12-14
- III.** Sennehed CP, Holmberg S, Stigmar K, Forsbrand M, Petersson IF, Nyberg A, Grahn B. Referring to multimodal rehabilitation for patients with musculoskeletal disorders – a register study in primary care.  
BMC Health Services Research 2017;17(1):15.
- IV.** Sennehed CP, Stigmar K, Grahn B, Rivano M, Forsbrand M, Nyberg A, Petersson IF, Holmberg S. Evaluation of a multimodal pain rehabilitation programme in primary care based on register data – a feasibility study.  
Manuscript.

## Description of contribution

### Paper I

Study design	Charlotte Post Sennehed, Gunvor Gard, Sara Holmberg, Kjerstin Stigmar, Malin Forsbrand, Birgitta Grahn
Data collection	Charlotte Post Sennehed
Data analyses	Charlotte Post Sennehed, Gunvor Gard, Sara Holmberg, Birgitta Grahn
Manuscript writing	Charlotte Post Sennehed
Manuscript revision	Charlotte Post Sennehed, Gunvor Gard, Sara Holmberg, Kjerstin Stigmar, Malin Forsbrand, Birgitta Grahn

### Paper II

Study design	Charlotte Post Sennehed, Sara Holmberg, Iben Axén, Kjerstin Stigmar, Malin Forsbrand, Ingemar F Petersson, Birgitta Grahn
Data collection	Charlotte Post Sennehed, Iben Axén
Data analyses	Charlotte Post Sennehed, Sara Holmberg, Iben Axén
Manuscript writing	Charlotte Post Sennehed
Manuscript revision	Charlotte Post Sennehed, Sara Holmberg, Iben Axén, Kjerstin Stigmar, Malin Forsbrand, Ingemar F Petersson, Birgitta Grahn

### Paper III

Study design	Charlotte Post Sennehed, Sara Holmberg, Kjerstin Stigmar, Malin Forsbrand, Ingemar F Petersson, Anja Nyberg, Birgitta Grahn
Data collection	Charlotte Post Sennehed
Data analyses	Charlotte Post Sennehed, Sara Holmberg, Birgitta Grahn
Manuscript writing	Charlotte Post Sennehed
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## **Paper IV**

Study design

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Charlotte Post Sennehed

Data analyses

Charlotte Post Sennehed, Sara Holmberg,  
Birgitta Grahn

Manuscript writing

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Manuscript revision

Charlotte Post Sennehed, Kjerstin Stigmar,  
Birgitta Grahn, Marcelo Rivano Fischer,  
Malin Forsbrand, Anja Nyberg, Ingemar F Petersson,  
Sara Holmberg



# Rationale

People of all ages suffer from musculoskeletal pain, mainly neck and back pain, and experience activity limitations and participation restrictions in their daily life. Musculoskeletal pain, is a common reason for work disability and thus for sick listing. These people are a large group seeking care in primary care.

There are many different treatment options available for this patient group, from the unimodal to the multimodal rehabilitation, but still with insufficient scientific evidence for which is preferable. It is valuable to be more aware of the importance of assessment before rehabilitation and if possible involve the workplace to support work ability, stay at work and, when applicable, return to work. Further research is needed in this area to gain deeper knowledge, a challenge that was the starting point of this thesis.



# Introduction

Work disability due to musculoskeletal pain (MSP) is one of the main causes of sick leave in western societies [4-6] and patients with MSP constitute a large group seeking help in primary care [7, 8]. The impact of work disability includes societal and economic consequences for both the individual and the society, including significant loss of health quality of life (HRQoL) [9, 10] as well as loss of productivity [4]. During 2012, 20-30% of the total number of visits to primary care in Sweden were patients with MSP [11] and patients with back pain utilized twice as much health care resources compared to the overall population [12]. The recurrence of such pain as well as chronization is high. About one-third of patients with previous acute back pain will have a recurrent episode within one year [13]. The odds of a recurrence within one year triples when the patient has experienced more than two previous episodes of back pain [13]. There are various options aimed at preventing acute/subacute back pain from deteriorating into chronic problems with decreased work ability, but there is insufficient evidence for the efficacy of these treatments [14-16]. Therefore more research is needed.

## Work ability

Work ability is a diverge concept and the scientific publications report multidimensional aspects with no unique shared definition of work ability [17]. A definition has been developing during the last decade and is now more described as the balance between individual resources, societal and work/organisational components [17-19]. In a lifetime this balance will likely change during different phases of work life depending on age, work demands and technology [20]. Specific work requires specific training in relation to a particular task assignments, unlike the general work that is put in relation to a job most people can cope with after a brief introduction [21]. Tengland's model claims that motivation is not a part of work per se, yet can be very important as an explanation for sick leave and presenteeism [21]. Motivation can determine if a person with kept work capacity stays home or attends work [22]. Motivation level has been reported as an important predictor of rehabilitation outcomes including work ability [23] and also a predictor of total costs to society [24]. In similar way activation strategies in

vocational rehabilitation states that people should make active choices in their way back to work and are important factors for empowerment [22]. Although largely positive, activation strategies could also lead to exclusion if the patients chose to avoid work. It is therefore important that vocational professionals gain insights into how the clients handle empowerment [22].

The individuals' mental and physical capacity, competence, motivation, job satisfaction, values and attitudes and work community are all factors described in Ilmarinen's theoretical model for work [19]. These factors are also related to work demands, organisation, work community and work environment. The work ability house is a further development of the model for work, where the aspects of work ability can be illustrated by the different floors of a building, each making the house more stable [18] (Figure1). This can be described as one's own resources (physical, psychological, social health and functional capacity) can be imagined as the first floor, and competence (education and experiences) as the second floor. Motivation, values and attitudes are the third floor. Work, work community and leadership are the fourth floor, and these depend on the underlying floors which determine whether the person has work ability or not. On this fourth level the employers play an important role by supporting the employees' resources and work ability in relation to duties and organisation. Furthermore, the family and the external environment such as relatives, friends, infrastructures, services and policies also affect work ability and must be highlighted (Figure1). During the process of aging both fitness and strength decrease, which means that with higher age, changes might be needed at the workplace, for example reduced physical work load, encouragement and guidance to physical exercise [18, 19].

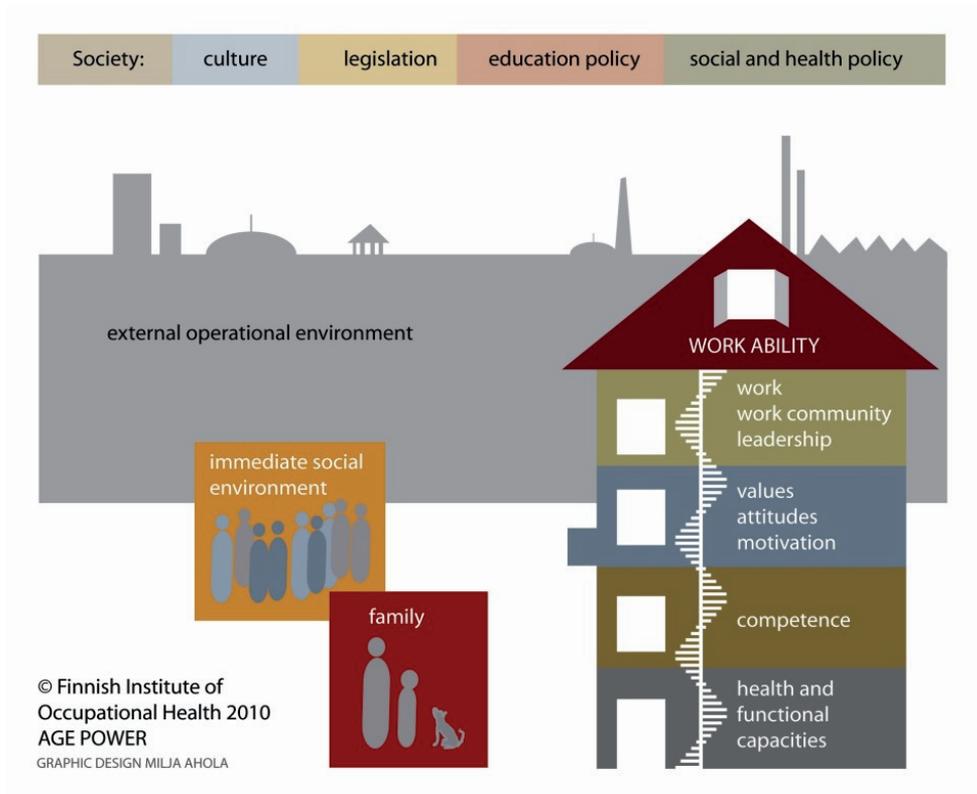


Figure 1. Work ability house. Reprinted with publication rights from the author (J. Ilmarinen).

There are studies with focus on promoting and maintaining work ability [25-27]. Most of these studies confirm that work ability is strongly associated with high quality of employment, job satisfaction and also forecasted a healthier meaningful and active retirement [28]. Work ability is associated with lifestyle factors, such as cigarette smoking, physical activity and BMI [29]. There are also associations between work ability and physical load [30], ergonomic conditions [31], environmental conditions, sociodemographic factors and musculoskeletal disorders [32], work stress [33, 34], social support [35], and balance between demands, control and support [36-41]. A 28-year prospective follow-up study found that perceived reduced work ability in midlife was associated with decreased health and functioning at follow-up [42]. The majority of patients in working age with musculoskeletal pain consulting physiotherapy in primary care are in early stages of illness/disease and mostly in work. Traditionally the treatments in primary care have focused on pain reduction and the promotion of function. Despite the fact that musculoskeletal pain is a strong risk factor for

disability and work loss [4-8, 43], primary care has not so far focused on promoting work ability in early stages of illness. An early workplace dialogue with the employer and the employees is usually lacking in primary care and more research is needed.

## Musculoskeletal disorders and musculoskeletal pain

The World Health Organization (WHO) defines musculoskeletal disorders (MSD) as “*health problems of the locomotor apparatus, i.e. of muscles, tendons, the skeleton, cartilage, ligaments and nerves*”. MSD includes all forms of ill-health ranging from light, transitory disorders to irreversible disabling disorders [44]. MSP is the most common symptom, and within the group MSD, neck and back pain is highly prevalent in the general population [6, 45] and at risk of sick leave [46]. These patients are mostly managed in primary care and a majority improve quickly [47]. Up to 90% of all patients recover in about six weeks [15], but for some patients the pain is long lasting [48]. Back pain is now seen more as a condition, as a persistent course and usually a lifelong experience of back pain episodes [49]. The one-year prevalence in 34 European countries during 2010, was 46.1% for back pain and 44.6% for neck/upper-limb pain [50]. The life-time prevalence for low back pain is high and has been reported to be 70-80% [51]. The life-time prevalence for neck pain is lower and has been reported to be 14-71% [52]. Frequent MSP is associated with a high risk for reduced work ability [33]. MSP is complex and the cause of both sick leave and Return to work (RTW) after rehabilitation is multifaceted with psychological and work load factors [37, 38, 41, 53, 54]. Old age, full time sick leave and number of physical symptoms at multidisciplinary medical assessments has been shown to be negatively related to work ability [55]. It has been shown that premature death rates were increased among people with sick leave caused by MSP [56]. There are reports that patients’ own responsibility for their MSD may positively affect the treatment result [57, 58]. Most previous rehabilitation studies have been focused on patients with chronic neck and back pain and RTW after sick leave. Therefore, rehabilitation studies on acute/subacute neck and back pain in primary care is needed [14].

