Physiotherapy in primary care for working-age patients with early back and neck pain

Screening tools, interventions and outcomes

MALIN FORSBRAND DEPARTMENT OF ORTHOPAEDICS | CLINICAL SCIENCES, LUND | LUND UNIVERSITY



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Screening tools, interventions and outcomes

Malin Forsbrand



DOCTORAL DISSERTATION

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Faculty opponent Professor Margreth Grotle Oslo Metropolitan University, Department of Physiotherapy, Oslo, Norway

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Physiotherapy in primary care for working-age patients with early back and neck pain Screening tools, interventions, and outcomes			neck pain
Screening tools, interventions, and outcomes Many people suffer from back and neck pain, and the condition affects both the individual, by causing pain and disability, and society, because of high costs caused by work disability and health care consumption. Clinicians need tools to identify patients at risk of poor outcome, in order to tailor interventions, and we need more knowledge about what interventions can promote work ability and also prevent long-standing disability. The overall aim of this thesis was to obtain deeper knowledge on health care interventions in primary care for working-age patients with acute or subacute back and neck pain, by studying screening tools, physiotherapy interventions and self-reported outcomes. Methods: Study I was a cross-sectional validation study where we compared the concurrent validity of the STarT Back Tool (SBT) and the ÖMPSQ-short form questionnaires, including psychometric properties and clinical utility, (n=315). Study II was a prospective psychometric validation study where we studied the predictive validity of the SBT for the outcomes work ability and health-related quality of life at long-term follow-up (n=238). Study III was a secondary analysis of self-reported function, health-related quality of life and work ability, in a prospective cluster- randomised controlled trial (WorkUp) with one-year follow-up (n=352). The intervention was a workplace dialogue (CDM) as an add-on to structured physiotherapy treatment. Study IV was a descriptive cohort study nested within the WorkUp trial where we described type and number of physiotherapy interventions provided for patients with neck and back pain at risk of work disability. We also examined whether patients in the intervention group received more occupational medicine interventions (n=343). Results/Conclusions: The correlations between the SBT and the ÖMPSQ-short scores were moderately strong for individuals with acute or subacute back and/or neck pain, and the SBT was feasible to use in clinical p			
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MADE IN SWEDEN

To my family

"People are human beings, produced by the society in which they live. You encourage people by seeing good in them"

Nelson Mandela

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Abstract

Patients with back and neck pain are frequently seen in primary care, where they are directed to physiotherapy as first-line treatment. The condition affects both the individual, by causing pain and disability, and society, because of high costs caused by work disability and health care consumption. Clinicians need tools to identify, at an early stage, patients at risk of poor outcome, in order to tailor interventions. We also need more knowledge about what interventions can promote work ability and prevent long-term disability.

The overall aim of this thesis was to obtain deeper knowledge on health care interventions in primary care for working-age patients with acute or subacute back and neck pain, by studying screening tools, physiotherapy interventions and self-reported outcomes regarding function, health-related quality of life and work ability.

Methods: Study I was a cross-sectional validation study where we compared the concurrent validity of the STarT Back Tool (SBT) and the ÖMPSQ-short form questionnaires, including psychometric properties and clinical utility, for patients with acute or subacute back and/or neck pain (n=315). Study II was a prospective psychometric validation study where we studied the predictive validity of the SBT for the outcomes work ability and health-related quality of life at long-term follow-up (n=238). Study III was a secondary analysis of self-reported function, health-related quality of life and work ability, in a prospective cluster-randomised controlled trial (WorkUp) with one-year follow-up (n=352). The intervention was a workplace dialogue (CDM) as an add-on to structured physiotherapy treatment. Study IV was a descriptive cohort study nested within the WorkUp trial where we described type and number of physiotherapy interventions provided for patients with neck and back pain at risk of work disability. We also examined whether patients in the intervention group received more occupational medicine interventions (n=343).

Results and Conclusions: The correlations between the SBT and the ÖMPSQ-short scores were moderately strong for individuals with acute or subacute back and/or neck pain, and the SBT was feasible to use in clinical practice. We therefore suggest that SBT can be used in primary care to identify individuals with both back and neck pain at risk of long-term pain and disability. We found that the SBT also can be used to identify patients at risk for a poor long-term health-related quality of life and/or work ability outcome in a population with acute or subacute back and/or neck pain. We found no effect of the CDM, as an add-on to structured physiotherapy, on self-reported function, health-related quality of life and work ability (point prevalence) at the 12-months follow-up. All self-reported outcomes improved over time in both the intervention and the reference group. We found that patients with neck and back pain at risk of work disability were offered many different types of interventions in primary care, with physical exercise being the most frequently used treatment

category. Patients in the intervention group received more occupational medicineoriented interventions than patients in the reference group.

This thesis has deepened the knowledge on health care interventions in primary care for working-age patients with acute or subacute back and neck pain. The Swedish STarT Back Tool, a brief screening tool designed for tailored interventions based on risk stratification/triage, has been validated for individuals with acute or subacute back and neck pain in primary care. Long-term effects of a workplace dialogue as an add-on to structured physiotherapy on self-reported measures have been evaluated. The broad spectrum of interventions used by primary care physiotherapists for patients with back and neck pain in working-age are described.

Svensk sammanfattning

Besvär från rörelseorganen, framför allt från rygg och nacke är en av de vanligaste anledningarna till sjukfrånvaro i västvärlden. Patienter med dessa besvär utgör en stor andel av de som söker primärvården där fysioterapi ofta är första linjens vård. Rygg och nacksmärta kan orsaka nedsatt funktion och aktivitetsförmåga vilket ofta innebär en betydande förlust av livskvaliteten samt ekonomiska konsekvenser för individen och samhället. Det finns behov av att hitta lättanvända frågeformulär i primärvården som kan hjälpa vårdgivare, att i tidigt skede identifiera de som riskerar att få långvariga besvär och därmed kunna individanpassa och förbättra kvaliteten på vården. Vi behöver mer kunskap om vilka behandlingar som kan stärka arbetsförmågan och vilka behandlingar som bäst förhindrar att en akut episod av rygg- eller nacksmärta utvecklas till ett långvarigt besvär.

Det övergripande syftet med denna avhandling var att få ökad kunskap om interventioner i hälso- och sjukvården riktade till patienter i arbetsför ålder som söker för nack- och ryggbesvär i primärvården, genom att studera frågeformulär, fysioterapeutiska behandlingar och resultaten av dessa avseende självrapporterad funktion, arbetsförmåga och hälsorelaterad livskvalitet.

Studie I var en metodologisk studie där vi prövade ett nytt frågeformulär "STarT Back Tool" (SBT) genom att jämföra det med ett mer använt frågeformulär, "ÖMPSQ-kort". SBT används för att klassificera patienter enligt risk för långvariga ryggbesvär till tre olika riskgrupper baserat på modifierbara fysiska och psykosociala riskfaktorer. Tydliga åtgärdsstrategier har definierats för respektive riskgrupp och visat sig vara en kostnadseffektiv strategi inom primärvården. Vi undersökte hur de båda frågeformulären stämde överens med varandra samt de båda frågeformulärens kliniska användbarhet för patienter med akut eller subakut rygg och/eller nacksmärta (n=315). Resultatet visade att frågeformulären stämde bra överens (måttligt starkt) och att SBT var ett kliniskt användbart frågeformulär. Därför föreslår vi att SBT kan användas i primärvården för att identifiera individer med risk för långvarig smärta och nedsatt funktion.

Studie II var också en metodologisk studie (prospektiv, psykometrisk valideringsstudie) där vi prövade om SBT formuläret kunde användas till att prediktera hälsorelaterad livskvalitet och arbetsförmåga vid långtidsuppföljning (n=238). Resultatet visade att SBT också går att använda för att identifiera individer med akut eller subakut rygg- och nacksmärta som riskerar att få nedsatt arbetsförmåga och/eller hälsorelaterad livskvalitet på lång sikt. I och med att SBT nu prövats i svensk version kan det användas av vårdgivare för att kunna ge säkrare prognoser och därmed en mer skräddarsydd vård till varje enskild patient vilket i förlängningen kan ge både en tids- och en kostnadsbesparing för vården och ett snabbare tillfrisknande för patienten.

Studie III var en prospektiv randomiserad kontrollerad studie i primärvården med ett års-uppföljning som inkluderade 352 patienter med akut eller subakut smärta i rygg eller nacke (interventionsgrupp, n= 146 och referensgrupp, n=206). Studien analyserade sekundära utfall i WorkUp; självrapporterad funktion, hälsorelaterad livskvalitet och arbetsförmåga (mätt som punktprevalens). Interventionen var Arbetsplats Dialog för Arbetsåtergång (ADA) där den behandlande fysioterapeuten hade en dialog i flera steg med patienten och arbetsgivaren som komplement till strukturerad fysioterapi. Vi fann ingen ytterligare effekt av ADA, som tillägg till strukturerad fysioterapi, när det gäller självrapporterad funktion, hälsorelaterad livskvalitet och arbetsförmåga vid 12-månaders uppföljningen. Alla självrapporterade mått förbättrades över tid i både interventionsoch referensgruppen. I tidigare studier har ADA visat positiv effekt på arbetsförmåga (mätt som frånvaro från arbetet fyra veckor i rad) och att metoden är kostnadseffektiv.

Studie IV var en deskriptiv kohortstudie som utfördes inom WorkUp studien. I denna studien beskrivs typ och omfattning av de olika fysioterapeutiska behandlingarna som erbjöds patienter med rygg- och nacksmärta, med risk för sjukskrivning, inom ramen för WorkUp. Vi har också undersökt om patienterna som tillhörde interventionsgruppen fick fler arbetsplatsinriktade åtgärder (t. ex ergonomiråd) jämfört med patienterna i referensgruppen. Resultatet visade att flest behandlingar gjordes inom kategorin fysisk träning och nästan alla patienter i studien fick åtminstone en sådan behandling. Patienter som tillhörde interventionsgruppen fick fler arbetsplatsinriktade åtgärder jämfört med patienter som tillhörde interventionsgruppen.

Denna avhandling har fördjupat kunskaperna om interventioner i hälso- och sjukvården riktade till patienter i arbetsför ålder som söker för rygg- och nackbesvär i primärvården. Den svenska versionen av frågeformuläret STarT Back Tool har validerats och kan nu användas för individer med akut eller subakut rygg- och nacksmärta i primärvården. Långtidseffekterna av en arbetsplatsdialog som tillägg till strukturerad fysioterapi gällande självrapporterad funktion, hälsorelaterad livskvalitet och arbetsförmåga har utvärderats. Det breda spektrumet av behandlingar som fysioterapeuter använder för patienter med rygg- och nacksmärta i primärvården har beskrivits i denna avhandling.

List of papers

- I. Forsbrand M, Grahn B, Hill JC, Petersson IF, Sennehed CP, Stigmar K. Comparison of the Swedish STarT Back Screening Tool and the Short Form of the Örebro Musculoskeletal Pain Screening Questionnaire in patients with acute or subacute back and neck pain. BMC Musculoskeletal Disorders 2017;18(1):89.
- II. Forsbrand MH, Grahn B, Hill JC, Petersson IF, Post Sennehed C, Stigmar K. Can the STarT Back Tool predict health-related quality of life and work ability after an acute/subacute episode with back or neck pain? A psychometric validation study in primary care.*BMJ Open*. 2018;8(12):e021748.
- III. Forsbrand MH, Turkiewicz A, Petersson IF, Sennehed CP, Stigmar K. Long-term effects on function, health-related quality of life and work ability after structured physiotherapy including a workplace intervention. A secondary analysis of a randomised controlled trial (WorkUp) in primary care for patients with neck and/or back pain. Accepted for publication in Scandinavian Journal of Primary Health Care 2020-01-09.
- IV. Forsbrand MH, Grahn B, Petersson IF, Post Sennehed C, Stigmar K. Manuscript. Physiotherapy interventions for working age patients with acute/subacute back and neck pain in primary care – a descriptive cohort study. *In manuscript*.

Description of contributions

Paper I

•	
Study design	Malin Forsbrand, Birgitta Grahn, Jonathan C Hill, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar.
Data collection	Malin Forsbrand
Data analyses	Malin Forsbrand, Birgitta Grahn, Ingemar F Petersson, Kjerstin Stigmar.
Manuscript writing	Malin Forsbrand
Manuscript revision	Malin Forsbrand, Birgitta Grahn, Jonathan C Hill, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar.
Paper II	
Study design	Malin Forsbrand, Birgitta Grahn, Jonathan C Hill, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar.
Data collection	Malin Forsbrand
Data analyses	Malin Forsbrand, Birgitta Grahn, Jonathan C Hill, Ingemar F Petersson, Kjerstin Stigmar, Mikael Åström.
Manuscript writing	Malin Forsbrand
Manuscript revision	Malin Forsbrand, Birgitta Grahn, Jonathan C Hill, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar.
Paper III	
Study design	Malin Forsbrand, Aleksandra Turkiewicz, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar.
Data collection	Malin Forsbrand
Data analyses	Malin Forsbrand, Aleksandra Turkiewicz, Ingemar F Petersson, Kjerstin Stigmar
Manuscript writing	Malin Forsbrand

Manuscript revision	Malin Forsbrand, Aleksandra Turkiewicz, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar.
Paper IV	
Study design	Malin Forsbrand, Birgitta Grahn, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar
Data collection	Malin Forsbrand, Birgitta Grahn, Charlotte Post Sennehed
Data analyses	Malin Forsbrand, Birgitta Grahn, Ingemar F Petersson, Kjerstin Stigmar
Manuscript writing	Malin Forsbrand
Manuscript revision	Malin Forsbrand, Birgitta Grahn, Ingemar F Petersson, Charlotte Post Sennehed, Kjerstin Stigmar

Thesis at a glance

	Study I	Study II	Study III	Study IV
Aim	To study the concurrent validity of the STarT Back Tool and the short form of the Örebro Musculoskeletal Pain Screening Questionnaire, including psychometric properties and clinical utility in a primary care setting.	To evaluate the predictive validity of STarT Back Tool on the outcomes health-related quality of life (HRQoL) and work ability at long-term follow-up.	To study the long- term effects of a workplace dialogue (CDM) in addition to structured physiotherapy regarding self- reported function, health-related quality of life and work ability.	To describe physiotherapy interventions provided for patients with neck and back pain at risk of work disability, and to examine whether patients in the intervention group received more occupational medicine interventions.
Study population	Acute/subacute BP and/or NP, 18-67 years, applying for physiotherapy in primary care, n=315.	Acute/subacute BP and/or NP, 18-67 years, applying for physiotherapy in primary care, n=238.	Acute/subacute BP and/or NP, 18-67 years, applying for physiotherapy in primary care, n=352.	Acute/subacute BP and/or NP, 18-67 years, applying for physiotherapy in primary care, n=343.
Design	Cross-sectional validation study.	Prospective psychometric validation study.	A secondary analysis of a C- RCT.	Descriptive cohort study.
Main results	The correlation for SBT and ÖMPSQ- short total scores was moderately strong (0.62, p<0.01). Classification showed moderate agreement (x=0.42), SBT had fewer miscalculations (13/315) than the ÖMPSQ-short (54/315).	Statistically significant differences between all three SBT risk groups were found in HRQoL and work ability at follow-up (p<0.001). The proportion of patients with poor HRQoL and poor work ability at follow-up was significantly higher in higher risk groups.	The mean differences in outcomes between groups were small and not statistically significant. The intervention group improved function from 46.5 (SD 19.7) to 10.5 (SD 7.3)(FRI); HRQoL from 0.53 (SD 0.29) to 0.74 (SD 0.20)(EQ-5D) and work ability from 5.7 (SD 2.6) to 7.6 (SD 2.1) (WAS).	Physical exercise was most common (59.7%) and almost all patients (99.7%) received at least one intervention from this category. 81.7% of patients in the intervention group and 54.2% in the reference group received occupational medicine interventions (p<0.001).
Conclusions	SBT is clinically feasible to use in primary care for this patient group.	SBT can identify patients at risk for a poor long-term health-related quality of life and/or work ability outcome.	CDM had no added effect on self- reported function, health-related quality of life and work ability (point prevalence) in addition to structured physiotherapy alone.	Different interventions were provided, with physical exercise the most frequent.The intervention group received more occupational medicine-oriented interventions.

Abbreviations

AUC	Area under the curve
BP	Back pain
CDM	Convergence Dialogue Meetings
EQ-5D	EuroQol five-dimension
FRI	Functional Rating Index
ICF	International Classification of Functioning, Disability and Health
HRQoL	Health-related quality of life
MMR	Multimodal/Multidisciplinary Rehabilitation
MSK	Musculoskeletal
MSP	Musculoskeletal Pain
NP	Neck pain
OR	Odds ratio
PROMS	Patient-reported outcome measures
RCT	Randomised controlled trial
SBT	STarT Back Screening Tool or STarT Back Tool.
WAI	Work Ability Index
WAS	Work Ability Score
ÖMPSQ	Örebro Musculoskeletal Pain Screening Questionnaire
ÖMPSQ-short	t Short form of the Örebro Musculoskeletal Pain Screening Questionnaire

Definitions

Acute/subacute	In this thesis, a pain duration of less than 12 weeks.
Back pain	In this thesis, back pain means low back pain or low back pain with pain from the thoracic region.
Concurrent validity	The degree to which the scores of a questionnaire are an adequate reflection of a 'gold standard' (1).
Function	Self-reported function was measured with the Functional Rating Index (FRI) (2).
Health-related quality of life	Self-reported health-related quality of life was measured with the EQ-5D-3L questionnaire (3).
Low back pain	Pain in the lower back is "pain and discomfort located below the costal margin and above the inferior gluteal folds, with or without leg pain" (4).
Neck pain	Neck pain is "pain located in the anatomic region of the neck with or without radiation to the head, trunk and upper limbs" (5).
STarT Back Tool	Synonymously with STarT Back Screening Tool where 'STarT' refers to Screening for Targeted Treatment. The STarT Back Tool is a brief prognostic tool that is specifically designed to help clinicians produce an index of treatment modifiable factors, to be used to stratify individuals into appropriate initial treatment pathways (6).
Treatment category	Physiotherapy interventions in this thesis were placed in five treatment categories: physical exercise, behavioural medicine interventions, manual therapy, occupational medicine interventions, and physical modalities (7).
Validity	The degree to which a questionnaire measures the construct(s) it is supposed to measure (1).
Work ability	Self-reported work ability, "current work ability compared with the lifetime best", was measured with Work Ability Score (WAS) which is the first single- item question from the Work Ability Index (WAI) (8).

Rationale

Back and neck pain is very common in the general population, and patients with these problems are often seen in primary care. The condition greatly affects the individual, by causing pain and disability, but also society, because of the high costs associated with work disability and health care consumption.

I have been working in primary care for many years and have met patients seeking treatment for back and neck pain. My experiences are that it is difficult for clinicians to prioritise between the large number of patients with different needs and complexity. Patients with complex needs are often identified too late, when the pain has already become chronic and the consequences for the individual have become severe. How can clinicians better identify and treat those who are at risk of poor outcome and maybe in need of more comprehensive interventions? How can clinicians better tailor interventions? Clinicians need useful tools that can guide them and their patients in the rehabilitation process.

In 2013, I was given the chance to become a PhD student within the WorkUp project and combine it with my work as a clinical physiotherapist. This combination gave me the opportunity to gain deeper knowledge on how we can improve and evaluate the care and treatment of patients with back and neck pain in primary care, and that formed the basis of this thesis.

Background

Back and neck pain

Prevalence, health care consumption and costs

Musculoskeletal pain (MSP), especially back pain and neck pain, is very common in the general population (9-12) causing disability for the individual and high costs for society. In 2015, the Global Burden of Disease Study reported that back and neck pain was the leading cause of years lived with disability in most countries worldwide (13). Between 2006 and 2016, the number of years lived with disability due to back and neck pain increased by approximately 20% (14), and the disability is most frequent in working-age groups (15).

Low back pain and neck pain are common among the adult population. The lifetime prevalence of low back pain is high, ranging between 51 and 84% (16). For neck pain, the lifetime prevalence is lower, ranging between 14 and 71% (10). The point prevalence is also higher for low back pain, ranging between 12 and 33% (11) compared to neck pain which ranges between 6 and 22% (10). In general, low back pain and neck pain are more common in women than in men (10, 11).

In European countries, individuals with back and neck pain constitute a large proportion of the users of primary care (17, 18). In 2012, 20-30% of the total number of visits to a general practitioner in Sweden were patients with MSP (19), and patients seeking treatment for back pain consume nearly twice as much health care as the general population (20). The consequences of MSP are large for both the individual, for health care and society, so it is important to obtain further knowledge about the treatment of working-age patients with back and neck pain in primary care.

Back pain and neck pain are one of the most common causes of work disability and sickness absence in the western world (21) and individuals presenting with these conditions are at higher risk of reduced work ability (22), decreased functional ability (23), and poor health-related quality of life compared to those without pain (24, 25). Low back pain and neck pain often occur together (26) further increasing the risk of sickness absence (27). Chronic pain is a major public health problem affecting around 19% of adult Europeans (28). Gustavsson et al. (29) estimated the total costs for patients with chronic pain to be EUR 32 billion per year, the

equivalent of about a tenth of the Swedish gross domestic product (29). The indirect costs for sick-leave and early retirement in Sweden constituted the largest cost component (59%) (29). It is therefore important to identify risk factors for work disability at an early stage (30) and to evaluate the effects of early interventions in primary care.

Definitions and aetiology of back and neck pain

Pain is defined by the International Association for the study of Pain (IASP) as:

"An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (31).

Pain is an individual and subjective experience that can be described in different ways and that has both a sensory and an emotional part. The experience of pain can be described by three components; sensory, affective and cognitive (32). These components reflect the complexity of pain and the need to view pain from a biopsychosocial context. Pain is a personal and multidimensional phenomenon and cannot be compared between individuals (32). Pain is an important survival mechanism that is meant to protect our bodies from potential damage, and it is first when the acute pain does not resolve as expected and turns into long-standing pain that it becomes problematic.

For most individuals presenting with back pain, the specific nociceptive source cannot be identified (15). About 85% of all low back pain and neck pain is classified as nonspecific, where the underlying disease or pathology remains unknown (33). Specific pain is equivalent to pain attributed to a recognisable or a known specific pathology, and nonspecific pain is attributed to all other back and neck pain. In primary care, specific pathology is rarely found (34).

Back pain and neck pain are commonly defined by the location of pain, and there are many different definitions. Low back pain is commonly defined as "pain and discomfort located below the costal margin and above the inferior gluteal folds, with or without leg pain" (4) and neck pain as "pain located in the anatomic region of the neck (between the superior nuchal line and the spine of the scapula from behind and covering the throat from the front), with or without radiation to the head, trunk and upper limbs" (5). The term 'back pain' can sometimes mean only 'low back pain' and sometimes 'low back pain and pain in other parts of the back such as the thoracic and neck region' (35). In a Delphi study, the majority (82%) of experts from 12 countries, agreed on the 'back pain' definition to only mean pain in the lower back (= low back pain) (35). In this thesis, back pain means low back pain or low back pain with pain from the thoracic region.

Pain and pain experience can also be described based on duration: acute or long-term pain (chronic) (36). Acute pain refers to pain that arises due to an injury or

illness and normally disappears when the injury is healed (36). If the pain remains intermittent or persistent for more than three months, it is often described as long-term pain (36). In this thesis, patients with back and neck pain are described as having acute or subacute pain, with a pain duration of less than 12 weeks.

Although back and neck pain in general is classified as non-specific, pain can also be classified based on its aetiology; nociceptive, neuropathic, idiopathic and psychological pain (32). Acute and subacute back and neck pain is mainly nociceptive or neuropathic. Nociceptive pain is due to stimuli from the musculoskeletal system, such as muscles, bones, cartilage tissue, joints, ligaments, tendons or bursae (32). Neuropathic pain refers to pain due to damage of the nerve fibre (36).

There are also other systems for classifying pain. Woolf et al. (37) proposed a mechanistic pain classification system where pain is divided into two broad categories: adaptive and maladaptive pain. Adaptive pain refers to the normal reaction of an acute injury or promoting healing when an injury has already occurred (nociceptive or inflammatory pain), and maladaptive pain is a pathological process of the nervous system with no meaning for the healing process (neuropathic pain or functional pain) (37). Maladaptive pain plays a major role in chronic pain states and has also been referred as "pathological generalized pain" and "central sensitization syndrome (CSS)"(38).

If there are no indications that pain has either a nociceptive or a neuropathic aetiology, the pain can be classified as idiopathic (32). The cause of the pain remains unknown, but there are no signs of injuries or diseases. A possible explanation for this type of pain is a dysfunction in the neurological system; examples of such conditions are long-standing back pain and fibromyalgia (32). A third descriptor of such pain has been recently introduced, namely nociplastic pain (39).

In a systematic review, the authors found associations between low back pain and findings from MRI: disc bulge, disc extrusion, spondylolysis and also Modic type 1 change (40). Even though these associations were found, it is still not clear how we can use these findings from MRI in the rehabilitation and recovery from back pain.

Multifactorial causes, risk and prognostic factors

Back pain and neck pain can be seen as multi-factorial and different risk and prognostic factors are described. In general, such factors are more frequently described concerning back pain compared to neck pain.

Back pain is often seen as multi-factorial, with many different factors and mechanisms contributing to the cause and recurrence (41). Also neck pain can be seen as having multifactorial causes (42). In a recent model, Hartvigsen et al. (15) presented different factors that can contribute to back pain and disability:

biophysical, comorbidities, genetic, social, and psychological factors. Therefore a biopsychosocial approach can be applied to capture the complexity of back and neck pain. In recent decades, the biopsychosocial model has become a dominant model in the conceptualisation of the aetiology and prognosis of back pain (43). The model can be applied also for neck pain (42). The first model was developed already in 1977 (44), and various models have been developed (45) (46) over the years. The biopsychosocial approach of pain posits that biological, psychological and social factors influence who develops chronic pain and that the chronic pain has biological, psychological and social consequences (42). As both back and neck pain can be seen from a biopsychosocial perspective with multifactorial causes (41, 42) also treatment should be multifactorial with a combination of physical and psychological therapies that pay attention to mechanisms at work or in daily living that may exacerbate the injury and delay the recovery thereof (41).

The International Classification of Functioning, Disability and Health (ICF, WHO 2001) (47) is a generic conceptual model that is widely used which can guide clinicians in both assessment and treatment of patients with back and neck pain. The framework is based on the biopsychosocial model. The ICF illustrates that an individual's disability and functioning arise from the reciprocal interactions between a health condition and contextual factors. The conceptual model can also support pain rehabilitation, where the physiotherapist together with the patient can set achievable goals (48).

Back pain should be looked upon as a long-standing condition, with different trajectory patterns, rather than single episodes (49). This starting point indicates the importance of being aware of various prognostic factors that can have considerable impact of the course of disease. The term 'prognosis' refers to the risk of future health outcomes in people with a given disease or health condition (50). Patients with different regional pains often share similar underlying attributes, source of symptoms and prognostic factors (51). Artus et al. (52) found that e.g. high pain intensity, widespread pain, high functional disability, somatisation, movement restriction and presence of previous pain episodes are generic prognostic factors for several musculoskeletal conditions (including back and neck pain) in primary care (52). The severity of functional disability and pain can therefore contribute to more long-standing disability for patients with both back and/or neck pain (53, 54).

Cognitive functioning and increased psychological or psychosocial stress can also affect the prognosis (53, 55). Being depressed or suffering from anxiety is associated with a worse outcome. Pain catastrophising (56), fear avoidance beliefs and self-doubts about the ability to influence the condition (self-efficacy) (57) can also contribute to more long-standing problems, even though we cannot fully understand these associations. The fear-avoidance model (58), which describes how fear of pain leads to the avoidance of activities and to disability, is commonly applied to musculoskeletal pain, e.g. back pain. Today this model also includes pain cognitions, which are found to be important for the development of long-standing

pain and disability. Pain cognitions include both thinking and behavioural aspects. Psychosocial risk factors play a key role in the transition from acute to chronic pain and the development of long-term disability (59-62).

Personal characteristics, such as being older or having poor general health, have a negative impact on the outcome of the disability (53), and societal factors such as low education and income also have a negative influence on the outcome of the disorder (63). Physical inactivity and high body mass index (BMI) have shown to be associated with an increased risk of chronic pain in the low back and neck/shoulders in the general adult population (64).

Well-known physical factors in different type of occupations and in the work environment, such as physically demanding work, can impact the start and maintenance of back pain (53). It is not only physical factors that are important; social relations at work and the psychosocial work environment in general are also important to consider (53, 65).

Clinical course and prognosis

Most individuals with new episodes of back and neck pain usually improve rapidly, and many studies show that most of the pain will resolve within a few weeks (66-68) but with little change in pain thereafter (66). In a systematic review of the prognosis of acute low back pain, rapid improvements were also seen for disability and return to work within one month (69). In a study of acute low back and neck pain in the general population, it was found that the pain remained unchanged over the follow-up year for individuals who had equal pain in the neck and low back areas at baseline and for those reporting four or more pain sites at baseline (66). The same study also reported that only 20% of individuals with acute neck and low back pain seek health care for their complaints (66).

Although most individuals with an acute episode of low back or neck pain have good prognosis, more than a third of patients will still have symptoms and recurrences one year later (42, 70). Having more than two previous episodes of low back pain triples the odds for future recurrences (70). For some individuals, the pain becomes persistent and disabling (71). In a Swedish cohort of individuals seeking care for nonspecific low back pain or NP, about half of the population reported pain and disability five years after onset (72). Evidence is mounting that back pain (BP) should be treated more like a long-lasting condition with a variable course and different trajectory patterns rather than unrelated episodes (15, 49).

Back and neck pain in primary care

Patients with back and neck pain are often seen in primary care (73). In Sweden, patients with musculoskeletal complaints are directed by triage to physiotherapists rather than to general practitioners. Patients can also apply directly to physiotherapy without a referral. This is called direct access and is widely used globally and means that the physiotherapist is generally the first professional that examines the patient. This triage method is considered safe for the patient and cost-effective (74, 75). If the patient needs a referral to imaging, a sick leave note or prescription of an anodyne drug, a physician must be seen. In a recent systematic review on how patients with back pain are treated by GPs or in emergency units, the authors found that less than 20% of patients with low back pain that saw a GP received evidence-based treatment for their back pain, and also found an overuse of referrals to imaging and opioid prescriptions (76).

The evidence of the effectiveness of different interventions is often summarised in clinical guidelines, and many guidelines recommend similar approaches for the assessment and management of low back pain (77). Non-pharmacological pain management is recommended as first-line treatment in guidelines for spinal pain, and a biopsychosocial framework should guide management (77-79). For the diagnostic procedure of patients with low back pain, evidence-based guidelines recommend considering the medical history and a physical examination to identify 'red flags', neurological testing to identify radicular pain, no routine use of imaging (unless there are signs of serious pathology present), and assessment of psychosocial factors ('vellow flags') (80). Guidelines recommend staying active, reassurance on the favourable prognosis, training that supports self-management, return to work, encouraging physical activity and avoiding bed rest as first-line care for all patients with low back pain (77, 78). For patients with persistent symptoms or patients who are judged to be at higher risk of poor outcome, a more complex and intensive treatment is recommended, including exercise therapy and psychological programmes (77, 78). For patients with neck pain, the same treatment strategy can be applied (79, 81).