# Provisions/regulations for sick leave

## Primary care

The main goal for health care is to support the patient in recovering, but also when possible stay at work and when appropriate RTW. In Sweden primary care is responsible for basic healthcare and most patients in Sweden with MSP get their first treatment in primary care. When patients need they can receive further rehabilitation by referral from the primary care centre (PCC) to appropriate secondary and tertiary healthcare. The county councils are responsible for organisation and allocation of health care that can be both publicly and privately managed. Clinical guidance is created centrally but decision-making and obligation for provision is in Sweden decentralised to local level [59].

The PCCs need to be accredited by the local county council and the reimbursement paid to the PCC follows the patient. The PCCs are obligated to participate in follow-ups on quality of care. In Sweden in general, PCCs are multiprofessional with physicians, nurses, physiotherapists, occupational therapists and psychologist or counsellors [60]. Patients who do not actively choose a PCC are passively registered based on the latest visit or the shortest distance to a PCC. Co-payments for visits to health care professionals has a small annual cost ceiling of 1100 SEK (140 USD) for health care visits. In Sweden about 75% of the healthcare is funded by local council taxes and the rest is funded from the central government [59].

## Regulations for sick leave

Differences in policies for the right to sick leave economical compensation for MSP problems contribute to differences in RTW rate, while health, medical interventions and patients' characteristic are reported less important [61]. European countries have varying levels of workplace health and safety provisions, which may influence work environment and the impact of adverse working conditions on health [62]. In Sweden employers are responsible for the provisions about physical, organisational and social work environment to be followed. The provision regulates knowledge requirements, goals, workloads, working hours and victimisation. The purpose is to promote a good work environment and prevent risks of decreased health due to organisational and social conditions in the work environment [63].

In Sweden the employer pays 80% of the salary as "sick pay" for the first fourteen days of a period of illness, with the exception of a waiting period of normally one day. After being absent due to illness for one week, the employee has to provide a

doctor's certificate to their employer. The employer then decides if sick pay can be paid or if other temporary duties can be offered [64]. Then the patient can apply for sickness benefit from the Social Insurance Agency and can receive sickness benefit for at most 2.5 years.

The employer is responsible for rehabilitation measures in the workplace. The Work Environment Act regulates the employer's liability to implement measures to facilitate the RTW. Rehabilitation measures can be discussed together with the employee at a coordination meeting. This meeting normally involves the employee, social insurance agency, the doctor who signed the employee off work and the employer. Others who have a significant role in the rehabilitation process may also be involved. A time schedule for rehabilitation has been introduced in 2008. During the first days of sick leave work ability is assessed in relation to ordinary work tasks and possible adjustments. For days 90-180 the employer must look for other work tasks in the organisation. After 180 days of sick leave the work ability should be related to all kinds of jobs on the labor market [64]. Early interventions at the workplace [65, 66] and the employer's commitment and efforts [67] of employees' RTW has proved of great importance in earlier studies. In Sweden, research on short term sick leave,  $\leq 14$  days, is missing due to register data from The Social Insurance Agency can be retrieved only from  $> 14$  days sick leave. Increased knowledge of short term sick leave patterns would be valuable for improving the rehabilitation at an early stage to strengthen work ability.

## Sick leave and return to work

The "Illness flexibility model" and "sickness absence model" are models to explain sick leave [68, 69]. These models consist of three dimensions; illness flexibility at work, adjustment latitude and attendance requirement, which together show associations between sick leave and sickness attendance. Furthermore, the interaction of work ability and motivation is important when it comes to sick leave. If the individual has the opportunity to adapt her work according to what her health permits it seems to affect work ability in a positive direction [70, 71]. Attendance requirements or absence requirements affect whether a person with reduced working capacity considers that they should go to work or not. If the absence means that the duties accumulate when the person is sick, it may imply attendance requirement. Incentives for attendance or absence affect whether the person in this situation wants to go to work or not. In addition, if the work is stimulating this implies motivation for work despite sickness. This may mean that a person returning to work is affected more by the fact that conditions within and outside the work are changed than being healthy [69].

Work conditions are of great importance and influence health, work ability and sick leave [72]. Health, work and sick leave are all interrelated and a low level of adjustment latitude at work can be a risk factor for increased sick leave [68, 70, 71]. RTW is one way to describe work ability and often an outcome measure in studies, which requires that it is assumed that the work incapacity occurred before RTW [73]. A model for RTW is the Readiness for Return-to-Work Model where the individual is given a variation of interventions at a specific timing and that the person is ready to return to work [74]. This model was developed from the Phase Model of Disability and the Readiness for Change Model. These models complement each other in a broader framework by which employees interact with the workplace, the insurance systems and the healthcare system in relation to RTW. Social support, work attitude, and behavioural characteristics are associated with a shorter time to RTW [75]. For reincentivising, i.e. RTW or go on working, the sick listed patient needs strategies to regain physical, mental and social functions [76].

## Patient assessments in primary care

### The flag system

Screening for different health status or risks is generic in health care in general and is often described as different type of clinical “flags”. The flag system has been developed for the assessment of risk factors and recommended as an investigative methodology and until now especially so in regards to MSP [77]. The identification of red and yellow flags is established and provides valuable information to clinicians in health care. Red flags are screening for severe health problems or diseases in need for more extensive diagnostic investigations [78] and yellow flags assess mental and emotional health risk factors [79].

Blue flags are defined as the individual’s perception of work-related factors that can have an impact on disability. Screening for blue flags is intended for identification of work-related psychosocial and physical risk factors, for example job satisfaction, supervisor relationships, physical job demands, ability to modify work, job stress, workplace social support or dysfunction, expectation for resuming work, and fear of re-injury [80]. Earlier research indicates that health care should use questionnaires that cover these types of risk factors in order to support work ability [80, 81]. Work support [82] and formalised peer support at the workplace [83] has been found to be associated with reduced low back pain and reduction in sick leave. For this reason, there are recommendations that the examination of the patient also should include assessment of work-related

psychosocial risk factors, which can predict the risk of chronic disabling back pain [84, 85]. Questionnaires focusing blue flags, such as the Back Disability Risk Questionnaire (BDRQ) [80], the Occupational Role Questionnaire (ORQ) [86], the Obstacles to Return to Work Questionnaire (ORTWQ) [87] and the Psychosocial Aspects of Work Questionnaire (PAWQ) are all designed to be used in occupational health settings, hospitals and rehabilitation clinics. They are not designed to be used for screening for work-related psychosocial risk factors among patients in primary care.

Clinical work and patient assessment is different in primary care as compared to occupational rehabilitation settings. The time available for each consultation is generally much shorter and the patient population is unselected. Many patients are in early stages of illness or disease when consulting primary care for advice and medical evaluation of symptoms. The assorting function in primary care is important and an approach that identifies disease, guides treatment, and prevents unnecessary medicalization is warranted. The importance of robust early screening methods helping clinicians to deliver relevant counselling and treatment is thus central in healthcare development and procedures [88-92]. Until now there is to our knowledge no useful instrument, that is easy to handle and that takes a short time to complete recommended to help professionals in primary care to identify important work-related psychosocial risk factors that can affect health and work ability [81].

### The General Nordic Questionnaire for Psychological and Social Factors at Work (QPS<sub>Nordic</sub>)

“The General Nordic Questionnaire for Psychological and Social Factors at Work” (QPS<sub>Nordic</sub>) is an established well-known questionnaire for the assessment of psychological, social and organisational working conditions as well as individual work-related attitudes. QPS<sub>Nordic</sub> is the most comprehensive, reliable and valid questionnaire used in the Nordic countries today. This questionnaire has been used for organisational development, documentation of changes in working conditions, evaluation of organisational interventions and research [93-100]. The questionnaire includes 129 items divided into 13 different content areas classified according to task level, social and organisational level and individual level [101]. QPS<sub>Nordic</sub> was constructed after extensive development and published in 2000. Two data sets were collected in Sweden, Norway, Denmark and Finland within various occupational fields. The factor structure of the questionnaire and the structural properties of the scales were studied in the first data set (n= 1015). The second data set (n= 995) was used to test the structural and predictive validity of the scales. The internal consistencies (alpha values 0.60-0.88) and test-retest reliabilities (0.55-0.82) were studied for each scale. In the content areas

concerning working conditions Cronbach's alpha has been found to be 0.69-0.85 [101]. However, a clinical questionnaire in primary care needs to be short and easy to handle and QPS<sub>Nordic</sub> is too extensive to be useful in clinical practice.

## Multimodal rehabilitation – a Swedish National Rehabilitation Program

In 2008, the Swedish government introduced a National Rehabilitation Program with the ambition to provide evidence-based rehabilitation in primary care to all working age inhabitants in Sweden [102]. This includes that equal treatment related to the patient's needs (health equality) should be offered to all inhabitants regardless of where they live and which PCC they visit. Health equality is a concept that is emphasized in the Swedish health care [102]. Different specialized rehabilitation programmes for long-lasting pain have been evaluated and there is some evidence that MMR is effective in relation to RTW [103, 104] and also cost effectiveness has been proven [105-107]. When rehabilitation has been combined with workplace interventions, MMR has been found effective [105-110].

There have been attempts to design follow-up studies within the National Rehabilitation Program in primary care with reference groups retrieved from registry data. The Swedish Social Insurance Inspectorate (ISF) analysed MMR outcomes in comparison with a reference group [111]. They applied a matching approach by using broad register data to identify reference pain patients not given MMR treatment. The ISF concluded that MMR was expensive and not cost effective, mainly due to increased sick leave during and after MMR, compared to the reference group. Busch et al. [112] studied the effect of MMR on sick leave in an observational study and also applied a matching approach by using broad register data to identify reference pain patients. They found that sick leave was not decreased after MMR treatment compared to treatment-as-usual. However, this study also included MMR within specialised rehabilitation clinics and a large proportion of the included patients were on disability pension at baseline and not the target group for MMR, since they lacked any possibility of RTW.