In general, guidelines recommend prudent use of medication, imaging, and surgery (77, 78). A recent guideline review (78) identified two different approaches to guide the management of low back pain. Firstly, the traditional approach, which divides patients according to acute, subacute or chronic pain. Clinicians use a 'stepped-care approach', which begins with simple therapies and only progresses to more complex treatments if the treatments are not sufficiently effective. This approach commonly features in US (82) and Danish guidelines (83). Secondly, a newer approach, where clinicians use short-risk prediction tools to match patients to treatment packages based on their risk of poor clinical outcome, e.g. the STarT Back Tool (84), the ÖMPSQ-short form (85) or PICKUP (86) used in the UK, NICE (87), and Belgian guidelines (88).

A wide range of treatment options is available for patients with back and neck pain in primary care (51, 80, 81) but there is insufficient knowledge about which treatment is the optimal intervention for preventing an acute back or neck pain episode from becoming chronic (89).

Risk assessments of patients with back and neck pain

Evidence-based treatment includes screening for serious pathology (90) (red flags), for psychosocial risk factors (yellow flags) (91) and for work-related psychosocial risk factors (blue flags) (92, 93). Red flags may include severe pain, back pain starting in older age (>65 years for men, >75 years for women), a previous accident that caused the pain, constant or worsening of pain, history of malignancy, steroid use, drug abuse, severe mobility limitations, increased pain after movement, weight loss, problems urinating, visible deformity, sensitivity loss in groin and inside thighs, loss of sphincter control, or severe muscle weakness and walking difficulty (90, 94). It is also important to identify whether there are signs of an inflammatory joint disease, such as successive onset after age 40, persistent joint stiffness, joint stiffness in the morning, distal joints also affected, inflammatory processes in the eyes, or heredity (95, 96).

Yellow flags are "a set of psychological and social risk factors involving maladaptive cognitions and beliefs about the pain and the consequences of pain related to work and daily activities" (97), and cover aspects such as beliefs about the condition and pain, coping, self-efficacy and fear avoidance (91, 98). Blue flags address conditions at work that can contribute to the development of different disabilities (92).

Red flags are examined both by physicians and physiotherapists, to identify whether a severe condition is present and whether there is need for immediate treatment. Yellow flags do not need such urgent attention but are important to examine as soon as possible, to prevent long-term pain and disabilities. In recent years different risk stratification tools to examine yellow flags have emerged to help and support clinical decision making in primary care, to prevent long-term pain and disabilities.

Screening tools for yellow flags

The Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ) is a screening questionnaire developed to assist in the early identification of yellow flags and patients at risk of developing work disability (measured as sickness absenteeism) due to the pain (99, 100). The ÖMPSQ is one of the most widely used screening questionnaires, and several studies demonstrate the utility of the ÖMPSQ, both in research and clinical settings (97, 99, 101-103). The ÖMPSQ with 25 items has satisfactory psychometric properties and has demonstrated the ability to predict

long-term pain, disability and sick leave outcomes for patients with acute or subacute spinal pain (102, 104).

A short form of the ÖMPSQ (ÖMPSQ-short) with ten items was constructed to further increase the clinical utility of the ÖMPSQ (85). The short form was validated against the long form in two samples of people with musculoskeletal pain – one occupational health care population and one primary care population. The correlation between the short and long form was 0.91, and the receiver operating characteristic curve (ROC) was nearly identical for the long and short versions of the questionnaire for both the primary care population (0.84 vs 0.81) and the occupational sample (0.72 vs 0.70). The authors conclude that the ÖMPSQ-short can be used for identifying patients with work disability as measured by sick leave in both settings (85).

The STarT Back Tool (SBT) (https://startback.hfac.keele.ac.uk/) is a short risk stratification tool specifically designed for primary care settings comprising nine questions on predictors for long-term disabling back pain, enabling individuals to be matched with appropriate targeted treatments, according to their prognostic profile (6). The SBT was developed to classify patients with nonspecific LBP into one of three prognostic groups, low, medium or high risk for long-term pain and disability, with the high-risk group characterised by psychosocial prognostic factors. Matched treatments are defined and linked to each of the risk groups (Figure 1). Patients at low risk of poor outcome are directed to supported self-management, education and advice, including pain relief and encouragement to stay active, and are also informed about an overall good prognosis (treatment A). Those at medium risk are offered evidence-based physiotherapy interventions such as manual therapy and exercise (treatment B). For those at high risk, a combined physical and psychological intervention is offered (treatment C) (105). The SBT exemplifies stratified care (106) based on prognostic subgrouping and matched treatments. Patients at high risk of poor outcome are offered a more extensive treatment while those at low risk of poor outcome can be reassured and offered minimal treatment. The overall aim of stratified care is to optimise treatment response, increase healthcare efficiency and reduce unnecessary harm by offering the right treatment to the right patient at the right time (106). Stratified care has now become a clear research priority (107, 108).

Using the SBT together with targeted treatment has shown improved efficiency in terms of patients' clinical outcomes and cost-effectiveness in the UK (the STarT Back trial), primarily due to reductions in disability, health-care costs and work absence (84, 109). The STarT Back risk stratification approach has been tested and implemented in family practice and the IMPaCT back study (Implementation to Improve Patient Care through Targeted Treatment) replicated the findings of the STarT Back trial (110).

Matched treatment Treatment C Treatment B Medium risk Low risk Complexity

Figure 1.

The STarT Back Tool is a subgrouping tool that allocates patients into low-, medium- or high risk of long-term pain and disability in order to guide decision making about treatment and referral. There are matched treatments defined and linked to each of the risk groups. Reprinted with permission from the author (J Hill)

The discriminant validity, internal consistency, repeatability and predictive validity of the SBT were assessed in a sample of participants with nonspecific back pain in a UK primary care population (6). The SBT showed ability to identify individuals with poor back-specific disability (measured by the Roland and Morris Disability Questionnaire, RMDQ) at six months (6). The psychometric properties of SBT have been tested in several countries and it is now used in a number of different international settings (111-118). The SBT has previously been cross-culturally adapted and validated in Swedish in a small low back pain population (n=62) (119).

The UK National Institute for Health and Care Excellence guidelines recommend using brief questionnaires to identify individuals of poor outcomes and stratify care (87), but such tools are lacking for use in primary care. There is also a need to further develop and test evidence-based and practically useful methods for the biopsychosocial assessment of back pain (120). The SBT has earlier been compared with the ÖMPSQ-short for patients with low back pain (115,119,121) but not yet for a large primary care population with patients applying for physiotherapy treatment due to both back pain and neck pain. The SBT is developed and validated to predict future disability due to back pain of any duration (6, 112,113,122,123) but it has not yet been studied for the outcomes of HRQoL and work ability for a population with acute or subacute back and neck pain in primary care.

SBT has been further developed (124), and the Keele STarT MSK tool, which covers a wider range of musculoskeletal conditions (e.g. back pain, neck pain, shoulder pain, knee pain and multisite pain), has recently been validated (125). A

study has also investigated the most appropriate primary care treatment options for MSK patients stratified according to prognostic risk (126). A randomised controlled trial, the STarT MSK Trial is currently testing whether matching treatments to the different categories of risk for these conditions is better than usual treatment (https://www.keele.ac.uk/startmsk/).

Physiotherapy interventions for back and neck pain

Physiotherapy

The World Confederation for Physical Therapy (WCPT) describes physiotherapy as "services that develop, maintain and restore people's maximum movement and functional ability" with the goal to maximise people's quality of life and movement potential by looking at physical, psychological, emotional and social wellbeing" (127). The definition of physiotherapy includes the promotion of health and wellbeing and prevention of impairments, activity limitations, and participation restrictions. Physiotherapists strive to increase function, reduce pain, and set goals that can be both functional or activity-based depending on the patients' needs, and the physiotherapist often takes into account personal factors such as lifestyle, coping styles and fear avoidance beliefs.

The physiotherapy process includes examination/assessment, evaluation, diagnosis, prognosis/plan, intervention/treatment and re-examination. Physiotherapists also make recommendations for self-management and provide consultation within their area of expertise, and decide when patients need to be referred to another healthcare professional (127). Physiotherapists in Sweden practice autonomously and choose the appropriate interventions based on the examination/assessment of the patient. The methods used should always be based on evidence-based practice, which means that the physiotherapist integrates the best available external research findings with the individual's clinical expertise and patient preferences (128).

Physiotherapy interventions can be offered either as a single intervention or as part of a more complex intervention, or rehabilitation together with other health care professionals, i.e. multimodal rehabilitation. Physiotherapists may provide many different interventions for patients with back and neck pain, which may include counselling, coaching, pain management, training, therapeutic exercise and different types of manual therapies with the aim of maintaining or improving functional limitations or disabilities (127) (Figures 2-4). Physiotherapists in primary care in Sweden use many different interventions for patients with acute or subacute back and neck pain, the most common being advice on posture and staying active, and different types of exercises (129).



Figure 2. The physiotherapist gives information and advice. Photo: Region Blekinge

Physical exercise

Physical exercise is a fundamental treatment method in physiotherapy and is a commonly used intervention for treating back pain and neck pain (130,131). Physical activity is defined as "any bodily movement produced by skeletal muscles that require energy expenditure" (132). The term physical exercise is a subgroup of physical activity and is planned, structured, repetitive and purposeful in the sense that the improvement or maintenance of one or more components of physical fitness is the objective (133). Different types of exercises can be applied, e.g. stabilisation exercises (134) or McKenzie exercises (135, 136) which are treatment methods that have shown moderate strength of evidence for improving acute or subacute low back pain (129). For patients with chronic and recurrent low back pain, motor control exercises have been shown to be superior to general exercises (137). Although there is strong evidence that exercise therapy has beneficial effects on short and long-term pain for musculoskeletal conditions (51), there is no evidence that one specific exercise is more effective than another (51).

Advice and counselling on physical activity can be delivered by different health care professionals, such as physiotherapists, through 'physical activity on prescription' (PAP). This is a concept for promoting physical activity to enhance health and promoting prevention for individuals with a high risk of developing lifestyle-related diseases due to inactivity (138). PAP is an individual written prescription of physical activity that all licensed physiotherapists and healthcare providers in Sweden are recommended to use to prevent and treat illness.



Figure 3. Instruction on physical exercise. Photo: Region Blekinge

Manual therapies

Manual therapies are methods used to reduce pain and to restore joint function and range of movement. For patients with acute/subacute neck pain, cervical mobilisation or manipulation have been shown to have a moderate level of success compared with placebo or other treatments (139) and a combination of these interventions with exercises are recommended (140). For patients with acute or persistent low back pain, spinal manipulation is recommended as a second-line treatment or as an adjunctive treatment option in other therapies (77). Massage (in this review defined as soft-tissue manipulation using the hands or a mechanical device) can also be used for pain relief (141).Traction is another manual technique commonly used by physiotherapists and is often supplemental to other interventions, but the efficacy of traction has been questioned in systematic reviews for both neck and back pain (142, 143).



Figure 4. Manual mobilisation of the lumbar spine. Photo: Region Blekinge

Physical modalities

Other methods can be used for relieving pain, such as physical modalities, acupuncture, transcutaneous electrical nerve stimulation (TENS), ultrasound, taping and ice/hot packs, which have shown varying degrees of evidence of effectiveness (51, 77, 144). However, acupuncture is recommended for persistent low back pain in most guidelines (145) and heat therapy has shown to be beneficial in acute low back pain (77).

Multimodal rehabilitation

The physiotherapist is an important and vital part of multimodal rehabilitation or multidisciplinary rehabilitation (MMR). This includes physical and behavioural and/or psychological interventions recommended for patients with persistent pain, especially patients with high levels of disability or distress (145). These interventions are often group-based and include education and training in different psychological techniques to improve coping with pain and also physical interventions to improve health (146). MMR is team-based and involves different professionals, such as physician, physiotherapist, psychologist and occupational therapist, and the patient is also part of the team (147).

Many different MMR programmes have been evaluated. and there is some evidence that MMR is effective in relation to return to work (148,149) and also cost-effective for patients with neck and back pain (150). However, Kuoppala et al. (151) concluded that workplace interventions must be integrated with rehabilitation to be effective in the long term (151). Patients with musculoskeletal disorders (mainly back and neck pain) who have been offered MMR in a national rehabilitation

programme in Sweden significantly improved their health-related quality of life and functional ability after MMR rehabilitation, especially those who were not on sick leave or had no disability pension the year before rehabilitation (152). Factors such as earlier periods of sick leave/disability pension, problems with exercise tolerance functions or mobility after rehabilitation were negatively associated with sick leave at follow-up (152). Advice to remain active and specific education about the condition is an essential part of physiotherapy treatment for all patients with back and neck pain, regardless of pain duration (77, 81).

Ergonomic advice

Physiotherapists can give ergonomic advice as a complementary intervention to other physiotherapy interventions. The advice can be linked to risk factors such as bent and twisted torso, repetitive work, static postures, work over shoulder height or below knee height, heavy lifting (including pulling and pushing) (153-156). Ergonomic advice aims to reduce these risk factors by providing advice on work technology, new equipment or other workplace designs. Ergonomic advice and ergonomic interventions are commonly used by physiotherapists and are often applied in treating work-related neck pain (157,158) but ergonomic advice has been shown to be sparingly used for patients on sick leave (159).

Back and neck pain and work

In general, work is good for health (160), giving structure to our daily lives, providing us with a salary, generating social relationships, and promoting meaningful activities. Being unemployed or off work can result in poorer general health and higher health care and drug consumption (160). It is therefore important to support patients to remain at work or, if sick-listed, return to work. Patients with back and neck pain can, in general, continue to work, unless the work involves inconvenient working positions or strenuous work tasks. Heavy physical work or poor work environment is associated with decreased work ability (155). Psychosocial factors also play an important role for work ability (161). Perception of high demands and lack of control strongly impact work ability (155).

Work ability

The concept of work ability is described in different ways in the literature. Fadyl et al. (162) described six categories that contribute to work ability: physical functioning, psychosocial functioning, thinking and problem-solving skills, social and behavioural skills, work place factors, and factors outside the work place. Ilmarinen (163) described the "work ability house", where the concept is described

from an even broader perspective and includes different competences, values and attitudes and societal factors (164). In a broad review, Lederer et al. (165) conclude that work (dis)ability is generally seen as a relational concept, i.e. different factors on different levels that affect each other. This means that work ability should be seen in the context of contextual factors (165). How work ability is defined is important for legislation, but also for how we use different outcomes in research.

Work ability can also be seen as a continuum, where work ability varies during the life span (166). Different supportive and destructive factors occur and affect how work ability is experienced (166). In this model, Lindberg argues for the existence of a tipping point when work ability is so decreased that sick leave is necessary.

Work ability for the individual is always to be seen in the perspective of contextual factors, such as environmental factors (i.e. family, work, laws, cultural beliefs) and personal factors (i.e. age, gender, race, educational level, coping) (167).

Self-reported work ability is often used as an outcome in research on rehabilitation back to work (8, 168). Work ability can be seen as the individual's experience of their own ability to work and must not be synonymous with sick leave.

Sickness absence and presenteeism

If work ability is decreased due to sickness or disease, an individual can be placed on sick leave. This is verified in a medical certificate issued by a physician. In Sweden, The Social Insurance Agency makes the final decision on whether the individual can receive economic benefits, based on the medical certificate. During the first week of sickness absence, there is no need for a sick leave note, but absence after day eight requires this.

Different sociodemographic factors such as age, sex, marital status and area of residence are in general associated with increased risk for sick leave (169-172). Unhealthy living habits such as smoking, overweight and limited physical activity also increase the risk of sick leave (173,174). Factors in the work environment and job content also contribute to an increased risk of sick leave. These include strenuous work tasks, inconvenient working postures, heavy lifting and static workload (161, 175). There is also evidence that psychological factors, such as low level of control over the working situation, are associated with sick leave (172). Work-related psychosocial factors are also important, influencing work ability and sick leave (93).

Presenteeism is described in different ways in the literature (176), but can generally be seen as individuals who remain at work although they experience decreased work ability due to sickness (176). This means that an employee can experience both decreased work ability and different symptoms, but still decides to go to work. Haglund et al. (177) found that 45 percent of patients with spondyloarthritis experienced reduced work productivity (presenteeism) and that worse quality of life, disease activity, physical function, self-efficacy and depression were all associated with reduced productivity at work (177). The decision to go to work despite the pain can be based on feeling forced to work due to a heavy workload and solidarity to other employees, but may also be due to economic reasons.

Interventions that support return to work or remaining at work

Patients with back or neck pain often consult primary care for treatment (17, 18). Different types of medical interventions can be important in improving the disability but, in a systematic review, Cullen et al. (178) conclude that multi-domain interventions were strongly supported. The return to work was accelerated by combining medical and vocational rehabilitation interventions. The multi-domain interventions also encompass coordinating the different interventions. Tjulin et al. (179) emphasised the need for developing collaboration with different stakeholders, and contacts with the employer have been highlighted (180). In the SWAP trial, patients with MSP received vocational advice (181). The results showed that the patients in the intervention group were less absent from work, but there were no differences in how pain was experienced.

In conclusion, patients with back and neck pain often apply for health care in primary care and are directed to physiotherapy treatment. These patients often experience pain and decreased function, but also work ability limitations. To develop and improve how these patients are treated, we need further knowledge on how we can identify patients at risk for developing long-term pain and disability, and on how interventions can be tailored.

Aims

Overall aim

The overall aim of this thesis was to obtain deeper knowledge on health care interventions in primary care for working-age patients with acute or subacute back and neck pain, by studying screening tools, physiotherapy interventions and selfreported outcomes.

Specific aims

The aims of the individual papers were:

- I. To compare the concurrent validity of the STarT Back Tool and the short form of the Örebro Musculoskeletal Pain Screening Questionnaire, including psychometric properties and clinical utility, in a primary care setting.
- II. To evaluate the STarT Back Tool's predictive validity for health-related quality of life and work ability outcomes at long-term follow-up in a population with acute/subacute back and/or neck pain.
- III. To study the long-term effects of a workplace intervention in addition to structured physiotherapy regarding self-reported measures in patients with acute/subacute neck and/or back pain.
- IV. To describe physiotherapy interventions provided for patients with neck and back pain at risk of work disability and to compare if patients in the intervention group received more occupational medicine interventions.

Methods

Setting

The setting for all four studies was the WorkUp trial – a prospective cluster randomised controlled trial in primary care, including one-year follow-up (ClinicalTrials.gov ID: NCT02609750). All accredited and tax-financed, public and private primary care centres, in three regions in southern Sweden (Region Skåne, Kronoberg and Blekinge), were invited to participate in the study. A total of 32 primary care centres, linked to 20 primary care rehabilitation units including physiotherapy, agreed to participate. In Sweden, physiotherapy is first-line treatment for patients with musculoskeletal pain and no referrals are needed.

The 20 primary care rehabilitation units that declared an interest in participating in the WorkUp trial were classified on the basis of similar size (number of patients listed and community size of the units' location), the registered patients' morbidity (ACG-Adjusted Clinical Groups) and socioeconomic status (CNI-Care Need Index). The primary care rehabilitation units were then matched in pairs, based on the criteria above. Primary care rehabilitation units were then randomised pairwise into 10 intervention and 10 reference primary care rehabilitation units, with the randomisation process performed by an independent statistician. Each rehabilitation unit, and all physiotherapists working at the unit, were regarded as either an intervention unit or a reference unit, but never mixed. The staff of the primary care rehabilitation units (including physiotherapists) were therefore not blinded to allocation.

Patients were recruited to the study from January 2013 to December 2014. A total of 67 physiotherapists worked at the 20 rehabilitation units with patients included in the study. All physiotherapists engaged in the trial received continuous updates on evidence-based treatments.

The main objective of the WorkUp trial was to examine whether early and structured physiotherapy treatment, including a workplace dialogue as an add-on, can lead to improved work ability and health-related quality of life in patients with back and/or neck pain. All patients in the trial received structured physiotherapy treatment, including examination, assessment, diagnosis, and return visits to the physiotherapist at three-, six- and 12-month follow-up, where patient- and clinician-

reported outcomes were completed. All physiotherapy interventions were recorded during the study period.

Patients of working age (18-67 years) were consecutively recruited to the trial when they applied for physiotherapy due to an episode of acute or subacute (<12 weeks) back and/or neck pain. It could be either a first episode or a recurrent episode of back and/or neck pain, after a period of at least three months of no substantial pain. The patients were included if they had worked at least four consecutive weeks in the previous year, were considered at risk of sick leave (\geq 40 points on ÖMPSQshort) (85), had no long-standing sick leave (\leq 60 days) due to acute/subacute back and/or neck pain. Exclusion criteria were full-time disability pension, addiction diagnosis, ongoing medical treatment for an acute disease, pregnancy, or inability to understand the Swedish language.

Study design

All studies in this thesis were based on quantitative data. The four studies required different designs and methods according to the different aims and research questions. To study the concurrent validity of the SBT questionnaire against the ÖMPSQ-short, a cross-sectional design was used (study I). Study II examined the predictive ability of the SBT for self-reported outcomes at long-term follow-up, so was based on a prospective psychometric validation study. Study III was a prospective, cluster-randomised controlled trial, studying secondary outcomes at long-term follow-up of a workplace intervention (CDM), in addition to structured physiotherapy. The aim of study IV was to describe physiotherapy interventions provided for patients with neck and back pain in the WorkUp trial, and a descriptive design was therefore used. An overview of the studies is presented in Table 1.

Table 1.

Overview of the design, setting, participants, sample size, outcomes and analysis methods included in the studies.

	Study I	Study II	Study III	Study IV
Design	Cross-sectional validation study	Prospective psychometric validation study	Prospective cluster randomised controlled trial - a secondary analysis	Descriptive cohort study
Setting	Primary care rehabiliation units, WorkUp	Primary care rehabiliation units, WorkUp	Primary care rehabiliation units, WorkUp	Primary care rehabiliation units, WorkUp
Study population	Patients with acute/subacute back and/or neck pain applying for physiotherapy in primary care.	Patients with acute/subacute back and/or neck pain applying for physiotherapy in primary care.	Patients with acute/subacute back and/or neck pain applying for physiotherapy in primary care. All patients included in WorkUp	Patients with acute/subacute back and/or neck pain applying for physiotherapy in primary care. All patients included in WorkUp
Sample size	n=315	n=238	n=352 intervention n=146, reference n=206	n=343 intervention n=142, reference n=201
Instruments and Outcomes	STarT Back Tool and short form of Örebro Musculoskeletal Pain Screening questionnaire	STarT Back Tool HRQoL* (EQ-5D**) Work ability (WAS***)	Function (FRI****) HRQoL* (EQ-5D**) Work ability (WAS***)	Physiotherapy interventions
Analysis method	Descriptive statistics, non- parametric, Spearman's rank correlation, cross tabulation, Cohen's kappa	Descriptive statistics, non- parametric, Kruskal-Wallis, Chi square test for trend, logistic regression, area under the curve (AUC)	Descriptive statistics, parametric, linear mixed effect regression model	Descriptive statistics, Non-parametric, Chi-square test Mann-Whitney U test

*HRQoL=Health-related quality of life, **EQ-5D=EuroQoI five-dimensions, ***WAS=Work Ability Score (single-item question from Work ability Index, WAI), **** FRI= Functional Rating Index

Study populations and procedure

All patients in the four studies were included in connection with the WorkUp trial. Patients, 18-67 years, who applied for physiotherapy in primary care due to acute or subacute back and neck pain, who were not currently on sick leave or had no long-standing sick leave (≤ 60 days), and who had been working at least four weeks in the previous year were screened with ÖMPSQ short. Patients completed the SBT and the ÖMPSQ-short questionnaire during the first physiotherapy visit. The SBT and the results of the screening were not actively used to stratify care. If there were medical conditions requiring urgent need for medical care or examination (red flags) (90), patients were referred to a medical doctor without delay and not included in the studies.

Studies I and II (validation studies of the questionnaire STarT Back Tool) involved patients that were both included and not included in the WorkUp trial (scoring \geq 40 or <40 points respectively at ÖMPSQ-short), to ensure a broad sample. Studies III and IV only involved patients who were included in WorkUp trial (scoring \geq 40 points at ÖMPSQ-short).

Patient populations and time periods of the studies are presented in Figure 5.

Patients, 18-67 years, not on sick leave or sick leave \leq 60 days, worked \geq 4 weeks past year, who applied for physiotherapy in primary care due to acute or subacute back and neck pain 2013-01-01 – 2014-12-31. Screened with ÖMPSQ-short.

-	-	-	-
Study I n= 315 Patients who applied for physiotherapy 1 Jan 2013 – 1 Jan 2014 with complete data on SBT from baseline	Study II n= 238 Patients who applied for physiotherapy 1 Jan 2013 – 1 Jan 2014 with complete data on SBT from baseline and with complete follow-up data on WAS, EQ-5D and FRI Included in WorkUp: Intervention n=61 Reference n=99	Study III n= 352 Patients included in the WorkUp-trial ≥40 p at ÖMPSQ-short Intervention n=146 Reference n=206	Study IV n= 343 Patients included in the WorkUp-trial ≥40 p at ÖMPSQ-short and complete data on physiotherapy interventions during 12- smonth follow- up Intervention n=142 Reference n=201
	baseline and with complete follow-up data on WAS, EQ-5D and FRI Included in WorkUp: Intervention n=61	n=146 Reference	physiotherapy interventions during 12- smonth follow- up Intervention n=142 Reference
	Not included in WorkUp, treatment unknown n=78		

Figure 5.

Study populations in this thesis.

Studies I and II

In studies 1 and II, patients were consecutively recruited between January 2013 and January 2014 (Figure 5). Patients, 18-67 years, who applied for physiotherapy due to acute or subacute back and/or neck pain, who were not currently on sick leave or had no long-standing sick leave (≤ 60 days) and who had been working at least four weeks in the previous year were asked to participate. If there were medical conditions requiring urgent need for medical care or examination (red flags) (90), patients were referred to a medical doctor without delay and not included in the studies.

The questionnaires were scored by the physiotherapist according to the methods specified by the instrument developers (6, 100). The data from the SBT and the ÖMPSQ-short questionnaires was then manually entered into a SPSS 22.0 database and thoroughly checked and validated.

Patients in study I were excluded if they had any missing item on SBT and, for the $\ddot{O}MPSQ$ -short, missing items were treated as described by the original $\ddot{O}MPSQ$ (182), where one missing item was permitted. The physiotherapist's calculation of total score/subscore of SBT and total score of $\ddot{O}MPSQ$ -short were independently checked and errors corrected. All miscalculations were saved. Of the original sample, 329 patients completed the questionnaires. Three patients were excluded due to wrong age (<18 years, n=1, >67 years, n=2) and 11 patients were excluded because of missing items on the SBT questionnaires. The final sample for study I was 315/329 patients (96%) with complete baseline data from the SBT and $\ddot{O}MPSQ$ -short questionnaires (Figure 1), 62.5% females and 37.5% males.

For study II, we used the same sample as in study I (n=315) but the patients also required follow-up data on work ability and HRQoL. To obtain follow-up data for patients not included in the trial (n=78), questionnaires were sent out by post. The design of study II was not settled when patients were recruited to the WorkUp trial, so we needed informed consent from these patients who were not included to enable collection of follow-up data. We sent a total of 124 letters asking for consent, and 120 accepted.

We sent out questionnaires by post in May 2015 (median 22, range 16-27 months after baseline) to the consenting patients (n=120), and 67% (n=78) responded to the questionnaire on follow-up on work ability and HRQoL.

The analyses were restricted to those who had complete data for work ability (n=235) and HRQoL (n=238) at 12-month follow-up (Figure 1). Of these, 160 (67%) participants were females and 78 (33%) were males. The sample included patients included in the trial (intervention n=61 and reference n=99) and patients not included in the trial (n=78).

Study III

Study III involved patients that were included in the WorkUp trial (n=352) between 1 January 2013 and 31 December 2014 (Figure 5).

Patients who met the inclusion criteria were invited consecutively to participate in the study and were screened using the ÖMPSQ-short. No record was kept of the number of ineligible and non-consenting patients, or the reasons for this. After information verbally and in writing, 352 individuals (mean age 43.7 [SD 12.2] years, 65.3% women) were included in the trial after giving informed consent, 146 in the intervention group and 206 in the reference group. Patient-reported outcome measures (PROMS) on function, HRQoL and work ability were collected at baseline and at 3-, 6- and 12-month follow-up. At 12-month follow-up, 115 patients (79%) in the intervention group and 171 patients (83%) in the reference group had completed the self-reported questionnaires (Figure 6).

A dataset was compiled with baseline data, including type of treatment received (intervention or reference), age, sex, educational level, whether born in Sweden, whether on sick leave, ICD10 diagnosis, employment (yes/no), comorbidity (symptoms of anxiety and/or depression: yes \geq 8 points on 'HADS' (183) and symptoms of exhaustion (no, moderate or pronounced exhaustion, according to the 's-ED') (184), and PROMS from the questionnaires completed at baseline and 3-, 6- and 12-month follow-up.

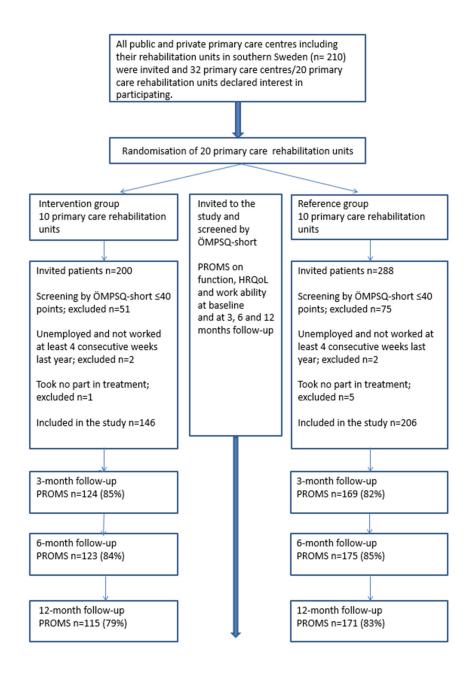


Figure 6.

Flowchart of inclusion and follow-up of primary care rehabiliation units. Number and proportion of patients who completed the patient-reported outcome measures (PROMS) at follow-ups.

Study IV

Study IV involved patients that were included in WorkUp between 1 January 2013 and 31 December 2014 (Figure 5).

In the WorkUp trial there were 352 patients for whom the physiotherapists were supposed to record physiotherapy interventions during the treatment period. Of these, nine patients (four from the intervention group and five from the reference group) were excluded due to incomplete protocols, so this study was based on 343 patients (n=142 intervention group, n=201 reference group).

The physiotherapists recorded all interventions provided for each treatment visit (date) in a treatment protocol, which was kept in the patient's records and followed the patient throughout the treatment period. Each treatment visit could include more than one intervention.

The treatment protocol included 26 pre-defined intervention alternatives: Acupuncture, Relaxation training, Basic body awareness therapy, Circulation/Range of movement training, Ergonomic advice, Physical activity prescription (PaP), Advice on posture, Cardiovascular training, Laser therapy, Joint manipulation. Joint mobilisation, MDT/McKenzie therapy, Motivational interviewing, Nerve mobilisation, Advice to stay active, Stabilising training, Stress management, Muscle strengthening training, Shockwave therapy, Taping, Transcutaneous Electrical Nerve Stimulation (TENS), Traction, Trigger point pressure, Ultrasound, and Vibration training or Heat/cold. There was also an 'Other' option where the physiotherapist could add textual information about any other type of intervention not included in the alternatives.

The physiotherapist also recorded whether any orthosis or medical aids were recommended and when the treatment period started and ended. The records also showed if the patient was referred for treatment to other health care professionals or for team rehabilitation. The intention was to provide the physiotherapists with a protocol that covered commonly used interventions for this patient group in primary health care. The intervention options, which were not graded as more or less evidence-based, were written in alphabetical order. The protocol was developed by four physiotherapists, three of them with long-standing and ongoing clinical experience from treating patients with neck and back pain. One was also an experienced researcher.