In Sweden, the government financially reimbursed the county councils for this evidence-based rehabilitation directed to patients in working age, 16-67 years of age, with mild to moderate mental disorders and patients with MSD, mainly neck, shoulder and back pain. The National Rehabilitation Program was proposed to strengthen the opportunities for rehabilitation for the two large patient groups at risk for developing long-lasting problems and sick leave [102, 113] and was intended to improve function, work ability and to reduce social costs due to ill health and sick leave.

Patients with musculoskeletal pain were offered MMR after referrals in primary care. The rehabilitation could be provided by private or public contracted units all funded by the county councils. To get a referral to MMR the patient had to visit primary care for medical assessment. Thus, it was not possible for the patient to access MMR without a referral. MMR involved a multiprofessional team with physician, physiotherapist, psychologist and occupational therapist. MMR was offered full or part-time over four to eight weeks and included physical therapy, cognitive behavioural therapy and patient education. The rehabilitation was mainly provided as group treatments. Therefore it was not possible to get only individual treatment within the MMR programme. For each completed MMR the unit delivering the care received financial compensation. During the first years of the National Rehabilitation Program the county councils was compensated with 45 000 SEK (5473 USD) per patient.

Much attention in the evaluations of the National Rehabilitation Program has been on patient outcomes [114] and on process [115]. We know from other contexts, for example regarding use of diagnostic methods and antibiotic treatment, that there are big inexplicable differences between caregivers and geographical areas [116, 117]. Evaluation of treatment effect is important since this programme was implemented nationally in primary care based on limited evidence from specialist rehabilitation research. Since RCTs are missing in this area additional studies with relevant reference groups are needed.

# Aims

## Overall aim

The overall aim of this thesis was to obtain deeper knowledge on assessment, referrals and rehabilitation of patients with musculoskeletal pain in a primary care setting, focusing on work ability.

## Specific research questions

- Study I* To test the validity of a short “Blue flags” questionnaire, which focuses on psychosocial risk factors and any need for contacts and/or actions at the workplace.
- Study II* To study the effect of structured physiotherapy including a workplace intervention with Convergence Dialogue Meeting (CDM) on work ability for patients with acute/subacute neck and/or back pain in primary care in a randomised clinical trial.
- Study III* To study the impact of health care provider and community related factors on referral rates to multimodal rehabilitation in primary care patients with musculoskeletal pain.
- Study IV* To study the feasibility of identifying a defined treatment group and a comparable reference group for possible evaluation of multimodal rehabilitation in primary care for patients with musculoskeletal pain on short-term sick leave.



# Methods

In Sweden primary care is responsible for basic healthcare and most patients in Sweden with MSP get their first treatment in primary care. The patient who needs help, take contact to the primary care, mostly through a telephone call. The professional in primary care guide the patient with advice and self-care, mostly by the nurse. Patient in need to visit a physician or another profession, a time will be booked for assessment, examination, and treatment. During this time period, within three months, the Study I and Study II were conducted. After treatment most patients recover, but if not, they may need further examination and perhaps referrals to other treatments, for example multimodal rehabilitation. During this time period Study III and Study IV were conducted. The flowchart of this thesis is described in Figure 2.

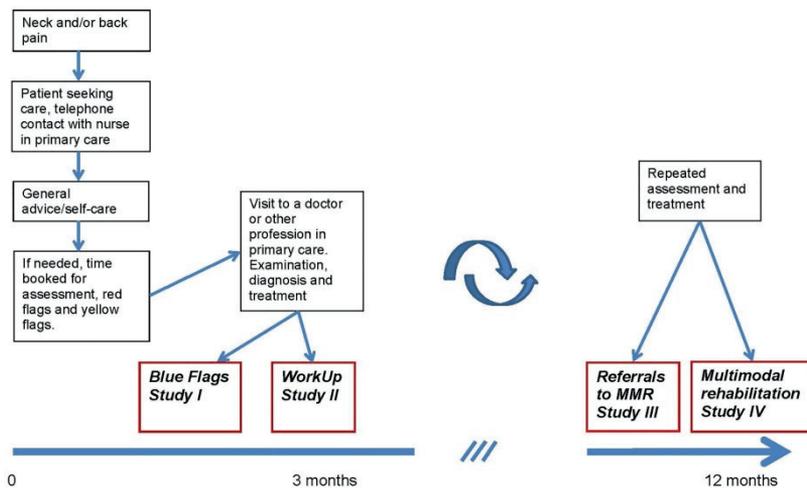


Figure 2. Flowchart of the patient way from the first primary care contact due to neck and/or back pain and where in the timeline the four studies were conducted in this thesis.

## Study design

The four studies with four different cohorts required different methods and designs. The validation of a short questionnaire regarding work-related psychosocial risk factors was a methodological study with two study populations. The effect on work ability, when adding a workplace dialogue in physiotherapy practice, was studied in a randomised clinical trial in primary care. We conducted two register-based cohort studies in primary care. The impact of health care providers and community related factors on referral rates to MMR was based on prospectively ascertained register data in primary care. The second register study was to assess the feasibility of identifying a defined treatment group and a comparable group for possible evaluating of a MMR programme. All studies are presented in Table 1.

Table 1. Overview of studies I-IV, design, setting, study population/data, sample size, outcomes analyses methods.

	Study I	Study II	Study III	Study IV
<b>Design</b>	Methodological study, focusing validity	Prospective pairwise cluster randomised trial WorkUp	Cohort study	Register-based longitudinal observational cohort study
<b>Setting</b>	Primary care and occupational health	Primary care rehabilitation units	Primary care	Primary care
<b>Study population/data</b>	Expert panel including professionals and patients. Patients in the WorkUp study	Patients with acute/subacute pain in neck and/or back seeking physiotherapy in primary care	PCCs in Region Skåne 2010-2012 and patients registered at the PCCs in Region Skåne	Patients with > 3 months pain in neck and/or back seeking treatment in primary care
<b>Sample size</b>	Face and content validity: 111 experts Concurrent validity: 75 patients	352 patients in primary care, intervention group n =146, reference group n = 206	153 PCCs	Intervention group n=3831 patients. Reference group n=101877 patients
<b>Outcomes</b>	Content, structural and concurrent validity	Work ability	Referrals/1000 inhabitants	Work ability
<b>Analysis method</b>	Content validity index, Kaiser-Meyer Olkin measure, Principal Components analysis, Spearmans rank correlation, Cronbach's alpha	Descriptive statistics, parametric, multiple stepwise regression analyses	Descriptive statistics, non-parametric and multiple stepwise regression analyses	Descriptive statistics, non-parametric

# Settings and material

## Study I

For the *content validity* we included PCCs, occupational health services, specialized pain rehabilitation centers and inpatient centers in the southern parts of Sweden. For the *structural and concurrent validity* we included patients in the WorkUp study in Region Skåne, Region Kronoberg and Blekinge county council.

### *Content validity*

The recruitment criterion of the professional panel in health care was experience of work-related health issues and to have a broad and relevant representation of experience; both from pain rehabilitation, vocational rehabilitation and from primary care. The recruitment criterion of the patient panel was their individual experience as a patient in primary care with an episode of back pain and having risk for developing work disability.

Professional panel: Sixty-five professionals from six units were recruited by personal contacts (19 men, 45 women and for one; sex unknown), mean age 45 years (range 21-63 years). The represented professions were physiotherapists (n = 30), occupational therapists (n = 13), physicians (n = 8), social workers (n = 4), nurses (n = 6) and psychologists (n = 4). The professionals had been working in health care for many years (74%  $\geq$  10 years), mostly in primary care (65%) and in occupational health (23%).

Patient panel: Forty-six patients from nine PCCs agreed to evaluate the items (10 men, 36 women), mean age 45 years (range 21-62 years), with pain problems in neck (n = 19), back/lumbar back (n = 24) and shoulder (n = 3).

### *Structural and concurrent validity*

A cohort of patients from the RCT WorkUp (WorkUp, ClinicalTrials.gov, ID NCT 02609750) were recruited consecutively in the study when they applied for physiotherapy due to an episode of acute or subacute non-specific neck and/or back pain and were identified as having risk for developing work disability according to the Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ), short form [118]. Other inclusion criteria in the WorkUp study were to not be currently on sick leave or being sickness absent less than 60 days. In all, 75 patients were included (73 with employment). Mean age was 44 years, (range 22-64 years).

## Study II

Patients, 18-67 years of age, seeking physiotherapy in primary care in Region Skåne, Region Kronoberg and Blekinge county council due to acute or subacute (< 12 weeks) neck and/or back pain were eligible for inclusion. Patients who were not on sick leave or had no more than 60 days sick leave and considered at risk by scoring  $\geq 40$  points at “ÖMPSQ-short” [118] and had been working at least four consecutive weeks the last year were asked to participate in the study. Exclusion criteria were; full time disability pension, addiction diagnose, on-going medical treatment of acute disease, pregnancy and not able to understand the Swedish language. After screening, inclusion resulted in 146 intervention patients and 206 reference patients (Figure 3).

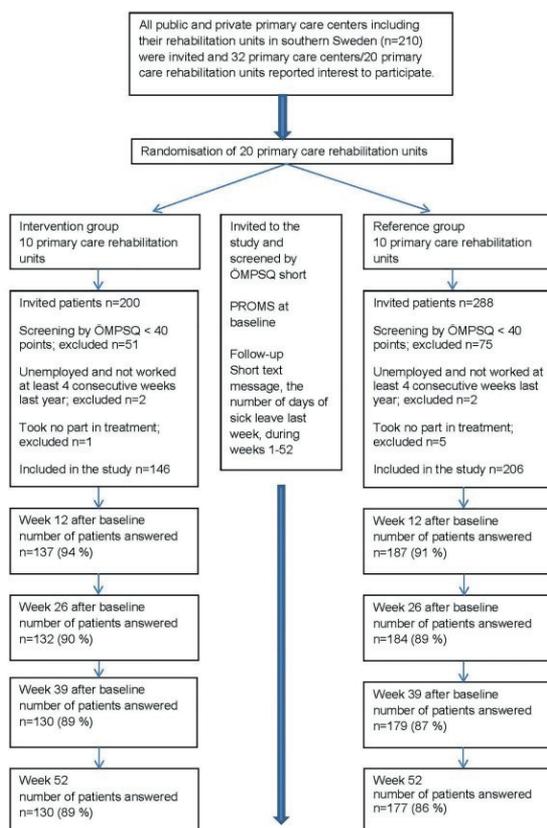


Figure 3. Flowchart of inclusion and follow-up of primary care rehabilitation units. The proportion of patients who reported days on sick leave last week, by answering the text message.

### Study III

All accredited PCCs contracted in Region Skåne, who had issued any referrals during 2010-2012 were included in the study. We identified and included 153 PCCs (Figure 4).