A set of data was completed with the total number and type of interventions (26 and Other) for each patient during the whole treatment period. All data were manually entered into the database. Baseline characteristics of age, sex, educational level, ICD-10 diagnosis, whether on sick leave, and employment (yes/no) were merged from the main data set of WorkUp. All data were thoroughly validated.

Interventions

All patients included in the WorkUp trial received structured physiotherapy and, for the intervention group, a workplace dialogue was added.

At the first visit, all patients were examined by a physiotherapist. Signs of serious medical conditions (red flags) (90) and psychosocial risk factors (yellow flags) (91) were considered. If there were medical conditions requiring urgent medical care or examination, patients were referred to a doctor without delay. The patients completed a questionnaire with self-reported measures; these were also completed after three, six and 12 months. The structured physiotherapy treatment included examination, assessment, diagnosis, treatment and return visits to the physiotherapist at three-, six- and 12-month follow-up. The treatment was individualised in terms of content and duration according to needs and condition. Depending on patient needs and clinical assessments, other health care professionals could be engaged, e.g. a medical doctor, psychologist or an occupational therapist. Further referral to these professionals was based on ordinary clinical assessments, such as red and yellow flags. In the WorkUp trial, patients also received short, weekly text messages for one year, where they answered three questions on the impact of the acute/subacute neck and/or BP on work and leisure time (185). Patients were also asked to complete some clinician-reported measures at baseline and at follow-ups (data to be published).

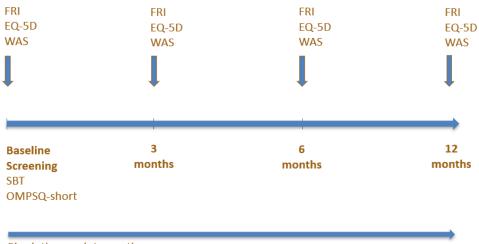
Intervention group

In addition to the structured physiotherapy treatment, all patients in the intervention group were offered a workplace dialogue according to the Convergence Dialogue Meeting (CDM) method (186), as an add-on to the structured physiotherapy treatment. This method was originally developed for patients on long-term sick leave due to burnout syndromes (186). The CDM model consists of a three-step structured dialogue where the patient, the health care professional (in this case the physiotherapist) and the employer meet and together identify the needs for workplace adjustments. The dialogue was structured, with questions that focused on neck and/or BP in relation to work, and on possible or already implemented workplace adjustments.

The aim of the CDM was to find concrete suggestions and actions to support and maintain work ability or, if sick-listed, facilitate return to work. The physiotherapist first held an individual interview with the patient, which included asking the patient for consent to contact the employer. In the second step, the employer was invited to talk with the physiotherapist, either in person or by phone. In the third step, the patient and the employer were invited to a convergence meeting together with the physiotherapist. The final meeting, involving the patient, the employer and the physiotherapist, concluded with a written plan of action including suggested workplace adjustments and changes to the patient's everyday life habits. The plan could also include contacts with other stakeholders. The plan of action was then followed up in the return visits to the physiotherapist. Each step in the workplace dialogue meetings lasted approximately 30-60 min. All patients were offered the CDM, but there were differences in the number of steps involved. Ninety-one patients (62.3%) took part in at least the first two steps, i.e. interview I (physiotherapist and patient) and interview II (physiotherapist and employer).

Instruments and outcomes

Two screening instruments, The STarT Back Tool (SBT) (6) and the short form of the Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ-short) (85), were used. Four different patient-reported outcome measures were used – function (Functional Rating Index, FRI), health-related quality of life (EQ-5D), work ability (Work Ability Score, WAS) and physiotherapy interventions – with corresponding procedure codes in five different treatment categories. Figure 7 shows when the various instruments and outcomes were applied in the four studies.



Physiotherapy interventions

Figure 7.

When the screening instruments and outcomes were used. FRI, Functional Rating Index; EQ-5D, EuroQol fivedimensions; WAS, Work Ability Score; SBT, STarT Back Tool; ÖMPSQ-short, Short form of the Örebro Musculoskeletal Pain Screening Questionnaire.

STarT Back Tool

Baseline data from the StarT Back Tool was used in study I and study II. The SBT is a nine-item questionnaire with questions relating to modifiable physical (items 1-4) and psychosocial (items 5-9) risk factors for long-term disabling BP, designed to support clinicians in directing individuals to different levels of care (6). The SBT has three risk subgroups where patients are classified into low, medium or high risk for poor disability outcomes. The SBT produces two scores: an overall score and a psychosocial subscale score (6). The psychosocial subscale score is used to identify the high-risk group.

The SBT overall score ranges between 0 and 9. Items 1-4 concern referred leg pain, neck or shoulder pain, difficulties in walking and difficulties in dressing. Items 5-9 form the psychosocial subscale that screens for fear of physical activity, anxiety, pain catastrophising, depressive mood and overall impact from their BP. Items 1-8 have a dichotomous response option: "disagree" (0p) or "agree" (1p). Item 9 uses a 5-point Likert Scale from "not at all" to "extremely", where responses "very much" or "extremely" are counted as one point and the other responses as zero. A total score of \leq 3 points indicates low-risk group, a total score \geq 4 points in combination with <4 points on the psychosocial subscale (items 5-9) are medium-risk group, and a psychosocial subscale score of \geq 4 points indicates a high-risk group for poor disability outcomes (6).

Short form of the Örebro Musculoskeletal Pain Screening Questionnaire

The ÖMPSQ-short was used as an instrument for comparison (gold standard) with the SBT in study I. The ÖMPSQ-short is a ten-item questionnaire with questions about psychosocial risk factors for work disability due to pain (85). The ÖMPSQshort is based on the original ÖMPSQ (100) and covers two items from each of five concept areas: pain (items 1-2), self-perceived function (items 3-4), distress (items 5-6), return to work expectancy (items 7-8) and fear avoidance beliefs (items 9-10).

Item number 1 (duration of pain) has ten categories, ranging from 0 to 1 week to more than 52 weeks, scoring is from 1-10 points. Items 2-10 are rated from 0 to 10 point on a scale anchored by extremes, for example, "completely disagree" to "completely agree" or "no pain" to "pain as bad as it could be". Items 3, 4 and 8 have inverse scoring. A total score is calculated (range 1-100) where 1 to 50 points indicate low risk and 51 to 100 points indicate higher estimated risk for future work disability and higher levels of pain (85). In the WorkUp trial, we decided to choose a lower cut-off for inclusion (\geq 40 points on ÖMPSQ-short) because we wanted to include patients at risk of work disability at an early stage and clinically relevant for treatment in primary care.

Health-related quality of life - EQ-5D

Health-related quality of life (HRQoL) was measured in studies II and III using the EuroQol five-dimension (EQ-5D) questionnaire (3). We used the five question part of the EQ-5D where each question has three options. The EQ-5D is a widely used generic questionnaire (187,188) from which a single-index value of the respondent's health status can be derived, based on a health profile of three levels in five dimensions – mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The digits for the five dimensions are combined into a 5-digit number describing the respondent's health state (189). The 5-digit number is given a value between -0.59 and 1.0 where 1 corresponds to full health, and lower EQ-5D values reflect lower HROoL. In this thesis, the UK tariff was used (190). In study II, health-related quality of life was also dichotomised into 'poor' HRQoL (EQ-5D <0.6) and 'good' HROoL (EO-5D >0.6), based on a proposed cut-off for having sufficient capacity to work for a population with back and neck pain (191).

Work ability - WAS

In studies II and III, work ability was measured by self-reports using Work Ability Score (WAS) (164) which is the first single-item question ("current work ability compared with the lifetime best") from the widely used Work Ability Index (WAI) (8, 168). In a recent study of workers at risk of work disability due to previous long-term sickness absence, a poor WAI score was associated with disability pension and longer duration of sickness absence (192). The WAS is a good alternative to the complete WAI and a reliable measure for assessing the status and progress of work ability (193, 194). The WAS has also shown to have predictive power for future disability from 0 representing "cannot work at all right now" to 10 representing "my work ability as at its best right now". The WAS classifies work ability using the same type of categorisation as the entire WAI, namely poor (0-5 points), moderate (6,7), good (8,9) and excellent work ability (10). Work ability was also dichotomised into 'poor' work ability (WAS<8 points) and 'good' work ability (WAS \geq 8 points) using a previously published cut-off score (194).

Function - FRI

In study III, function was measured with the Functional Rating Index (FRI) which is an instrument designed to measure the subjective perception of functional status and pain in patients with spinal pain (2). Using a five-point scale for each item, the patient ranks their perceived different functions and activities in relation to daily life. The instrument consists of ten questions on pain intensity, sleep, personal care, travelling/driving, ability to work, recreation, frequency of pain, lifting, walking and standing (2). The total score is calculated by adding all the responses, as recommended by Feise et al. (2) (total score/40)×100%) with the scores ranging from 0 to 100% disability. The higher the number, the higher the perceived disability and pain. The FRI is considered to be a valid and reliable instrument for measuring subjective function and pain in the spinal musculoskeletal system (2, 197).

Categorisation of physiotherapy interventions

In study IV, each recorded physiotherapy intervention was classified with a procedure code and grouped into one of five treatment categories according to a protocol used by Abbott et al. (7): physical exercise, behavioural medicine interventions, manual therapy, occupational medicine interventions and physical modalities.

Data analyses and statistical methods

Study I

In study I, the aim was to compare the concurrent validity of the SBT and the ÖMPSQ-short, including psychometric properties and clinical utility. A non-parametric approach was chosen because most of our data came from questionnaires based on ordinal data, which are based on the ranks of observations. The data were not considered as normally distributed because of the ordered, categorical nature.

Spearman's rank correlation coefficient was used to study the correlations between the SBT total scores and the ÖMPSQ-short total scores. The correlation coefficient is used to discover the strength of a link between two sets of data, where a coefficient near 1 is a strong, positive correlation and a coefficient near 0 is weak. A correlation coefficient less than 0.3 was considered as poor, 0.3-0.5 as fair, 0.6-0.8 moderately strong and greater than 0.8 was considered very strong (198).

We conducted subgroup analyses, based on pain sites reported by the patients, gender and age. For pain sites, we divided the population in two groups based on the answer to question number two in SBT, which is about neck or shoulder pain. All patients who reported neck or shoulder pain were allocated to the NP+BP group (a mixed group of patients with neck or shoulder pain with or without BP). Patients who did not report neck or shoulder pain were allocated to the BP group and were regarded as having BP only. The reason for not analysing patients with neck pain only was that we were unable to identify them as we had no access to their diagnoses. For gender, we divided the study population into females and males. For age, we divided the population into three age groups (\leq 39, 40-49 and \geq 50 years).

We found these age groups clinically relevant to study, as the age 40-49 years is a period of life often associated with higher demands both at home and at work and might therefore result in a higher sick leave.

To describe the observed agreement regarding classification into risk groups, between the ÖMPSQ-short (low and high risk) and the SBT (low, medium and high risk), the Cohen's kappa test was used, where <0.20 was considered poor agreement, 0.21 to 0.40 fair agreement, 0.41 to 0.60 moderate agreement, 0.61 to 0.80 good agreement, and values over 0.80 very good agreement (199). We chose this test because we wanted to compare our results with a previous, similar study by Fuhro et al. (121). We chose the weighted Cohen's kappa test, as this test also takes into account the degree of disagreement between the two instruments. This is especially relevant when the ratings/questions are ordered.

To enable comparison between the ÖMPSQ-short (with two risk groups) and the SBT (with three risk groups), we needed to merge two of the risk groups for the SBT in the analysis. We performed two analyses. First, we merged the low- and medium-risk group for the SBT (low/medium vs high risk) and in the second analysis, we merged the medium- and high-risk group for the SBT (low vs medium/high risk). We chose to present the results of the second analysis, in line with Fuhro et al. (121), as this appeared to be the most clinically relevant solution (6).

The McNemar test was used to identify any differences regarding allocation to the low- or high-risk group by the two instruments, and to determine whether the disagreement observed was balanced or skewed towards the lower or higher risk group. The proportion of observed agreement/disagreement was calculated by percentage.

We described the clinical utility of the two instruments as screening tools from a clinician's perspective. Clinical utility was described as clinician miscalculating and misclassifying total and/or subscale scores of the two instruments. First, we calculated the number of physiotherapists miscalculating ÖMPSQ-short total scores and SBT total and subscale scores. Then, we calculated the miscalculations that had led to a misclassification. To analyse whether a miscalculation of a total score had led to a misclassification to a higher or lower risk group, we used the cut-off scores specified by the instrument developers (85, 109), with three risk groups in the SBT (low, medium and high) and two risk groups in the ÖMPSQ-short (low and high) (85).

Study II

In study II the aim was to study the ability of the SBT to predict HRQoL and work ability outcomes. As for study I, we used a non-parametric approach, chosen based on the distribution of the data. Descriptive data on the study population were presented for the total population and for each SBT risk group. We evaluated the SBT specific risk groups separately and the SBT overall score.

We used different methods to measure the predictive performance of the SBT. First, cross tabulations were used to describe the proportion of participants in each SBT risk group that had poor outcome in long-term follow-up for each outcome. The Kruskal Wallis test was used to examine whether there were any differences between the SBT risk groups on follow-up data on HRQoL and work ability (median), respectively. Potential differences were confirmed with the Mann-Whitney U test. A Chi-squared test for trend was used to confirm potential differences concerning poor or good HRQoL and work ability.

Secondly, we calculated the odds ratios (95% confidence intervals) for SBT risk groups to predict poor HRQoL (EQ-5D<0.6) and poor work ability (WAS<8) using binary logistic regression. Age, sex, treatment group and time to follow-up were also included as independent variables in the analysis. We built a multiple logistic model where all independent variables were entered together with the SBT risk groups, as all these variables influence the outcome at the same time, as in real life. For SBT, we used the SBT low risk group as the reference group and for treatment groups (RCT intervention n=61, RCT control n=99, Not RCT n=78), we used the 'Not RCT group' as the reference group. The significance level was set at 5%.

Thirdly, we evaluated the ability of the SBT overall scores (0-9 points) to discriminate between individuals with poor or good HRQoL/work ability in long-term follow-up. We used the area under the curve (AUC) statistics from receiver operating characteristic (ROC) curves (200). The ROC curve was constructed by plotting the true positive rate (sensitivity) against the false positive rate (specificity) for each cut-off score of the SBT. The strength of discrimination was set according to the following descriptors: 0.7-<0.8 acceptable discrimination, 0.8-<0.9 excellent discrimination, and ≥ 0.9 outstanding discrimination (201).

The predictive validity of the SBT risk group cut-offs (low/medium and medium/high) was also assessed, by calculating sensitivity, specificity, positive predictive values (PPV), negative predictive values (NPV) and positive and negative likelihood ratios (LRs) against long-term HRQoL and work ability outcomes. The SBT risk group cut-offs (low/medium and medium/high) were used in line with the original study (6). The PPV is the probability that a poor outcome is present when the test is positive, and the NPV is the probability that a good outcome is present when the test is negative. Higher positive LRs and lower negative LRs indicate better discrimination. Likelihood ratios above 5 or below 0.2 are generally seen as supporting a strong test, whereas values close to 1 indicate poor test performance (202).

Study III

In study III, the aim was to study the effects of CDM on secondary outcomes. As we wanted to estimate the 'real-life' effect and take potential deviations from the protocol into account, as can be expected to happen in everyday clinical practice, we chose the intention-to-treat approach (203). Using this method means that all participants who are randomised are included in the statistical analysis and that participants are analysed according to the group they were originally assigned, regardless of the treatment they received. All persons with at least one measurement (at baseline, three, six or 12 months) were included in the analyses of WAS and EQ-5D. For the analysis of FRI, all persons with baseline value and at least one follow-up value were included.