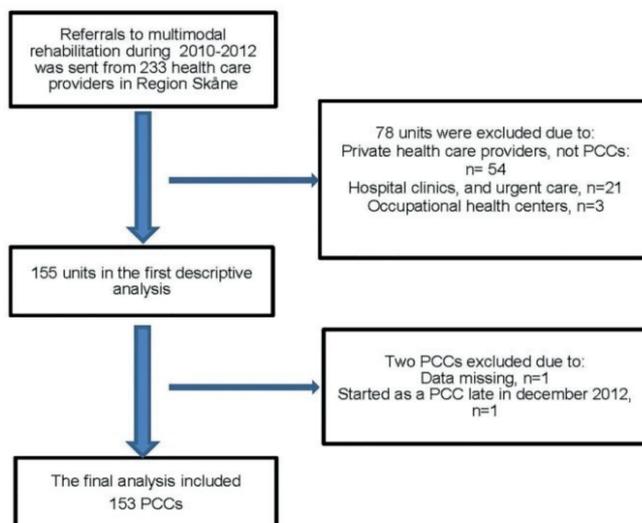


Figure 4. Flowchart of inclusion and exclusion of the PCCs in Region Skåne.

### Study IV

The study population in primary care in Region Skåne was identified in the Skåne Healthcare Register during the period 1 January 2010 to 31 December 2012. All patients of working age, 16-67 years, registered as having received MMR in Region Skåne were identified covering all publicly tax-financed health care in Region Skåne. The MMR patients should have had at least six treatment sessions during a period of maximum six weeks. Over the six weeks period the MMR patient should have had at least one treatment sessions/week during four weeks. A reference cohort was identified in the same register including patients that had been registered with the same MSP diagnose codes during the same period and who were also of working age.

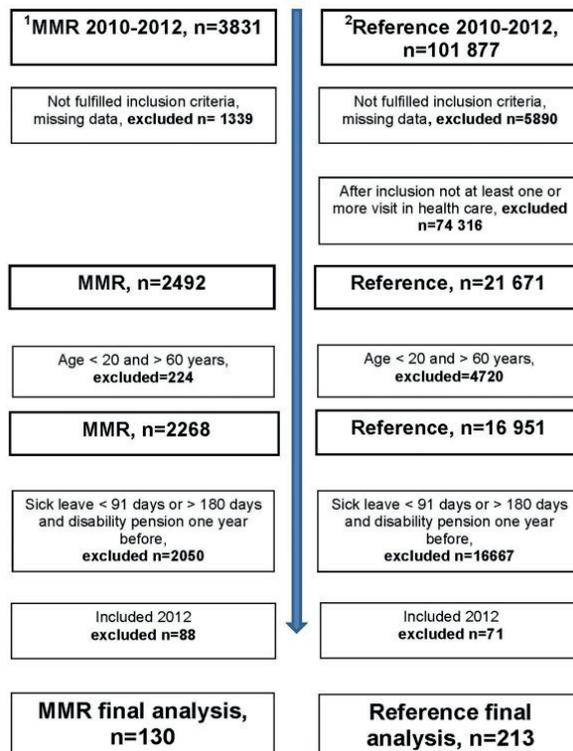


Figure 5. Flowchart of selection of the cohorts, in age 16-67 years with MSP diagnoses, <sup>1</sup>Multimodal rehabilitation cohort and <sup>2</sup> Reference cohort. The patients should have at least one or more additional consultation in health care due to the same diagnosis within three months. Due to a substantial proportion missing data during the second follow-up year for patients included during 2012, we restricted our analyses to patients included during 2010-2011.

We identified 3831 MMR patients, with relevant MSP diagnoses. Patients with incomplete treatment sessions of MMR and insufficient time for follow-up were excluded. We identified 101 877 reference patients with a relevant MSP diagnosis. Reference patients were excluded due to that they had been enrolled in MMR or have had more than one visit in specialised pain rehabilitation.

In order to limit the reference cohort to patients with a high likelihood of needing rehabilitation we applied the inclusion criterion that the reference patients should have at least one or more additional consultations in health care within three months due to the same diagnosis. According to the national rehabilitation program, MMR was intended for patients with MSP on sick leave or in high risk of sick leave. We included only patients with sick leave 91 to 180 days at baseline and excluded those with no sick leave, shorter or longer sick leave and those already granted a disability pension one year before baseline in the study. The rationale for this was that patients with no or very short-term sick leave often

recover spontaneously and many do not need more comprehensive rehabilitation efforts within primary care. Due to a substantial proportion of missing data during the second follow-up year for patients included 2012 we restricted our analyses to patients included during 2010-2011(Figure 5).

## Data collection and methods

### Instrument development (Study I)

From the 13 established content areas in the original QPS<sub>Nordic</sub> the research group identified five content areas with a total of 51 items which were considered to be most relevant when focusing on work-related psychosocial risk factors [119-124]. These areas were; job demands [98-100] social interactions [94, 96, 97], quantitative demands [93], equality [125, 126], bullying and harassment [95, 127]. Therefore, the selected QPS<sub>Nordic</sub> items covered these content areas with the following number of items; job demands (32 items), social interactions (6 items), quantitative demands (9 items), equality (2 items) and bullying and harassment (2 items). The answers in the QPS<sub>Nordic</sub> are given on a 5 - point Likert scale from one to five (1 = no problems and 5 = most problems). Fourteen items were selected from the identified QPS<sub>Nordic</sub> content areas and organized in a short questionnaire (“Blue flags”). This method is previous described as relevant in research when a long questionnaire is condensed into a shorter [118, 128]. The 14 items in the “Blue flags” questionnaire were 7 items on job demands, 2 items on social interactions, 2 items on quantitative demands, 2 items on equality and 1 item on bullying and harassment. The items related to equality and bullying have to some extent been reformulated to be better integrated in the “Blue flags”. The answers are given on a 5 - point Likert scale, as in the QPS<sub>Nordic</sub>.

### *Content validity*

One panel of professionals and one panel of patients were asked to give constructive feedback about the new short questionnaire [129-131]. The intention was to gather information on the representativeness and clarity of the items by the panels’ constructive feedback as well as suggestions for improvement [132]. They individually and anonymously evaluated the relevance of each item on a scale from one to three; 1 = not relevant, 2 = relevant and 3 = very relevant. They were also asked if there were items missing, unnecessary items or any need to rephrase items.

### *Structural and concurrent validity*

The patients answered both the short “Blue flags” questionnaire (14 items) and the original QPS<sub>Nordic</sub> (51 items) during one visit to one of ten PCCs in southern Sweden. The patients also answered questions regarding their professional background (Table 2).

Table 2. Descriptive data of the study population for structural and concurrent validity, n=75.

	n	%
<b>Women/men</b>	50/25	67/33
<b>Employment, yes</b>	73	97
<b>Profession</b>		
Health care professions	24	32
Administration	18	24
Industrial/heavy-duty work	24	32
Education/service work	9	12
<b>Type of employment</b>		
Permanent	63	83
Temporary	4	5
Hourly	4	5
Missing	4	5
<b>Time in current profession</b>		
< 6 months	4	5
6-12 months	3	4
1-5 years	23	31
>5 years	45	60
<b>Sick-leave, yes</b>	26	35

### Workplace intervention with workplace dialogue (Study II)

When meeting the inclusion criteria patients were invited to participate and were informed about the study verbally and in writing including the fact that if their primary care rehabilitation unit was randomised to either intervention or reference. The patients signed an informed consent form. All patients were examined by a physiotherapist, red flags were considered and all patients answered a baseline questionnaire. Based on needs contacts with other professionals could be included, such as doctor, psychologist, occupational therapist, employee or staff manager. The treatment was structured (including examination, assessment, diagnosis, evidence-based treatment and follow-up as a standard procedure among physiotherapists in Sweden) and was individualised in terms of content and duration in both groups according to each patients' condition. Within the framework of the study all participants were offered visits to the physiotherapist for follow-up examinations at 3, 6 and 12 months after baseline (number not shown). Both the intervention and the reference group received a short text

message every week during 52 weeks after baseline for follow-up of study outcome.

### *Baseline and follow-up measurements*

Both groups answered a baseline questionnaire regarding gender, age, marital status, education, employment, sick leave and health related quality of life. The physiotherapist diagnosed the patient.

### *Short text message*

We used a software called SMS-Track Questionnaire® to collect data with short text message concerning last week's number of days on sick leave [155, 156]. All questions and answers were encrypted and stored in a secure database, accessible to the first author via the web, password and firewall protected. The patients answered the question, "Last week, how many days were you on sick leave? Please answer with a number between 0 and 7". They responded with a number and all data was immediately collected in the database for subsequent analysis. Reminders were automatically sent to non-responders after two days by sending the question a second time. If there was no answer to the second message, the database recorded it as missing. In case of missing answers also in the following week, the patient was contacted by phone and if the patient could not be reached a reminder letter was sent. Figure 6 shows the proportion of text message answers in the intervention and the reference group during 52 weeks.

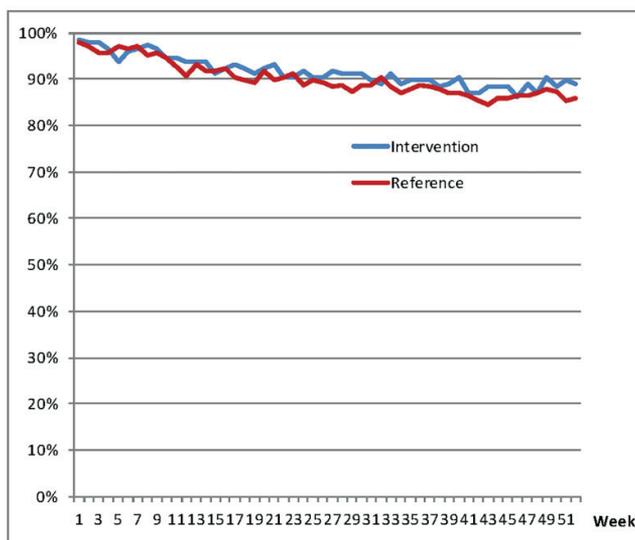


Figure 6. Proportion of text message answers per week after baseline, during 52 weeks, intervention n=146, reference n=206.

### *Intervention*

Patients in the intervention group were offered a workplace dialogue in addition to the structured physiotherapy care. The physiotherapist started a workplace dialogue by inviting the patient to an individual interview where the patient gave her/his informed consent of contacting the employer. In the second step, the employer was invited to talk to the physiotherapist, either in person or by phone. The conversations with the patient and the employer focused on the neck/back pain in relation to work and on possible or already conducted workplace adjustments to support RTW or to stay at work. Finally, the patient and the employer were invited to a meeting together with the physiotherapist. This meeting aimed at a plan of action with a written record of suggested workplace changes/improvements as well as changes to the patient's daily life with the aim of strengthening the patient's work ability and/or supporting RTW. This agreement was followed up when the patient met the physiotherapist at follow-up visits at month 3, 6 and 12 after baseline.