We used a linear mixed effect regression model, with the rehabilitation unit and the individual as random effects, and individuals were nested within rehabilitation units. The treatment group, follow-up time (as categorical variable) and their interaction were included as fixed effects. The estimates for the interaction effect between treatment group and follow-up time represent the between-group difference between the two treatments. The between-group difference at 12 months was the main outcome in these analyses. The regression model was adjusted for the baseline value of the respective outcome variable and for age, sex and whether on sick leave to account for a possible imbalance between the treatment groups. In a sensitivity analysis we repeated the above estimation using the regression model additionally adjusted for a) symptoms of anxiety and/or depression using HADS group (cut-off ≥ 8)(183) (three categories) or b) symptoms of exhaustion (yes or no) using the s-ED (184), as measured at baseline. All estimates are given with 95% confidence intervals (CI).

Descriptive statistics were used to describe changes over time regarding patientreported outcome measures by treatment group and by follow-time.

Study IV

Each type of intervention was given a procedure code according to the Swedish Classification of Health Interventions (KVÅ) (Classification of Procedures)¹ (204) used in Swedish health care. We chose the most appropriate procedure code and each intervention was classified with one procedure code.

¹ In 1964 the Swedish National Board of Health and Welfare (NBHW) introduced a national classification of surgical procedures based on an American classification of surgical procedures. Since 1997, a Swedish version of the NOMESCO Classification of Surgical Procedures has been in use. Over time, a classification of medical procedures has been added. Current procedures are listed in the Swedish Classification of Surgical and Medical Procedures (Swedish: klassifikation av vårdåtgärder) (issued by the NBHW).

In the treatment protocol there was also an option to record 'other' interventions. These were written in text form and were, if possible, provided with a procedure code. Where this was not possible, the intervention was described as 'other'.

All interventions given the procedure codes 'ergonomic advice' (QV010) or 'work and employment counselling' (QR002), were checked against the recording of the intervention CDM. If the CDM was present at the same date as a recording of 'ergonomic advice' or 'work and employment counselling', this intervention was excluded, to prevent inclusion of the CDM in this descriptive data set.

We then applied a treatment protocol used by Abbott et al. (7) to the set of procedure codes. The procedure codes were placed in five treatment categories (7) – physical exercise, behavioural medicine interventions, manual therapy, occupational medicine interventions and physical modalities. In the protocol by Abbott et al. (7), each treatment category included different procedure codes. All interventions in our study with a procedure code in line with the Abbott protocol were placed in one of the five different groups. If the procedure code was not present in the Abbott protocol, we had a discussion and decided to include the procedure code in the most appropriate treatment category. This means that we added procedure codes to the different treatment categories from the original Abbott protocol (7). The physiotherapists in the WorkUp trial had 26 intervention alternatives and one 'other' category. Only interventions with one or more recordings were added to the Abbott protocol. Interventions (with corresponding procedure codes) not used in our study (shockwave therapy, ultrasound and vibration training) were therefore not added to this protocol. In total, six procedure codes were added (Table 2).

Table 2.

Treatment categories by Abbot et al., with all procedure codes used in this study.

Treatment category	Intervention	Procedure code
Physical exercise	Range of movement training	QG001
	Cardiovascular training	QD016
	Stabilising training	QG003
	Muscle strengthening training	QG003
	Advice to stay active	DV132*
	Advice on posture	QM005
	Relaxation training	QG007
	Basic body awareness therapy	QB008*
	MDT/McKenzie therapy	QG000*
	Physical activity prescription	DV200*
Behavioural medicine interventions	Motivational interviewing	DU118
	Stress management	QK005*
	Supportive conversation	DU007
	Information/education on pain	QV007
Manual therapy	Joint mobilisation	DN006
manual therapy	Joint manipulation	DN008
	Nerve mobilisation	QG001
	Traction	QG001
	Trigger point pressure	DN007
	Massage	QB007
Occupational medicine interventions	Ergonomic advice	QV010
	Work and employment councilling	QR002
Physical modalities	Acupuncture	DA001
	Laser therapy	QB011
	TENS	DA021
	Taping	DN003
	Heat/Cold	QB011
	Orthosis	DN003
	Medical aids	QT007*
Other		

*Added procedure codes

If the procedure code could not be included in one of the treatment categories by Abbott, this intervention was classified as 'other'. Interventions not given a procedure code in our study were placed in the 'other' group (e.g. medical yoga, different types of treatment for dizziness, monitoring or health-counselling).

Descriptive statistics were used to analyse frequencies and distributions. A nonparametric approach was chosen based on the distribution of the data.

We calculated the total number of interventions offered to all patients during the study period, and how these interventions were distributed among the five treatment categories and the category 'other'. We calculated median number of treatment visits and the median length of a treatment period. The number of visits for each patient was divided into three categories: 1-2 visits, 3-6, or ≥ 6 visits. We also calculated the proportion of patients who had received at least one intervention from the different treatment categories and the proportion of patients who had received interventions from two or more different treatment categories.

The Chi-square test for proportions was used to examine whether a greater proportion of patients in the intervention group received occupational medicine interventions compared to patients in the reference group. The Mann-Whitney U test was used to examine whether patients in the intervention group received a higher number of occupational medicine interventions than patients in the reference group.

Ethics

All studies were conducted according to the Declaration of Helsinki and were approved by the Regional Ethical Review Board in Lund, Sweden. Prior to inclusion, all patients were given written information about the purpose of the WorkUp study and each individual gave informed consent about participation. All patients were informed that participation was voluntary and that they could withdraw at any time without consequences for future care.

The application for the WorkUp study (for studies III and IV) was approved by the Ethical Review Board in Lund, Sweden Dnr 2012/497 (28 September 2012), Dnr 2012/648 (30 October 2012) and Dnr 2012/833 (9 January 2013). For further development of the scientific issues in WorkUp (for the SBT validation studies, study I and II), further amendments were needed and approved; Dnr 2013/426 (12 June 2013) and Dnr 2015/214 (19 March 2015).

The first amendment (Dnr 2013/426) was to patients scoring <40 points on ÖMPSQ-short in studies I and II. A letter was sent to these patients with information about the purpose of the study, stating that they could decline participation without consequences for future treatment (opt-out). All patients gave their consent to participation. The second amendment (Dnr 2015/214) was for patients scoring <40 points on ÖMPSQ-short in study II. A letter was sent describing the purpose of the study, and they were informed that they could decline participation without consequences for future treatment (opt-out). We also asked for permission to send them a questionnaire on long-term follow-up data (work ability and HRQoL). The questionnaires were short and quickly completed, and we did not consider there were any risks for the patients completing them. If they did not wish to respond, they could decline participation in study II.

In study III, we were aware of that some patients may have been doubtful regarding the contact with the employer. Sharing health status is sensitive information. A few patients declined the dialogue with the employer for various reasons, for example due to self-employment or temporary work; in those cases, the work situation was discussed between the physiotherapist and the patient alone. The workplace dialogue was voluntary, and the patients could decline participation without consequences for future care. We found the benefits of the workplace dialogue for the patient greater than the risks.

Results

This thesis includes two validation studies of the SBT, secondary outcomes from an RCT, and a description of physiotherapy interventions in primary care for patients with acute or subacute back and neck pain. The main results of the four studies are shown in Table 3.

Table 3.

Overview of the main results of studies I- IV.

Aim	Main results
Study I To compare the concurrent validity of the STarT Back Tool and the short form of the Örebro Musculoskeletal Pain Screening Questionnaire, including psychometric properties and clinical utility, in a primary care setting.	The correlation for SBT and ÖMPSQ-short total scores was moderately strong (0.62, p<0.01), Classification to high or low risk for long-term pain and disability showed moderate agreement, 70.2% (κ =0.42), SBT had fewer miscalculations (13/315) than the ÖMPSQ-short (54/315).
Study II To evaluate the STarT Back Tool's predictive validity for health-related quality of life and work ability outcomes at long-term follow-up in a population with acute/subacute back and/or neck pain.	Statistically significant differences were found for HRQoL (p<0.001) and work ability (p<0.001) scores at follow-up between all three SBT risk groups. The proportion of patients with poor HRQoL was higher in higher risk groups (low risk 4%, medium risk 11%, high risk 36%)(p<0.001) and the same trend was seen for poor work ability (low risk 22%, medium risk 35%, high risk 68%)(p<0.001). Patients in the high risk group had a significantly increased risk of having poor HRQoL (OR 6.16, 95% CI 1.50 to 25.26) and poor work ability (OR 5.08, 95% CI 1.75 to 14.71) vs the low risk group at follow-up. The AUC was 0.73 (95% CI to 0.84) for HRQoL and 0.68 (95% CI to 0.76) for work ability.
Study III To study the long-term effects of a workplace intervention in addition to structured physiotherapy regarding self-reported measures in patients with acute/subacute neck and/or back pain.	Mean differences in self-reported outcomes between groups were small and not statistically significant. From baseline to 12 months, the intervention group improved function from 46.5 (SD 19.7) to 10.5 (SD 7.3)(FRI); HRQoL from 0.53 (SD 0.29) to 0.74 (SD 0.20)(EQ-5D) and work ability from 5.7 (SD 2.6) to 7.6 (SD 2.1) (WAS).
Study IV To describe physiotherapy interventions provided for patients with neck and back pain at risk of work disability and to compare if patients in the intervention group received more occupational medicine interventions.	Physical exercise was the most common treatment category (59.7%), with virtually all patients (99.7%) receiving at least one intervention from this category. 81.7% of patients in the intervention group and 54.2% in the reference group received occupational medicine interventions (p<0.001).

Concurrent validity of the STarT Back Tool and the ÖMPSQ-short questionnaire (Study I)

Correlations

The Spearman's rank correlation coefficient for the SBT total scores and the $\ddot{O}MPSQ$ -short scores was 0.62 (p<0.01) for the total population, and the correlation was considered to be moderately strong (Figure 8). The correlation between the SBT total scores and the $\ddot{O}MPSQ$ -short scores for patients with BP (0.63, p<0.01) and for patients with NP+BP (0.60, p<0.01) was also moderately strong.

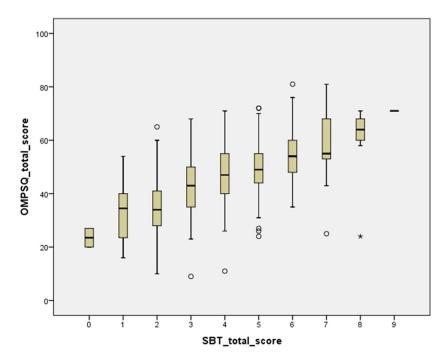


Figure 8.

Box-plot graph of the ÖMPSQ-short scores against the SBT total scores, n=315, r = 0.62. Asterix (*) represents extreme values. One person scored 9 points on SBT.

The statistical correlations for subgroup analyses, based on gender and age, are presented in Table 4. We found that the correlation for females was fair (0.57, p<0.01) and for males it was moderately strong (0.69, p<0.01). For participants aged \leq 39 years, the correlation was moderately strong (0.72, p<0.01) and for the 40-49 age group (0.57, p<0.01) and \geq 50 years (0.50, p<0.01), the correlation was fair. In further subgroup analyses, when we combined gender and age, we found the

correlation for males \geq 50 years to be moderately strong (0.71, p<0.01) but poor for females \geq 50 years (0.21, p=0.11) (Table 4).

Table 4.

Spearman's correlation	coefficient between S	SBT ¹ and ÖMPSQ-short ²	total scores n=315
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Population	Males	and Fem	ales		Females			Males	
	n	r	р	n	r	р	n	r	р
Total population	315	0.62	< 0.01	197	0.57	< 0.01	118	0.69	< 0.01
BP ³	121	0.63	< 0.01	62	0.58	< 0.01	59	0.62	< 0.01
NP+BP⁴	194	0.60	< 0.01	135	0.56	< 0.01	59	0.68	< 0.01
≤ 39 years	108	0.72	< 0.01	69	0.73	< 0.01	39	0.75	< 0.01
40-49 years	105	0.57	< 0.01	71	0.60	< 0.01	34	0.50	< 0.01
≥ 50 years	102	0.50	< 0.01	57	0.21	0.11	45	0.72	< 0.01

¹SBT STarT Back Screening Tool, ²ÖMPSQ-short Short form of the Örebro Musculoskeletal Pain Screening Questionnaire, ³BP Back Pain, ⁴NP+BP Patients with neck or shoulder pain (NP) with or without back pain (BP)

Observed agreement

The observed agreement between the SBT and ÖMPSQ-short subgroup classification is shown in Table 5. Participant classification to high/low risk by both questionnaires showed moderate agreement (κ =0.42, p<0.01). The SBT classified 53.7% (169/315) as high risk and 46.3% (146/315) as low risk. The ÖMPSQ-short classified 36.5% (115/315) as high risk and 63.5% (200/315) as low risk. The observed classification agreement was 70.2%.

We found differences regarding classification into low- and high-risk subgroups (regardless of whether the low- and medium-risk group or the medium- and high-risk group were merged for the SBT). The disagreement (29.8%) was significantly skewed towards the SBT high risk (high risk = medium + high risk) group with a higher proportion of patients allocated to the SBT high-risk group (53.7%) compared with the ÖMPSQ-short (36.5%) (McNemar, p<0.01).

Table 5.

Observed agreement of SBT¹ (high risk = medium + high risk) and ÖMPSQ-short² subgroups, *n*=315.

ÖMPSQ-short		SBT	
	Low risk	High risk	Score
Low risk	126	74	200
High risk	20	95	115
Score	146	169	315

¹SBT STarT Back Screening Tool, ²ÖMPSQ-short Short form of the Örebro Musculoskeletal Pain screening questionnaire.

Clinical utility

We studied the clinical utility from a clinician's perspective.

Physiotherapists had miscalculated more on total scores in the ÖMPSQ-short (54/315) than in the SBT (13/315). In the SBT questionnaires, we found 22 miscalculations of the SBT subscale scores. Among the miscalculations of total scores, seven of the ÖMPSQ-short questionnaires and five of the SBT questionnaires, led to misclassifications to a higher or lower risk group. In four and 21 SBT questionnaires respectively, total scores and subscale score were not calculated by the physiotherapists. The first author (MF) calculated these scores. There were no missing calculations of total scores in the ÖMPSQ-short.

Predictive validity of STarT Back Tool for long-term health-related quality of life and work ability outcomes (Study II)

At baseline, 43%, 45% and 12% patients were considered as low, medium and at high risk respectively. The median time to long-term follow-up was 13 (range 11-27) months. For patients in the clinical trial (n=160), the median time to follow-up was 12 months (range 11-19). For patients not included in the clinical trial who received a postal questionnaire (n=78), the median time to follow-up was 22 months (range 16-27).

Predictive performance

There were statistically significant differences in the distribution of HRQoL scores (n=238) between the SBT low-, medium- and high-risk groups at long-term follow-up (p<0.001). The proportion of patients with poor HRQoL (EQ-5D<0.6) was significantly higher in higher-risk groups (low risk 4%, medium risk 11%, high risk 36%) (p<0.001) (Table 6).

There were also differences in the distribution of work ability (WAS) scores (n=235) between the SBT low-, medium- and high-risk groups at long-term followup (p<0.001). The proportion of patients with poor work ability (WAS <8) was significantly higher in higher risk groups (low risk 22%, medium risk 35%, high risk 68%) (p<0.001) (Table 6).

Table 6.

Health-related quality of life and work ability at long-term follow-up - total population and stratified by SBT risk groups.

		SBT risk grou	ıp		
Follow-up measure	Total population	Low	Medium	High	
	n=238	n=103	n=107	n=28	P values
Health-related quality of life; median (range)	0.80 (-0.14-1)	0.80 (0.09-1)	0.76 (0.09-1)	0.67 (-0.14-1)	<0.001*
EQ-5D† <0.6, n (%)	26 (11)	4 (4)	12 (11)	10 (36)	<0.001§
Work ability‡; median (range)	8 (0-10)	9 (0-10)	8 (1-10)	7 (0-10)	<0.001*
WAS¶ <8, n (%)	78 (33)	23 (22)	38 (35)	17 (68)	<0.001§

*Kruskal-Wallis test.

†EQ-5D scores, range -0.59-1.

[±]Three missing from the high risk group (total population: n=235 and n=25 for the high risk group).

§X² test for trend.

VertWhere 0 equates to 'completely unable to work' and 10 equates to 'work ability at its best'.

EQ-5D, EuroQol five-dimension; SBT, STarT Back Tool; WAS, Work Ability Score.

In the regression analysis we found that patients in the high-risk group had a significantly increased risk of having poor HRQoL (OR 6.16, 95% CI 1.50 to 25.26) and poor work ability (OR 5.08, 95% CI 1.75 to 14.71) compared with the low-risk group at follow-up, which also applied after adjusting for age, sex, treatment, and time to follow-up (Table 7).

Table 7.

The ability of the SBT risk groups to predict poor health related quality of life* and poor work ability† at long-term follow-up.

DR	95% CI for OR				
	99% CHIOF UK	P values	OR	95% C. for OR	P values
			1		
.814	0.506-6.509	0.361	1.361	0.684	0.380
6.160	1.502-25.264	0.012	5.075	1.751-14.705	0.003
			1		
.411	0.073-27.252	0.820	7.631	1.284-45.341	0.025
.932	0.183-47.073	0.448	8.156	1.485-44.803	0.016
.949	0.734-1.227	0.688	1.146	0.983-1.336	0.081
.984	0.947-1.022	0.403	1.014	0.988-1.040	0.306
.449	0.183-1.106	0.082	0.706	0.381-1.309	0.269
² -test	P values	df	χ ²-test	P values	df
5.41	0.71	8	5.27	0.73	8
	.814 .160 .411 .932 .949 .984 .449 ²-test	.814 0.506-6.509 .160 1.502-25.264 .411 0.073-27.252 .932 0.183-47.073 .949 0.734-1.227 .984 0.947-1.022 .449 0.183-1.106	.814 0.506-6.509 0.361 .160 1.502-25.264 0.012 .411 0.073-27.252 0.820 .932 0.183-47.073 0.448 .949 0.734-1.227 0.688 .984 0.947-1.022 0.403 .449 0.183-1.106 0.082	.814 0.506-6.509 0.361 1.361 .160 1.502-25.264 0.012 5.075 .411 0.073-27.252 0.820 7.631 .932 0.183-47.073 0.448 8.156 .949 0.734-1.227 0.688 1.146 .984 0.947-1.022 0.403 1.014 .449 0.183-1.106 0.082 0.706	.814 0.506-6.509 0.361 1.361 0.684 .160 1.502-25.264 0.012 5.075 1.751-14.705 .411 0.073-27.252 0.820 7.631 1.284-45.341 .932 0.183-47.073 0.448 8.156 1.485-44.803 .949 0.734-1.227 0.688 1.014 0.983-1.336 .984 0.947-1.022 0.403 1.014 0.988-1.040 .449 0.183-1.106 0.082 0.706 0.381-1.309

*Poor HRQoL measured by EQ-5D questionnaire <0.6.

†Poor work ability measured by WAS <8.

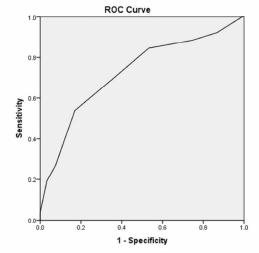
HRQoL: Cox-Snell R²=0.12. Nagelkerke R²=0.21, n=238.

Work ability: Cox-Snell R²=0.11. Nagelkerke R²=0.16, n=235.

EQ-5D, EuroQoI five-dimension; HRQoL, health-related quality of life; RCT, randomised clinical trial; SBT, STarT Back Tool; WAS, Work Ability Score.

The area under the curve (AUC) for overall STarT Back Tool scores to discriminate between individuals with poor health-related quality of life (EQ-5D <0.6) in long-term follow up was 0.73 (CI 0.61-0.84), which was acceptable (\geq 0.7) (Figure 9).

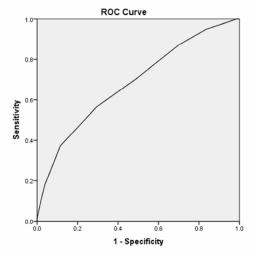
For work ability, the AUC for overall STarT Back Tool scores to discriminate between individuals with poor work ability (WAS<8) in long-term follow up was 0.68 (CI 0.61-0.76) which was just below the limit (\geq 7) for acceptable discrimination (Figure 10).



Diagonal segments are produced by ties.

Figure 9.

AUC and ROC curve for overall STarT Back Tool scores to discriminate between individuals with poor health-related quality of life (EQ-5D <0.6) in long-term follow up. Each point on the ROC curve has a corresponding cut-off value. The area under the ROC curve was 0.73. AUC, area under the curve; EQ-5D, Euroqol 5-dimension questionnaire; ROC, receiver operation characteristic.



Diagonal segments are produced by ties.

Figure 10.

AUC and ROC curve for overall STarT Back Tool scores to discriminate between individuals with poor work ability (WAS<8) in long-term follow up. Each point on the ROC curve has a corresponding cut-off value. The area under the ROC curve was 0.68. AUC, area under the curve; EQ-5D, Euroqol 5-dimension questionnaire; ROC, receiver operation characteristic.

The discriminative ability of the SBT risk group cut-offs (low/medium and medium/high) to predict poor HRQol and poor work ability in long-term follow-up is presented in Table 8. The LRs+ were higher and the LRs- were lower for HRQoL outcomes compared with work ability outcomes, which indicates better discrimination of the SBT for poor HRQoL than for poor work ability (Table 8).

Table 8.

Discriminative ability of the SBT risk group cutoffs (low/medium and medium/high) to predict poor HRQoL and poor work ability in long-term follow up.

Subgroups	Sensivity (%)	Specificity (%)	PPV (%)	NPV (%)	LR+ (95% CL)	LR- (95% CL
HRQoL (EQ- 5D <0.6)	1					
L vs. M/H	84.6	46.7	16.3	96.1	1.59 (1.29-1.95)	0.33 (0.13-0.82)
L/M vs. H	38.5	91.5	35.7	92.4	4.53 (2.35-8.74)	0.67 (0.49-0.91)
Work ability (WAS <8)						
L vs. M/H	70.5	51.0	41.7	77.7	1.44 (1.16-1.78)	0.58 (0.40-0.84)
L/M vs. H	21.8	94.9	68.0.	71.0	4.28 (1.93-9.47)	0.82 (0.73-0.93)

SBT, Star Back Tool; HRQoL, Health related quality of life; EQ-5D, EuroQol five-dimension; WAS, Work Ability Score; PPV, Positive Predictive Value; NPV, Negative Predictive Value; LR+, Positive likelihood ratio; LR-, negative likelihood ratio.

Long-term effects on function, health-related quality of life and work ability after structured physiotherapy including a workplace intervention (Study III)

Between-group comparisons

The mean differences in self-reported outcomes between the intervention and reference group (adjusted for age, sex, whether on sick leave, and the baseline value of the outcome) for all three outcomes were small and not statistically significant at 12-month follow-up (Table 9). The mean differences in outcomes between the intervention and the reference group after 12 months were -0.76 (95% CI: -2.39, 0.88) for function (FRI), 0.02 (95% CI: -0.04, 0.08) for health-related quality of life (EQ-5D), and -0.05 (95% CI: -0.63, 0.53) for work ability (WAS) (Table 9). The results were similar in all sensitivity analyses (Table 9).

		Adjusted ^a	Adjusted ^a + HADS	Adjusted ^a + Exhaustion
	Mean difference (95%Cl)	Mean difference (95%CI)	Mean difference (95%CI)	Mean difference (95%CI)
Function (FRI)				
3-month follow-up	-2.17 [-4.42,0.09]	0.28 [-1.80,2.36]	0.37 [-1.64,2.39]	-0.36 [-2.51,1.78]
6-month follow-up	2.16 [-0.83,5.16]	-0.42 [-2.02,1.18]	-0.42 [-2.02,1.19]	-0.06 [-1.71,1.58]
12-month follow-up	1.97 [-1.08,5.02]	-0.76 [-2.39,0.88]	-0.77 [-2.41,0.87]	-0.55 [-2.23,1.14]
HRQoL (EQ-5D)				
3-month follow-up	-0.05 [-0.11,0.02]	-0.05 [-0.11,0.01]	-0.05 [-0.11,0.01]	-0.05 [-0.11,0.02]
6-month follow-up	-0.00 [-0.06,0.06]	-0.01 [-0.07,0.06]	-0.01 [-0.07,0.06]	-0.02 [-0.08,0.05]
12-month follow-up	0.02 [-0.04,0.08]	0.02 [-0.04,0.08]	0.02 [-0.04,0.08]	0.01 [-0.05,0.08]
Work ability (WAS)				
3-month follow-up	-0.66* [-1.23,-0.08]	-0.69* [-1.26,-0.11]	-0.68* [-1.26,-0.11]	-0.66* [-1.25,-0.07]
6-month follow-up	-0.23 [-0.80,0.34]	-0.27 [-0.84,0.30]	-0.27 [-0.84,0.30]	-0.35 [-0.94,0.23]
12-month follow-up	-0.01 [-0.58,0.57]	-0.05 [-0.63,0.53]	-0.04 [-0.62,0.54]	-0.15 [-0.74,0.45]

Mean difference in self-reported function, HRQoL and work ability between the intervention and the reference group. The differences are presented at 3, 6 and 12 months.

Table 9.

^aadjusted for age, sex, whether on sick leave at baseline, and the baseline value of the outcome. HADS=Hospital Anxiety and Depression Scale, Exhaustion=self-rating of str related Exhaustion Disorder (s-ED), HRQoL=Health related quality of life, FRI=Functional Rating Index (0 to 100% disability), EQ-5D=EuroQol five-dimension (-0.594 to 1.0 where 1 correspond to full health), WAS=Work Ability Score (0 to 10 from 0 representing "cannot work at all right now" to 10 representing "my work ability as at its best right now".

Changes over time

Improvement was observed in both the intervention and the reference groups in terms of all self-reported outcome measures after 12 months (Figures 11-13).

Table 10 shows the measures on self-reported function, health-related quality of life and work ability, described by treatment group and by follow-up time from baseline to 3, 6 and 12 months.

For function, the improvement was most apparent after 3 months (Figure 11) and overall, disability decreased in the intervention group between baseline and 12 months from 46.5 (SD 19.7) to 10.5 (SD 7.3) and in the reference group from 49.8 (SD 18.7) to 11.7 (SD 8.2) on FRI.

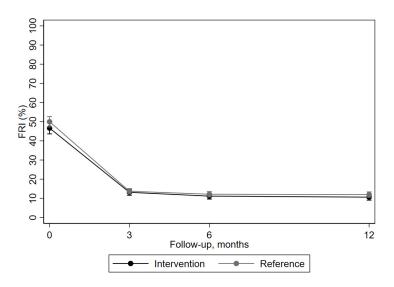


Figure 11.

Mean outcome per treatment group over follow-up time with 95% confidence interval estimated by the regression model regarding function as measured by FRI.

Health-related quality of life improved during the follow-up period (Figure 12). From baseline to 12 months, the intervention group improved from 0.53 (SD 0.29) to 0.74 (SD 0.20) and the reference group from 0.49 (SD 0.30) to 0.69 (SD 0.27) on EQ-5D.

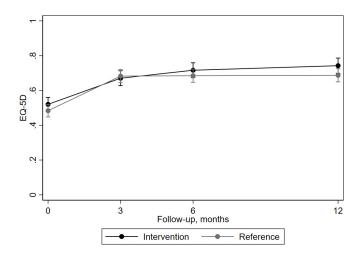


Figure 12.

Mean outcome per treatment group over follow-up time with 95% confidence interval estimated by the regression model regarding health related quality of life as measured by EQ-5D.

For work ability, patients in both groups improved during the follow-up time, also most apparent between baseline and 3 months (Figure 13). From baseline to 12-month follow-up, the intervention group improved from 5.7 (SD 2.6) to 7.6 (SD 2.1) and the reference group improved from 5.4 (SD 2.9) to 7.3 (SD 2.4) on WAS.

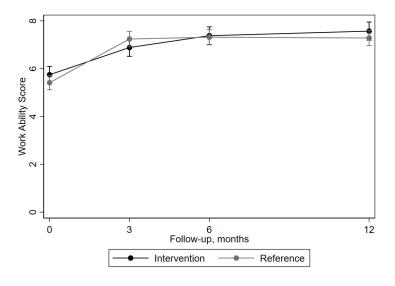


Figure 13.

Mean outcome per treatment group over follow-up time with 95% confidence interval estimated by the regression model regarding work ability as measured by Work Ability Score (WAS).

Table 10.

Self-reported outcome measures by treatment group and by follow-up time*.

Outcome measure and follow-up month	Reference group		Intervention gro	pup
	Number of individuals	Mean (SD) / Median [IQR]	Number of individuals	Mean (SD) / Median [IQR]
Function (FRI)				
0	205	49.8 (18.7)	145	46.5 (19.7)
3	169	13.4 (10.7)	124	13.3 (8.9)
6	168	11.9 (8.0)	121	10.7 (7.5)
12	161	11.7 (8.2)	112	10.5 (7.3)
HRQoL (EQ-5D)				
0	205	0.49 (0.30)	144	0.53 (0.29)
3	169	0.70 (0.23)	123	0.67 (0.26)
6	173	0.69 (0.25)	123	0.7 2 (0.23)
12	172	0.69 (0.27)	115	0.74 (0.20)
Work ability (WAS)				
0	204	5.4 (2.9) / 6.0 [5.0]	144	5.7 (2.6) / 6.5 [4.0]
3	167	7.3 (2.3) / 8.0 [3.0]	122	6.9 (2.3) / 7.0 [2.0]
6	173	7.4 (2.2) / 8.0 [3.0]	123	7.4 (1.9) / 8.0 [2.0]
12	170	7.3 (2.4) / 8.0 [3.0]	115	7.6 (2.1) / 8.0 [2.0]

*Unadjusted data

SD=standard deviation, IQR=interquartile range, FRI=Functional Rating Index, HRQoL=Health related quality of life, EQ-5D=EuroQoI five-dimension, WAS=Work Ability Score.

Physiotherapy interventions in primary care for working-age patients with acute/subacute neck and back pain (Study IV)

Total number of interventions and distribution by treatment category

For all patients (n=343), during the whole registration period (Jan 2013 to Dec 2014), a total of 5674 different interventions were recorded. Figure 14 shows how the total number of interventions was distributed by the five treatment categories. Physical exercise interventions were 59.7% (3390/5674) of the total number of interventions, so was the most commonly used treatment category (Figure 14). Manual therapy accounted for 18.9 %, physical modalities 11.1%, occupational medicine interventions that were not possible to categorise accounted for 1.3% of the total number of interventions. The vast majority of occupational medicine interventions (99%) involved ergonomic advice (Figure 14).

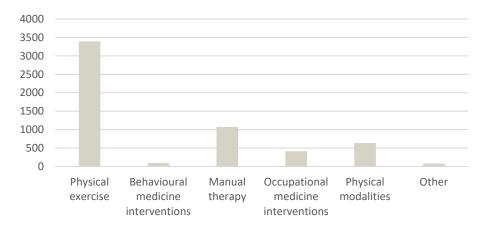


Figure 14.

How the total number of interventions was distributed by treatment categories for patients with acute/subacute neck and back pain in WorkUp, n=5674 during the registration period (Jan 2013-Dec 2014).

Treatment period, number of visits and type of intervention

The median length of treatment period was 43 days (range 1-411) and the median number of treatment visits was 5 (range 1-41). There were 68 (19.8%) individuals who had 1-2 visits, 168 (49.0%) who had 3-6 visits and 107 (31.2%) who had ≥ 6 visits.