The impact of health care provider and community related factors on referrals to MMR (Study III)

We obtained permission to use available data from the Healthcare Governance in Region Skåne. No questionnaires were sent to primary care or PCCs in order to obtain their opinions regarding sending referrals to MMR. Inclusion criteria were all accredited PCCs contracted in Region Skåne, who had issued any referrals during 2010-2012. We identified 233 health care units in the years 2010 to 2012 that had issued referrals to MMR in primary care. Number of inhabitants in the community (community size) where the PCC was located was retrieved from Statistics Sweden. From the Healthcare Governance in Region Skåne we assessed data about number of referrals/PCC, registered population/unit (PCC size), model of health care (public or private PCC), whether or not the PCC provided their own MMR team (internal/external MMR) burden of illness/burden of morbidity (ACG) and socioeconomic status (CNI).

Data from the Regional Council Skåne and Statistics Sweden were input manually into a SPSS 20.0 database for analysis. Data quality was thoroughly checked and validated. Excluded units were clinics in specialist care such as psychiatry, occupational health and individual health care providers not incorporated in the primary care organisation and hence not accredited. The majority of these excluded units had only occasional referrals to MMR over the three years and the referrals were returned to remittance. Another two units were excluded due to missing data and starting up the unit in late 2012, just a few days before the inclusion was closed. The final analysis therefore included 153 PCCs. Independent variables operationalising health care provider factors and community were chosen

based on clinical and organisational experience, in conjunction with previous research findings and limitations.

## Evaluation of MMR in primary care based on register data (Study IV)

### *Register data*

*The Skåne Healthcare Register (SHR)*: In the register all data on primary care, specialized inpatient and outpatient care are continuously collected concerning all individuals living in Region Skåne. This register includes personal identification number, age, sex, place of residence, health care provider, date of visits and diagnostic codes according to ICD-10. *The Statistics Sweden (SCB)*: Community size, education, profession, disposable income and employment status. *The Swedish Social Insurance Agency (SSIA)*: Sick leave and disability pension. *National Board of Health and Welfare*: Drug use measured as Defined Daily Dose (DDD) with regard to pain, sleep and depression medications.

## Outcomes

### Study I

The outcomes were content, structural and concurrent validity.

### Study II

The main confirmatory outcome was work ability measured as no days of sick leave and no disability pension for four consecutive weeks [133] at one-year after baseline.

### Study III

The main outcome was number of referrals to MMR/1000 registered in the population at the PCC (referral rate).

### Study IV

The main outcome was work ability, measured as no day on sick leave and no disability pension for four consecutive weeks [133], at two-year after baseline.

# Analyses

## Study I

Data from questionnaires were manually entered in the database. SPSS 23.0 for Windows was used for all analyses.

### *Content validity*

To compare the answers from the professional panel and the patient panel the ratings were dichotomised as relevant (relevant and very relevant were merged) or not relevant. Due to small sample size or no answers Fishers Exact Test was used, two sided, to test the difference in proportions. P-values less than 0.05 were considered significant. The Content Validity Index (CVI) was used to test content validity [134]. We considered the items in “Blue flags” to be relevant if the item-level CVI was  $> 78\%$  per item. The overall “Blue Flags” was considered relevant if the average of the sum of CVI for each item for the entire scale was  $\geq 90\%$ .

### *Structural validity*

An assessment of the factorability of the data was performed using Barlett’s test of sphericity and the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy [135]. Barlett’s test should be significant ( $p < 0.05$ ) for the factor analysis to be considered appropriate. The KMO index ranges from 0 to 1, with 0.6 as a minimum value for a good factor analysis [135]. To investigate the factor structure of the “Blue flags” a factor analysis was performed using the Principal component analyses extraction with the Varimax rotation. A minimum eigenvalue of 1 was specified as extraction criterion and the criterion for factor loading was set at  $\geq 0.5$ .

### *Concurrent validity*

Concurrent validity was studied as the correlation between the 14 work-related psychosocial items in the “Blue flags” compared to the 51 corresponding items from the QPS<sub>Nordic</sub> questionnaire. The items in both questionnaires have the same direction, i.e. a low value indicates better working conditions and answers that indicate problems have a higher value. Since both questionnaires provided ordinal data, we used a non-parametric approach and calculated Spearman’s rank correlation coefficient ( $r_s$ ) [136] between the two questionnaires. We had in accordance to Chan [137] set the limit in this study for values of  $r_s$  at 0.3-0.5 as fair correlation,  $r_s$  at 0.6-0.8 as moderately strong correlation and a very strong correlation at  $r_s > 0.8$ . Internal consistency was analysed by Cronbach’s alpha coefficient. We considered values of  $\alpha \geq 0.7$  as good [138, 139].

## Study II

Statistical power calculations were based on a significance level of 5% and a power of 80%. To detect a 30% reduction of sick leave in the intervention group and a 10% reduction of sick leave in the reference group and an intra-class range between 0.1 to 0.4 [140] we needed a minimum of 20 clusters/primary care rehabilitation units. The estimated sample size per group was slightly more than 500 patients (259 per group). All analyses were performed according to an intention to treat approach on patient level. The main outcome was work ability measured as no days of sick leave or disability pension for four consecutive weeks [133] at 12 months after baseline. Descriptive statistics for baseline variables were analysed with Chi-square test for proportions. Comparisons were made between the groups over time and were analysed at baseline and at 3, 6, 9 and 12 months with Chi-square test with a significance level  $p < 0.05$ . Finally, a forward stepwise logistic regression analysis was performed to assess the odds ratio (OR) of work ability (no sick leave or disability pension) four consecutive weeks at 12 months after baseline. The tested independent variables were gender, education level (high/low) and health related quality of life (EQ-5D was categorised in two groups,  $<$  and  $\geq 0.6$  at baseline). The significance level was  $p < 0.05$ .

## Study III

Descriptive statistical analyses for the three years were made by percentage, median and quartiles. In order to do statistical analysis, the independent variables were grouped. The cut off values were decided using a pragmatic approach based on the a priori hypotheses in combination with the data generated.

The Kruskal-Wallis test was used to analyse group differences for PCCs location and size, Adjusted Clinical groups (ACG) measured as values  $> 1.0$  indicated increased morbidity and health care burden. Care Need Index (CNI) measured as values  $> 1.0$  indicated lower socioeconomic status and higher risk of developing illness. The Mann-Whitney test was used when comparing public and private PCCs and whether or not the PCC provided their own MMR. Finally, multiple linear regression analyses were performed to find factors independently associated with referral rate/1000 registered population to MMR. In the nonparametric tests and the multiple linear regression analyses we used data from 2012. The reason for this was that MMR in Region Skåne was introduced in late 2009 and our intention was to study referrals to MMR after implementation had been stabilized. To achieve the final model, significant variables were provided from a stepwise procedure with  $p < 0.05$  as inclusion criterion and  $p > 0.1$  as the removal (of already included variables) criterion.

## Study IV

The main outcome, work ability, was measured as no day on sick leave and no disability pension four consecutive weeks, at month 24 after baseline. Baseline data was compared with 1 and 2 years follow-up data within the MMR group and the reference group respectively. For the descriptive statistics we used Fisher's exact test and Chi-square test for proportions and T-test for continuous variables. For non-normally distributed variables we applied Mann-Whitney U test. The Wilcoxon's signed rank test was used to compare baseline data with 1 and 2 years follow up data. P-values < 0.05 were considered significant.

## Ethical considerations

All studies were conducted according to the Declaration of Helsinki and approved by the Regional Ethical Review Board in Lund, Sweden. Study I: Dnr 2012/497 and 2013/426, Study II: Dnr 2012/497, Dnr 2012/648, and Dnr 2012/833, Study III: Dnr 2012/290 and Study IV: Dnr 2014/290. In Region Skåne the PCCs are obligated to participate in follow-ups on quality of care. The patient groups to which the studies refer is one of the largest diagnostic groups in terms of sick leave. It is important to develop methods for strengthening work ability and reduce social costs. The study's results can make a contribution to the assessment of future treatment guidelines and be used for policy decisions, public health work and efficiency improvements in healthcare. Information about diagnoses, treatments and sickness benefit/sickness compensation are sensitive information and requires attention and care when conducting analyses. All data was unidentified during processing and all analyses were conducted at the group level.

Study I: Useful instruments to help clinicians pay attention to working conditions are lacking in primary care and are therefore important to develop. The "Blue flags" questionnaire is intended to screen for psychosocial risk factors and any potential need for action at the workplace in addition to the medical interventions at the PCC. The number of questions was limited, the questionnaire was quick to respond and the estimation was that there was no burden for the patients. Nevertheless there was a risk that the questions could raise concern, but our assessment was that the risk was low, and when patient needed, the physiotherapist was always available. Participation was voluntary and they could withdraw at any time without consequences.

Study II: In the early stages of neck and back pain there is a strong incentive for the employer to take action, and a well-functioning workplace usually has lower short-term sick leave and higher production. The patients in Study II had the

opportunity to deny the employer contact for example because of temporary work, project employment, self-employed or maternity leave. The patient received written information to hand over to the employer about the purpose of the physiotherapist contact. The first workplace dialogue was with the patient/employee and the next step was the physiotherapist dialogue with the employer. This means that the employer became aware early that the employee had work-related problems, actions could be taken to help and support so that the employees might fulfil their duties. This could possible affect the employee's position at the workplace.

Answering weekly text messages in during 52 weeks could be perceived as a burden and perhaps expensive. The cost was usually marginal, since most had phones where text messages were sent free of charge, but if the patient requested, compensation for the extra costs was paid. The SMS-Track Questionnaire system was an automatically computer system where the response message went into a computer file to be used for data analysis. There was a built-in encryption of the system for protection of participants' data when data were exchanged between patients and the server.

Study III and Study IV: The assessment was that there was no risk or increased inconvenience for the participants when contributing in the studies. Participants in study IV were informed of the study when they visited primary care and/or through advertisement in the daily press, which could mean that everyone neither was nor reached by the message, but we had no indications that this did not work satisfactorily. The participation was voluntary and they could refuse without affecting the continued treatment. No further ethical problems were expected to arise.



# Results

The main results of the four studies included in this thesis are represented in Table 3.

Table 3. Overview of the main results of the studies, study I-IV.

Aim	Main results
<p><b>Study I</b>  <b>To test the validity of a short “Blue flags” questionnaire, which focuses on work-related psychosocial risk factors and any potential need for contacts and/or actions at the workplace.</b></p>	<p>The two panels considered the 14 psychosocial items to be relevant and all 14 items showed satisfactory loadings on all factors. The overall correlation was very strong <math>r_s=0.87</math> (<math>p&lt;0.001</math>). Correlations were moderately strong for factor one, <math>r_s = 0.62</math> (<math>p &lt; 0.001</math>) and factor two, <math>r_s = 0.74</math> (<math>p &lt; 0.001</math>). Factor three and factor four were weaker, but still fair and significant at <math>r_s = 0.53</math> (<math>p &lt; 0.001</math>) and <math>r_s = 0.41</math> (<math>p &lt; 0.001</math>) respectively. The internal consistency of the whole “Blue flags” was good with Cronbach’s alpha of 0.76.</p>
<p><b>Study II</b>  <b>To study the effect on work ability when adding a workplace dialogue in physiotherapy practice for pain patients in primary care.</b></p>	<p>Significantly more patients in the intervention group reached work ability (108/127, 85%) compared to the reference group (127/171, 74%) (<math>p=0.02</math>). The intervention nearly doubled the odds of having work ability at one-year follow-up also after adjustment for baseline health related quality of life (OR 1.85, CI 1.01-3.38).</p>
<p><b>Study III</b>  <b>To study the impact of health care provider and community related factors on referral rates to MMR in patients with MSP in primary care.</b></p>	<p>Factors related to more MMR referrals/1000 registered patients in the multiple regression analyses were PCCs located in medium and large communities and with above average socioeconomic status among the registered patients at the PCCs, private PCC and PCCs providing their own MMR.</p>
<p><b>Study IV</b>  <b>To study the feasibility of identifying a defined treatment group and a comparable reference group for possible evaluation of a MMR programme in primary care for patients with MSP on short-term sick leave.</b></p>	<p>We were unable to identify big enough groups for comparisons. A minor part of the MMR cohort fulfilled all criteria at baseline and only 130 (3.4%) of the original 3831 patients were selected. By applying the set of criteria to the original reference cohort the reduction was even larger, from 101 877 to 213 patients (0.2%). The patients in the reference group had in general better health at baseline. The proportion of patients with full work ability increased over time and at the two year follow-up it reached 52% in the MMR group and 73% in the reference group.</p>

## Validity of the "Blue flags" questionnaire (Study I)

The two panels (n=111) considered the overall items to be relevant with a Content Validity Index of 90% with a range of 73-97%. A majority of the professionals considered each of the 14 items to be relevant. The patients were more doubtful when it came to "My tasks at work are too difficult" (41%) and "There has been bullying and harassment at my workplace during the last 6 months" (57%). All items in the "Blue flags" showed satisfactory loadings with a range of 0.514-0.872 (Table 4).

Table 4. Factor analyses of the 14 questions in the "Blue flags" (n=75). All 14 items showed satisfactory loadings with a range of 0.514-0.872. Factor one and two reflected two different aspects of job demands (job tasks and job control). Factor three reflected equality and factor four was mixed.

Rotated Component Matrix <sup>a</sup>	Factor 1	Factor 2	Factor 3	Factor 4
<b>My tasks at work are too difficult</b>	0.844			
<b>There are incompatible demands for me at my work</b>	0.713			
<b>I have too many tasks, too much work to do</b>	0.671			
<b>I can count on that if necessary, get help and support from my colleagues</b>	0.514			
<b>I can count on that if necessary, get help and support from my immediate supervisor</b>		0.723		
<b>My work contains positive challenges</b>		0.705		
<b>There are clear goals for my work</b>		0.637		
<b>I can decide how fast I work</b>		0.544		
<b>I have control in my work situation</b>		0.523		
<b>Old and young staff are treated equally at my workplace</b>			0.872	
<b>Men and women are treated equally at my workplace</b>			0.849	
<b>I can solve problems that arise at work</b>				0.614
<b>There has been bullying and harassment at my workplace during the last 6 months</b>				0.600
<b>The work requires me to concentrate all the time and can make decisions</b>				-0.569
<b>Variance explained, initial eigenvalues (%)</b>	25.2	14.9	10.9	8.3
<b>Rotated sums of squared loadings, variance explained (%)</b>	18.0	17.1	13.8	10.5

Extraction method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.

<sup>a</sup> Rotation converged in 7 iterations, rotation varimax

There was very strong correlation between the 14 items in "Blue flags" and the corresponding 51 items in QPS<sub>Nordic</sub> ( $r_s=0.87$ ,  $p<0.001$ ). The correlation between the "Blue flags" groups and the corresponding QPS<sub>Nordic</sub> items were moderately strong for factor one and factor two, weaker for factor three and four, but still fair and significant (Table 5).

Table 5. Correlations between the “Blue flags” and QPSNordic using Spearman correlation coefficienta.

QPSNordic 51 items	Blue Flags 14 items					p <sup>b</sup>
	Factor 1	Factor 2	Factor 3	Factor 4	All	
	Job demands, 4 items	Job tasks, 5 items	Equality, 2 items	Mixed, 3 items	14 items	
<b>Corresponding 20 items</b>	0.62					<0.001
<b>Corresponding 18 items</b>		0.74				<0.001
<b>Corresponding 2 items</b>			0.53			<0.001
<b>Corresponding 11 items</b>				0.41		<0.001
<b>All, 51 items</b>					0.87	<0.001

<sup>a</sup>Spearman's rank correlation coefficient ,  $r_s \geq 0.6$  was considered to indicate satisfying correlation

<sup>b</sup>p-values < 0.05 were considered significant

## The effect of workplace dialogue in addition to physiotherapy (Study II)

A workplace dialogue in addition to structured physiotherapy resulted in significantly improved work ability at one-year follow-up compared to physiotherapy only. Work ability was reached by significantly more patients in the intervention group (108/127, 85%) compared to the reference group (127/171, 74%) ( $p=0.02$ ). (Figure 7).

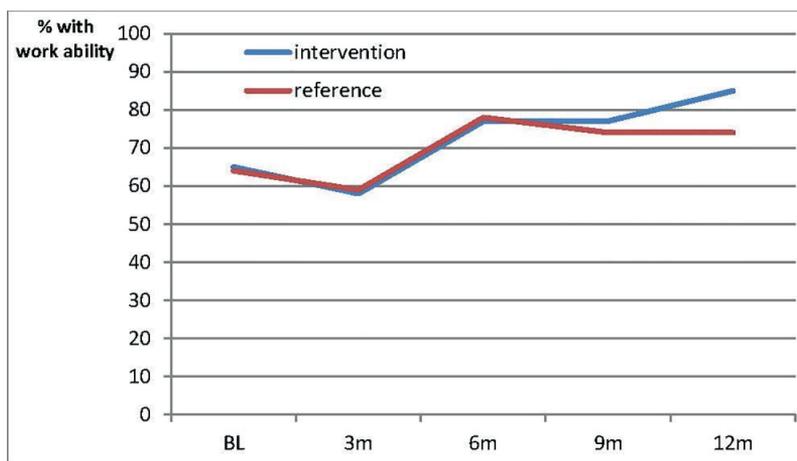


Figure 7. Proportion of patients with work ability at baseline and four consecutive weeks month 3 (week 9-12), month 6 (week 23-26), month 9 (week 36-39) and month 12 (week 49-52) after baseline.

The forward stepwise logistic regression analysis showed that patients in the intervention group reported work ability to a higher extent at one-year compared to the reference group also after adjustment for baseline health related quality of life (Odds ratio 1.85, CI 1.01-3.38). Patients with EQ-5D  $\geq$  0.6 at baseline were more likely to report work ability at one-year compared to patients with EQ-5D  $<$  0.6, regardless of which group they belonged to (odds ratio 1.92, CI 1.09-3.40) (Table 6). There were no significant associations between gender or education level with work ability, and there were no significant interactions between gender, education level or health quality of life.

Table 6. Result of logistic regression analysis. Odds ratio for having work ability one year after baseline.

Model <sup>a</sup>		OR	95% C.I. for OR		p
			Lower	Upper	
Step 1	Reference	1			
	CDM intervention	1,847	1,011	3,376	0,046
	EQ-5D <sup>b</sup> < 0.6	1			
	EQ-5D $\geq$ 0.6	1,921	1,086	3,398	0,025

<sup>a</sup>Forward stepwise logistic regression with  $p < 0.05$  as inclusion and  $p > 0.1$  as removal criterion. Variables tested for, but not meeting the inclusion criteria were gender and education level. <sup>b</sup>Health Related Quality of Life.

## The impact of health care provider and community related factors on referral rates to MMR (Study III)

PCCs located in larger communities sent more referrals/1000 registered patients compared to smaller communities ( $p=0.020$ ). Private managed PCCs sent more referrals/1000 registered patients compared to publicly managed PCCs ( $p=0.035$ ). Factors related to more MMR referrals/1000 registered patients in the multiple regression analyses were PCCs located in medium and large communities and with above average socioeconomic status among the registered patient population at the PCCs, private PCC and PCCs providing their own MMR. The explanatory value (R squared) for the final model was 24.5% (Table 7).

Table 7. Health care provider factors independently related to referral rate to MMR

Model <sup>a</sup>	95% Confidence interval for B			p
	B <sup>c</sup>	Lower bound	Upper bound	
(Constant) <sup>b</sup>	5.36	3.26	7.46	<0.001
<b>35-100 000 inhabitants with higher socioeconomic status</b>	4.88	1.15	8.61	0.011
<b>&gt;100.000 inhabitants with higher socioeconomic status</b>	16.98	10.44	23.51	<0.001
<b>&gt;100.000 inhabitants with lower socioeconomic status</b>	7.29	3.26	11.31	<0.001
<b>PCC, private model of health care</b>	3.95	1.33	6.57	0.003
<b>PCC, provided its own MMR</b>	4.41	1.35	7.47	0.005

<sup>a</sup> Multiple regression analysis, R<sup>2</sup>=0.245. <sup>b</sup>Constant was very small and small communities, communities with inhabitants with lower socioeconomic status, PCC public model of health care and PCC not providing its own MMR.

<sup>c</sup>Unstandardized B coefficient.

## The feasibility of identifying a defined treatment group and a comparable reference group for possible evaluation of MMR (Study IV)

Using a stepwise application of sets of criteria we were unable to identify big enough groups for comparisons. The process of adequately identifying relevant requirements to be met by both MMR and reference groups to enable comparison resulted in an extensive size reduction in the original cohorts. The majority of patients in the original reference cohort did not have an additional consultation due to the same diagnosis within three months. Only 13% of the MMR cohort and 3% of the reference cohort fulfilled the inclusion criterion of sick leave 91-180 days. The final MMR group totalled 130 patients, which was 3.4% of the entire MMR cohort of 3831 patients. The final reference group was comprised of 213 patients, only 0.2% of the entire reference cohort of 101 877 patients (Figure 4).

The MMR patients were at baseline to a greater extent younger and more were women compared to the reference group ( $p < 0.001$ ). Diagnoses such as myalgia and pain were more prevalent in the MMR group than in the reference group (39% vs. 29%,  $p=0.001$ ) and the MMR patients had one year before more frequent contacts with physicians than the reference group (mean 19 contacts vs. 14 contacts,  $p < 0.001$ ). Drug use targeting pain, sleep and depression was higher in the MMR group one year before than in the reference group. Also, the number of sick leave days during the year prior to baseline was higher in the MMR group than in the reference group (mean 136 days vs. 125 days,  $p=0.001$ ). In summary, the differences in baseline characteristics between the MMR patients and the reference patients were significant for all studied variables except for employment status and disposable

income. The proportion of MMR patients with full work ability increased successively during the follow-up and was 52% at 24 months after baseline. In the reference group the proportion of patients with full work ability 24 months after baseline was 75% (Figure 8).

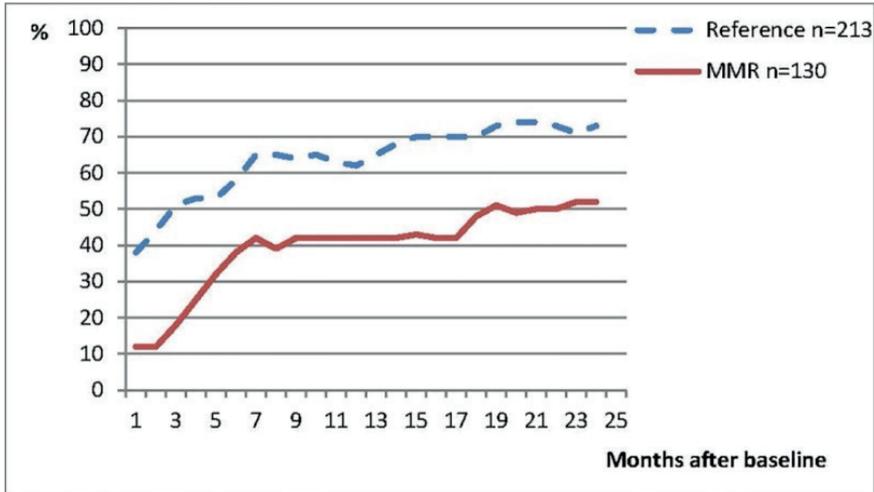


Figure 8. Results after baseline, MMR and reference included 2010-2011. Proportion of patients in percent per month, with full work ability, who did not have any sick leave days or disability pension (0 days) during the follow-up months.

# General discussion

The overall aim of this thesis was to obtain deeper knowledge on assessment, referrals and rehabilitation of patients with musculoskeletal pain and impaired work ability in a primary care setting. This thesis has deepened the knowledge on musculoskeletal pain rehabilitation in primary care focusing the patients work ability. A new assessment tool has been validated and an early intervention with workplace dialogue was found effective. Furthermore, knowledge has deepened about the impact of organisational and community factors on referral rates to rehabilitation in primary care. Finally, this thesis highlights the difficulties with evaluating effect of multimodal rehabilitation using register based data.

## Work related assessment and factors related to rehabilitation referrals

### Assessment of work related factors

Clinical work and patient assessment is different in primary care as compared to occupational rehabilitation settings. In primary care time available for each patient consultation is short (about 20 minutes) and the patient population is unselected. Recommendations have been made suggesting the use of screening methods to identify patients in early stages of illness with the purpose to guide them to the best treatment, yet avoiding over-treatment [89-92]. Despite these recommendations, assessing work-related psychosocial risk factors and any potential need for contacts and/or actions at the workplace as a standardised procedure in primary care is still not sufficiently established. It is well known that wellbeing at work is an important psychosocial work area and an important aspect of the psychosocial environment [39, 40, 72], and the short “Blue flags” questionnaire contains these dimensions. This was the first development of a short clinical questionnaire on work-related psychosocial risk factors, and to identify any need for action at the workplace in addition to the medical interventions in primary care. Our findings support the short “Blue flags” questionnaire as suitable for further development in clinical contexts. Adding a few ergonomic items could

be considered. Evaluation regarding feasibility and predictive validity is warranted.

## Referring to MMR

Previous research on MMR has focused on patient related factors, but one can expect that outcomes may also depend on factors related to the health care system. We found in Study III that PCCs in the largest community and private PCCs did send more referrals/1000 registered patients than those in smaller communities and public PCCs. This was in contrast to the Swedish model where everyone should be offered equivalent care [141]. According to our results health care providing factors such as PCC location, PCC size, public or private PCC, whether or not the PCCs provided their own MMR treatment, the burden of illness and the socioeconomic status in the area were of importance for access to rehabilitation. Differences in attitudes to MMR might also be important to explain referral rates, but this could not be captured by the present study design, since Study III was based on register data only. Our results shed light on factors related to referral rates to MMR and indicate that patients with MSD were not offered the same opportunities for rehabilitation since this depended on which PCC they visited. So, if there were differences in who actually was offered MMR, this could eventually impact patient outcomes after MMR.

The analysis thus revealed higher MMR referral rates from private than from public managed PCCs. This could be related to private PCCs having more experience and knowledge of MMR and which patients that would benefit from it. Patients in private PCCs could more frequently have requested MMR, or be more motivated and/or have the resources to participate in MMR. Participation in MMR requires motivation, the opportunity to be on sick leave and the ability to receive theoretical instructions. About 1100 PCCs in Sweden are accredited in Sweden and thus financed by the Swedish health care insurance system. Of these 33% are private managed [60]. This was an increasing number of privately managed yet publicly financed PCCs in Sweden during the time of this study [60]. The reimbursement paid to PCCs followed the patient and an increasing number of registered patients and high flow of rehabilitation assessments would be monetary incentives especially for privately managed PCCs. Private PCCs were in this study in many cases more recently established compared to public PCCs and the registered population in private PCCs had higher socioeconomic status compared to the registered population at public PCCs [142]. Patients with higher socioeconomic status may have better prerequisites to choose among health care alternatives and also being able to choose among different rehabilitation alternatives. This is confirmed in an earlier report which focuses on Swedish patients' ability to register with a PCC of their choice [143]. Women, highly

educated and young people more often changed or considered to change PCCs, while the less-educated and people living in smaller communities were less inclined to change PCC [143]. An unjustified difference between population groups often arises in the meeting between patients and health care professionals and therefore medical professionals have an important role of being aware of this and working towards a more equal health care [144].

Residential areas with lower socioeconomic status patients often have a lower PCC consultation frequency because of a combination of financial difficulties and in the Swedish health care co-payments for visit [145, 146]. This might lead to differences in health care use despite higher health care needs in such patient groups. Another reason for differences in health care could be patients' ability to influence the care given, propensity to make demands and ability to understand and process the information given [145, 146]. Large financial compensation for completed MMR has probably been a motivating factor for referring to MMR and this might also account for the higher referral rates among units with internal MMR.

## Work ability

Work ability is a multifaceted concept with several explanatory definitions influenced by the context in which work ability is described, and a consensus is reported that “*work (dis)ability is a relational concept resulting from the interaction of multiple dimensions that influence each other through different ecological levels*” [17]. This thesis did not analyse the quality of work ability, such as the individual dimensions, the organisational, and the social dimensions [17]. Furthermore, is it well-known that being at work despite work disability, presenteeism, with modified tasks and reduced abilities at work is important to consider when work ability is analysed [147-149]. Study II analysed work ability measured as no sick leave during four consecutive weeks at one-year follow-up [133], not the individuals' work ability in a longer perspective, which should be emphasized as important [19]. Study IV analysed work ability measured as no registered sick leave during four consecutive weeks at two-year follow-up.

In Study II, which was a well-designed RCT, about 95% of the patients were employed and in an early stage of neck and back pain. The intervention and the reference group did not differ at baseline in any of the studied variables. The study was well done and measuring work ability four consecutive weeks at one-year follow-up was satisfactory for evaluating the effect of the added workplace dialogue. In Study IV, the register-based MMR group differed significantly compared to the reference group at baseline. The outcome measure four weeks

without sick leave might not be relevant in regard to the characteristics of that population with more chronic pain.

It is unusual for primary care to contact the employer at early stages of ill health. Generally, employer contacts are made by occupational health services and when actualised in primary care it is mostly at later stages when the patient has a more pronounced morbidity or impaired work ability and it might be necessary to change work. The WorkUp research project (Study II) tested whether it was possible for physiotherapists in primary care to be the point of contact with the employer and if this was a successful method to initiate a dialogue about adjustments at the workplace to strengthen the employee's work ability or RTW. It must be emphasized that the effect of early workplace dialogue on work ability in Study II was shown at the end of the follow-up year. The result indicates that employer contact in early phases of MSP may promote work ability at one-year follow-up.

Our results showed that CDM/workplace dialogue previously tested only in patients with burn out, also can be used for patients with MSP in primary care [150]. In WorkUp the method was modified and unimodal, in that one profession, the physiotherapist, was responsible for assessment, treatment and the structured workplace dialogue model. We considered involving other professions in the study, but the patients were in early stages of back/neck pain, working or on short term sick leave. At such early stages engagement of more team members in primary care might give the patient indications that the problems are extensive and may therefore contribute to nocebo effects or medicalizations. Involvement of several professions might also have resulted in prolonging the time for treatment to start, which may be a risk factor for the development of long-term problems. Carlsson et al. reported that early multidisciplinary assessment for patients with short sick leave resulted in increased sick leave compared to a reference group [151], which strengthened our decision of the unimodal WorkUp design. Yet, in cases where patients' needs increased during treatment there were no obstacles to interact with multimodal interventions or to contact occupational healthcare or other specialised care. In the recent review of Cullen et al., a multi-domain treatment approach is considered as having the best evidence for reducing time off work [152]. According to the results of our study, workplace dialogue can be successfully carried out in primary care. The workplace dialogue initiated by a physiotherapist was found beneficial for patients with neck and back pain to promote work ability or RTW. Our results are in line with clinical experiences from occupation health services where early involvement with the employer is common practice in work rehabilitation.

## Possibilities to evaluate effects of rehabilitation

The RCT, Study II, was well designed and well implemented within the participating primary care rehabilitation units. The randomisation process was performed by an independent statistician who used a computer-generated program (random sample uniform distribution). The primary care rehabilitation unit and all physiotherapists working at the unit were either an intervention unit or a reference unit, never mixed. The randomisation was successful and the intervention and the reference group were largely comparable at baseline. The comparison between the groups included all patients and this method is known as an intention-to-treat analysis. According to Altman [136] this is the only reliable way to deal with patients who have not followed the study protocol. In Study II data were missing for 54 patients for the main outcome. The strict intention-to-treat analyses showed that patients in the intervention group reported work ability to a higher extent at one-year follow-up compared to the reference group, which strengthened the study.

Observational studies based on register data is second best, but it is crucial to find appropriate reference groups comparable to those in treatment. The requirements for this method to give valid results are that relevant criteria are used to define treatment and reference groups and that the groups are comparable at baseline. In clinical practice, interventions are often studied after implementation, sometimes because randomisation is inappropriate for ethical, economical or practical reasons. Alternative methods for evaluation of rehabilitation may be to limit implementation to specific areas (county councils) and keep other areas as reference in a national follow-up.

Despite an ambitious attempt to identify an adequate register-based reference group in Study IV, there were significant socio-demographic and health differences at baseline hindering a fair statistical comparison of the treatment effect between the groups. Strict inclusion and exclusion criteria were used in order to limit the study population to the intended target population with MSP, with a need for rehabilitation and potential for RTW, and for the MMR cohort restricted to those who received complete treatment. The finding that only a small fraction of the original MMR and reference cohorts fulfilled the criteria indicates that the implementation of the National Rehabilitation Program did not meet the intentions.

To achieve comparability between the groups we considered it vital that patients in the MMR and the reference groups had similar medical histories/disease burden. Therefore, our aim was to identify a reference group of patients with similar morbidity as the MMR group regarding diagnoses, health care contacts, extent of sick leave and drug use. Despite the use of strict inclusion and exclusion criteria in order to control these conditions the MMR group had more complex health

problems compared to the reference group before treatment. This was represented by more complex MSP diagnoses, higher number of sick leave days, higher number of contacts with physicians and higher drug use. There were also major gender and profession differences prior to treatment.

This indicates doubts as to if appropriate treatment was given to the right patients and shows that a significant part of patients given MMR did not belong to the intended target population, which has been confirmed in previous research [112].

For patients with MSP, MMR was offered after referrals in primary care and the units received a substantial financial compensation, which could result in displacement risks for patients with other needs for care. Financial incentives may also result in patients without rehabilitation potential being included, such as patients with previous long term sick leave, disability pension and patients with previously failed rehabilitation efforts.

It is also important to realize that no rehabilitation within health care services can create new suitable employments for patients with health problems that limit work ability in their current work. Initiatives and studies involving the labor market, the workplace, employers and rules for conversion of work and remuneration are needed.

## Methodological considerations

### Strengths

An overall strength in this thesis is that four different cohorts with different designs and different analyses were involved and cites different dimensions with regard to assessment and rehabilitation of patients with acute/subacute/chronic neck and/or back pain in primary care. The population of southern Sweden, where this thesis was carried out, represents approximately 20% of the Swedish population and the characteristics of people living in the region are comparable to Sweden as a whole [153]. The studies have been designed and undertaken based on high quality data and might indicate that these results are possible to generalize.

The patients in Study I, who assessed either content validity or structural and concurrent validity were recruited from several PCCs and from different areas in southern Sweden, which strengthens the possibilities to generalize the results. It could also be regarded as a strength that there were two different groups of patients in the content and structural/concurrent analyses, respectively.

Few drop-outs in Study II at follow-up indicate that the study was well-designed. It was a new challenge for the physiotherapists to have contact with employers to discuss patients' needs for workplace action [154]. However, the implementation of CDM worked well at the majority of units with minor exceptions. The primary care rehabilitation units had good geographical spread with localization in both smaller and larger communities as well as private and public modes of operation. The interventions were carried out within the framework of regular clinical activities further strengthening the generalizability of results.

To prevent type I errors a significance level of  $< 0.05$  was chosen [136]. The intended power for the study was not achieved, even though the recruitment period was prolonged by one year. Despite this, significant results with higher work ability at one-year after the CDM intervention were observed. This indicates an even higher potential for treatment effect than anticipated.

The use of short text messages has previously been tested and reported to be reliable when collecting weekly data in long term follow-ups [49, 155, 156]. The method is recommended when studying conditions where individual variation, details of fluctuation or periodicity is wanted. This study confirmed that this was a successful method of collecting data on short-term sick leave over one year follow-up as it resulted in high response rates for both the intervention and the reference groups. There were some missing data for the confirmatory outcome collected by short text messages. We performed analyses on the patients reporting one-year outcome, and in addition, we performed a strict intention-to-treat analysis including all patients. The results were similar strengthening the validity of our study.

Study III was designed and undertaken based on high quality data and the data covered an entire county council area. Region Skåne is in many ways representative for Sweden in terms of socio-demographic variables.

A major strength in Study IV was that Region Skåne had introduced a comprehensive program with clear pathways that made it possible to study large register-based cohorts that included all treated patients with MSP for certain periods of time. Feasibility studies mostly report positive results. We are convinced that even negative results need to be published.

## Limitations

Study I did not include establishment of cut-off points nor did we test for predictive validity. The "Blue flags" is not yet ready for use in clinical practice before further development. The questionnaire was tested using a Swedish version in a Swedish context and needs validation in other clinical settings.

There were large gender differences in Study II and Study IV. Women were represented in a higher proportion compared to men in both studies. Sweden is characterised by a traditional labor market, which is also reflected in Study IV with a majority of women working in health care, office, service and sale. A majority of men were working in industry, craftsmen and agriculture. The few studies available on gender segregation in the labor market indicate that both women and men have highest sick leave in gender segregated professions [157]. The patients' professions and which actions that were taken after the workplace dialogues for women and men respectively will be addressed in forthcoming analyses within the WorkUp trial [14].

In this thesis work ability was measured in Study II and Study IV defined as no day on sick leave and no disability pension during four consecutive weeks [133] and no other work ability dimensions were measured [17-19]. The reason for this in Study II was the used method with weekly text message answers for one year. Including the multidimensional aspects would have deepened the analysis of the work ability outcome, but this was not the purpose of Study II. In future studies we plan in-depth analysis how work ability is associated with other factors, such as work performance and leisure activity. To our knowledge Study II is the first trial to evaluate an early workplace dialogue in physiotherapy practice in primary care. For patients with acute/subacute neck and back pain the results are promising. However, before implementing the model in ordinary primary care the intervention needs to be replicated in additional studies.

We had no access to diagnostic data in Study III and could not analyse number of referrals in relation to number of diagnosed registered patients. Another limitation in this study was that we had no knowledge of pain patients not offered MMR and if they were offered other customized pain treatments/rehabilitations. No comparison was made between recently established PCCs and PCCs with long experience and established team routines. Study III focused on the organisational level and on different PCCs in a region in Sweden. Important limitations were that we had no data on details regarding the provided MMR. Discussions or recommendations regarding MMR taking place between patient and physician and whether the patient was expected to benefit from MMR were not captured. Furthermore, PCCs internal working methods, staff conditions and teamwork have not been analysed due to lack of data, factors which may also be of importance. Likewise data concerning MMR staff competence were not available, which therefore could not be taken in to account in this study, but might be important in future research.

Evaluations of MMR in observational studies are fraught with difficulties. Registered diagnoses as criterion for inclusion of referents in Study IV was problematic since diagnoses are affected by physicians' assessments [158].

Patients registered with the same MSP diagnosis may differ in vital areas associated with work ability and sick leave. One example is the diagnosis lumbago, M545 (ICD-10), which covers everything from a first episode of mild discomfort with high work ability and no sick leave days to a period of severe pain with largely decreased work ability and many sick leave days. Study IV demonstrates the difficulties inherent when trying to identify a relevant reference group, based on retrospective register data for this patient group. Consequently it questions the validity of retrospective comparisons between MSP patient groups treated with MMR and referents. In summary, the large reduction of the original study cohort due to the strict inclusion and exclusion criteria can be regarded as a weakness since the final study population was small. However, we argue that this was necessary in order to address selection bias within an observational study design.

## Ethics

Ethically, the four studies met the ethical requirements as a whole described in the methodology, but some aspects should be highlighted.

In Study II, there were a few patients who for various reasons denied the employer contact for example due to temporary work, project employment, self-employment or maternity leave. In these cases the work situation was discussed with the patient alone. In forthcoming qualitative studies the patients', the employers' as well as the physiotherapists' experiences of the workplace dialogue in physiotherapy practice in primary care will be analysed.

There were patients feeling stressed by answering the short text messages every week. In contrast to these reactions, there were several patients who lacked the weekly text message contact with primary care. There were also a small proportion of patients who had trouble managing smart phones or had poor mobile connection. If individuals needed alternative solutions to answer the question, they were offered to respond by letter or by e-mail, alternatively they were called weekly during the follow-up period. Their answers were then manually entered in the database. This alternative data collection was needed for 15 patients. Six patients responded by letter, four via phone calls and five responded by e-mail. The high response rate during the follow-up was the result of the simplicity of the method and some flexibility to offer alternative solutions to receive weekly responses. It may also be an ethical dilemma that those patients who could not speak the Swedish language did not have the same possibility of being included in the study.

In study III, we do not have knowledge of the actual circumstances, but it seemed that the care was not equal, which is a concept in the Swedish health care. We have no information about the current situation and what/if patients who needed care were offered alternative treatment instead of MMR. It is the same dilemma in Study IV, where we have limited knowledge regarding assessment of rehabilitation needs before MMR and if the most appropriate patient was offered MMR. If patients are offered rehabilitation without need, there might be overtreatment and risk for medicalization.

# Conclusions

This thesis has deepened the knowledge on musculoskeletal pain rehabilitation in primary care focusing the patients work ability. A new assessment tool has been validated and an early intervention with workplace dialogue was found effective. Furthermore, knowledge has deepened about the impact of organisational and community factors on referral rates to rehabilitation in primary care. Finally this thesis highlights the difficulties with evaluating effect of multimodal rehabilitation using register based data.

- The content, structural and concurrent validity was satisfactory in this first step of development of the “Blue flags” questionnaire on work-related psychosocial risk factors (Study I).
- Significantly more patients in the intervention group reached work ability compared to the reference group with an early workplace dialogue in addition to structured physiotherapy in primary care. (Study II).
- Referral rates to MMR in primary care were positively associated with PCCs location in larger sized communities with higher socioeconomic status among the registered population, private PCCs and PCCs providing their own MMR (Study III).
- It was not feasible to identify a comparable reference group for evaluation of MMR in primary care based on register data. The MMR treatment method has in other evaluations been questioned, but in absence of randomised trials, treatment effects cannot be fairly evaluated (Study IV).



# Future research

The results of our studies emphasize the need for further investigations in the field of rehabilitation in primary care focusing on work ability. To examine its usefulness in clinical practice the “Blue flags” questionnaire needs to undergo further evaluation regarding feasibility and predictive validity for identification of the need of workplace interventions. We also recommend that ”Blue flags” could be supplemented with a few ergonomic questions.

The interaction between patient related factors and organisational factors for possible referrals to rehabilitation and successful rehabilitation and work ability need to be analysed further. The providers’ way of working, the staff and the competence, perhaps with a quality approach, may deepen the knowledge in this area.

Patients’, employers’ and physiotherapists’ experiences of early contacts between health care professionals and the workplace need to be further explored in primary care. Whether the positive effect on work ability is sustainable over long term will be analysed in a three-year follow-up, which will also include register data on sick leave.

In order to be able to evaluate the effect of MMR in primary care, a carefully conducted RCTs is needed.



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