All but one patient, 99.7% (342/343), received at least one intervention of physical exercise during the treatment period (Figure 15). More than half of the study population, 65.6% (225/343), received at least one occupational medicine intervention, and one intervention of manual therapy, 57.1% (196/343) (Figure 15). 40.2% (138/343) of the patients received at least one intervention of physical modality, 14.6% (50/343) of behavioural medicine interventions and 8.7% (30/343) of 'other' interventions during the treatment period (Figure 15).

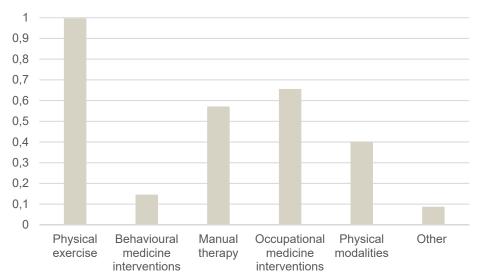


Figure 15.

The proportion of patients who have received at least one intervention from the different treatment categories, n=343. Note: A person may be present in more than one treatment category.

Patients received more than one type of intervention during the treatment period. Nearly two-thirds of the patients (63.2%) received interventions from three or more different treatment categories (Table 11).

Table 11.

The proportion of patients who received treatment from one to six different treatment categories¹, n=343 during the registration period (Jan 2013- Dec 2014)

Number of treatment categories	n	%
1	26	7.6
2	100	29.2
3	131	38.2
4	67	19.5
5	18	5.2
6	1	0.3

¹Physical exercise, behavioural medicine interventions, manual therapy, occupational medicine interventions, physical modalities or 'other'.

Referrals

There was a total of 45 referrals to other health care professionals for 37 patients (11%). Most referrals were to physicians (mainly in primary care) (n=24), but also to other professionals, for example to specialised physiotherapists (n=7), occupational therapists (n=4), social workers (n=2), chiropractors (n=2) or for team/multimodal rehabilitation (n=5) and occupational health care (n=1).

Comparison between the intervention group and reference group in terms of occupational medicine interventions

81.7% of patients in the intervention group and 54.2% in the reference group received at least one occupational medicine intervention (p<0.001) during the treatment period. Patients in the intervention group also received a greater number of occupational medicine interventions (md 1, range 0-6), p<0.001.

General discussion

The overall aim of this thesis was to obtain deeper knowledge on health care interventions in primary care of working-age patients with acute or subacute back and neck pain, by studying screening tools, physiotherapy interventions and patientreported outcomes. We examined the concurrent validity of the Swedish version of the STarT Back Tool against the ÖMPSQ-short form, and also the predictive validity of the STarT Back Tool for health and work ability outcomes. Long-term effects of a workplace dialogue in addition to structured physiotherapy for selfreported outcomes were also evaluated, and the broad spectrum of interventions used by primary care physiotherapists for patients with back and neck pain in working-age were described.

Risk assessment and stratified care in primary care

Modern primary care development often includes new ways of working, using tools for stratification of care for different patient groups and decision support systems for major patient groups. As patients with back and/or neck pain are frequent attenders in primary care (17, 18), there is a need to develop and evaluate different tools for risk assessment and stratification of diagnostic, treatment and rehabilitation methods used (87, 205-207). When preparing the WorkUp clinical trial on workplace intervention for patients with short term back or neck pain in primary care, we identified two different tools available in Swedish for risk assessment of these patient groups. The STarT Back Tool and the ÖMPSQ-short form have both been used in different populations, but the concurrent validity had never before been studied for a large primary care population in Sweden.

This is the first time that the SBT has been validated against the ÖMPSQ-short for patients with both back and/or neck pain in primary care. The correlation between the SBT and the ÖMPSQ-short total scores was found to be moderately strong, indicating that the SBT can be used as a clinical tool for patients with acute/subacute back and/or neck pain applying for physiotherapy in primary care. However, we also found differences between the instruments in terms of classification agreement (observed classification agreement was 70.2% and the observed disagreement was 29.8%) and clinical utility (the SBT had fewer miscalculations of total scores compared with the ÖMPSQ-short).

The ÖMPSQ-short was designed to identify risk factors for work disability measured as sick leave (85). ÖMPSQ was also designed to be used as a prognostic tool. The SBT was designed to identify modifiable prognostic factors for long-term back pain and disability and for stratified care (6, 84). The SBT is intended for use not only as a prognostic tool, but also for stratified care (106).

From our findings we conclude that both instruments can be used, but for different purposes (87, 208). However, we believe that with the broad knowledge in many different populations worldwide for the utility of the SBT (84, 111, 117, 207, 209) we would recommend it for use both in clinical practice and research studies. Further evaluations and studies of applicability are needed, to enable more detailed recommendations for the use of different instruments in routine clinical settings. From our experiences we would also recommend the SBT for studies of patients with neck pain and back pain, as the feasibility for these patient groups was good.

We conclude that screening processes are important in the care of patients with back and neck pain in primary care. It is important for clinicians to obtain prognostic information about their patients early in the rehabilitation process in order to tailor interventions (210). A clinical and research priority is therefore to, at an early stage, identify subgroups of patients with nonspecific back and neck pain who are at risk of developing long-standing disability, in order to optimize treatment (108, 120).

A potential benefit of using the SBT instead of the ÖMPSQ-short might be that the SBT was more feasible for clinicians to use than the ÖMPSQ-short. When clinicians choose a classification instrument they need to be aware of, that patients at medium risk and especially patients at high risk need a more enhanced treatment compared to those at low risk who can be reassured and offered less intensive treatment (105). Costs for misclassification and overtreatment of patients with a good prognosis can be high (84) and also detrimental in patients with acute back pain (211).

We believe that the SBT has an advantage compared with the ÖMPSQ-short, as it may provide clinicians with additional guidance in the level of care compared to the ÖMPSQ-short. The SBT is designed for stratified care, which involves targeted treatment to subgroups of patients based on their prognostic profile (106). The aim of stratified care is to tailor therapeutic decisions in ways that maximise treatment benefit, reduce harm and increase healthcare efficiency by offering the right treatment to the right patient at the right time (106). This may be an advantage in primary care, as clinical intuition does not always consistently match patient prognosis (212). When using stratified care, clinicians can minimise the risk of overtreatment for low-risk patients and give more appropriate treatment for medium- and high-risk patients (84) and thereby help the physiotherapist prioritise between different pathways at an early stage. Stratified care has also shown to improve clinical outcomes and to be cost-effective compared to usual care in the UK (84, 213).

The results suggested that using the SBT risk group classification enabled us to predict certain outcomes such as health-related quality of life and work ability in the long term, based on the baseline information obtained by the SBT. We found that the proportion of patients with poor health-related quality of life at long-term follow-up was higher in higher-risk groups (low risk 4%, medium risk 11%, high risk 36%) (p<0.001) and the same trend was seen for poor work ability (low risk 22%, medium risk 35%, high risk 68%) (p<0.001).

As all prediction results were based on the information obtained on a group level, we must be careful about a precise 'prediction-of-individual-risk' route rather than a pragmatic 'group treatment'. We are well aware of the dangers of misclassification when trying to develop and apply a simple clinical tool.

The validation studies in this thesis showed that the SBT now can be used as a prognostic tool in primary care to identify, at an early stage, subgroups of patients with acute or subacute back and neck pain who are at risk of long-term pain and disability. The SBT also can be used to identify patients at risk of poor health-related quality of life and work ability in the long term. The information on important modifiable risk factors and prognosis for this patient group may help clinicians in primary care to tailor treatment to the patient and develop personalised treatment strategies, which is a priority in research (214, 215). It may also help clinicians (GPs, physiotherapists, etc) to, at an early stage, avoid unnecessary treatments and overinvestigations, and direct a more extensive package of treatments to patients at medium or high risk of poor outcome. Using this stratified care approach has potential to improve patients' outcomes and reduce health care costs. Future studies are required to study whether the implementation of screening with SBT together with matched treatment pathways affect function, health-related quality of life and work ability outcomes in both short and long terms for patients with back or neck pain in primary care. Studies must also examine whether this strategy is costeffective.

The effect of a workplace dialogue on self-reported outcomes

Workplace dialogue was a key part of the WorkUp trial focusing on work ability (185). The main outcome, work ability, was defined as "working four weeks in a row without any sickness absence, at 12-month follow up". This intervention was offered in addition to structured physiotherapy interventions. In the published study on the confirmatory outcome, the results favoured the intervention (185). We wanted to increase understanding of whether there were any effects on self-reported function, health-related quality of life and work ability with the workplace dialogue as an add-on to an early intervention of physiotherapy in primary care. Self-reported

outcomes are increasingly recognised as valuable tools in clinical trials, since they add unique information about how a patient benefits from an intervention (216).

The WorkUp trial included evaluating the various work ability outcomes. One selfreported outcome used was the Work Ability Score (WAS single-item question from the Work Ability Index, WAI) (8) at 12-month follow-up. This outcome reflects the patients' own experience of their present work ability, compared to lifetime best Other tentative outcomes of work ability and work disability might include selfreported or register-based measures of sick leave. Sick leave measures have a focus on absenteeism whereas other measures, such as the WAS, may also include aspects of presenteeism (217). The main confirmatory evaluation in the WorkUp trial measured self-reported absenteeism using a text message service, where patients were asked to answer three questions about work ability every week for 12 months. The response rates for the text messages were high for both the intervention and the reference groups, 84% to 99% of patients responded weekly throughout the followup year (185) and we believe that the risk for recall bias in that setting (reporting on the previous week) was very low.

The findings on work ability included no significant improvement as measured by the WAS as a point prevalence. This differs from the reports of significantly improved work ability as measured by the self-reported text message service (185). However, the same pattern was seen in both studies with a tendency of an increasing effect of the workplace dialogue on work ability at the end of the follow-up year (Figure 9) even though we did not reach a statistically significant difference between groups when using the WAS as a point prevalence in this study. A point prevalence can give an answer that is relevant just for that particular day but may also reflect a longer time-period. Since WAS also reflects present work ability compared to lifetime best, it is reasonable to believe that patients with back and/or neck pain can experience decreased work ability while still at work. In the WorkUp trial, only onethird were on sick leave at baseline, and almost the entire study population were in employment (96%). Work ability can be measured in different ways and no instrument covers all its aspects (162). Work ability can be seen as a continuum, a dynamic process that changes over time depending on different supportive and destructive factors occurring during life (166). We conclude that the two different measurements of work ability used in the WorkUp trial need not necessarily concur with one another, as they measure different aspects of work ability.

We observed significant improvements in measures of function and health-related quality of life over time in both the intervention group and in the reference group, but with no significant differences. Similar results were found in the SWAP trial where a workplace intervention had positive effect on work absence but not on secondary self-reported health-related outcomes (181). Also in another recent study on intervention of the effectiveness of a participatory workplace intervention of industrial workers, they did not find any effect on health outcomes (218). The interventions used in the WorkUp trial resulted in significant improvement, forming

the basis for improved work ability. Many factors could explain why we could not identify any differences between groups for the WAS. These include the different aspects and perspectives of work ability included in different instruments, as well as the tentative assertion that the workplace dialogue does improve some aspects of work ability in the form of reduced absenteeism, but not aspects of presenteeism.

In contrast, in the confirmatory study of the WorkUp trial, a positive effect was found after structured physiotherapy including the workplace dialogue CDM when work ability was measured as absenteeism (185). The workplace dialogue may have had an effect by 'lowering the threshold' for returning to/remaining at work even though the patients did not experience better work ability. To provide more relevant and effective services for patients with back pain, it is important to inform physiotherapists that patients want their employers to be informed about their condition and that they desire help with workplace adaptation (219). We have not yet analysed what type of workplace adjustments were planned and implemented after the CDM. This information may give more detailed knowledge on the possible benefits of CDM. Previous studies have shown that early interventions and interventions involving the workplace are important in preventing work disability (220) and that multidomain interventions, with healthcare provision, service coordination and work accommodation components, are recommended (178, 221).

In the WorkUp trial, the workplace dialogue CDM was tested as an add-on to structured physiotherapy in primary care. All patients received structured physiotherapy and all participating physiotherapists received continuous updates on evidence treatments. The non-significant results on self-reported work ability, health-related quality of life and function can reflect that the comparison (reference group) received interventions that were more evidence-based than treatment as usual, no differences in favour for the intervention group could be detected. As we did not include a 'non-treated' control group, we cannot rule out that the improvement in outcomes within groups was the result of either regression to the mean, placebo or other contextual factors (222).

In this case, it was the physiotherapist who initiated the CDM, which is held in three steps – first, an interview with the patient, followed by an interview with the employer, and thirdly, a meeting between the physiotherapist, the patient and the employer. The aim was to strengthen the patient's work ability and to support the patient in remaining at work or returning to work by discussing possible changes or work place adjustments that could be made by the patient or the employer. Based on the results in Sennehed et al (185) we believe that the CDM had an impact on the patients' decision to stay at work or, if sick-listed, return to work.

During the follow-up period, HRQoL improved both in the intervention and reference group. It is important to notice that this improvement was above 0.6, which is suggested as a cut-off for work ability (191). HRQoL reflects how a patient experiences their health and can have an important impact on work ability.

Function also improved during the follow-up period. Since work ability is considered to be a multi-dimensional concept, all components in the ICF-model (47) must be considered. Work ability can be seen as activity and participation, but to enable a patient to be active and participate, different functions are required. The patients' different capacities must also be related to environmental factors.

Physiotherapy interventions for patients of working-age with early neck and back pain

In general, physiotherapy interventions are poorly described in detail in clinical trials (74, 89), and study IV has opened the box of physiotherapy tools used for patients with acute/subacute neck and back pain in primary care. The study showed that physical exercise was the most common treatment category (59.7%), with almost all patients (99.7%) receiving at least one intervention from this category. Nearly two-thirds of patients (63.2%) received interventions from three or more different treatment categories, and 81.7% of patients in the intervention group and 54.2% in the reference group received occupational medicine-oriented interventions (p<0.001).

We have studied the types and number of interventions offered to these patients in this specific setting, and thereby given a detailed description of the physiotherapy interventions offered in the WorkUp trial. For the safety of the patient and for health care, it is important to describe the types of interventions offered to patients in clinical trials.

We now understand more about physiotherapy in primary care, i.e. the contents of the physiotherapy toolbox. We believe that the results of this study are representative for physiotherapists in general in primary care. Physiotherapists seemed to give more ergonomic advice than we expected; this can be explained by the design and focus of work in the WorkUp trial. A large proportion of patients in both the intervention and reference group received ergonomic advice, although a greater proportion in the intervention group.

Our data and information support the hypothesis that physiotherapists tailor interventions to the patient. We could see that physiotherapists provided many different interventions, and 63.2% of the patients received interventions from three or more different treatment categories.

From our experience, we believe there is a need for supporting IT systems in the electronic medical records systems for physiotherapists in primary care. It should be easy to document what interventions the patients receive and to easily measure the effect of different interventions.

There is a perception that physiotherapists are treating patients according to a holistic approach, and also a biopsychosocial model. We saw that almost all patients received at least one intervention of physical exercise, and more than fifty percent of the patients received manual therapy, which corresponds to the 'bio' part in the biopsychosocial model. However, many patients also received occupational medicine-oriented interventions, which may correspond to the 'psychosocial' part of the model.

Few patients received cognitive behavioural medicine interventions. This was surprising as we found from the baseline data that 24.6% of the patients had signs of depression or signs of anxiety (\geq 8 points on HADS)(183), and that 27.5% had signs of exhaustion (184) (data not published). This information was not available to the treating physiotherapist. Apparently, the physiotherapists did not identify these conditions in the patients. Comorbidity between pain and mental ill-health is well known (223) and, since physiotherapists are first-line treatment in primary care, is it important that they have instruments that help them to identify patients in need of psychological care. We also found that there were almost no referrals to psychologist. This indicates that patients in the study might have been undertreated in terms of their mental health. Another explanation for the lack of referrals is that physiotherapists in general are not used to referring patients to other health care professionals. Only recently have physiotherapists become entitled to send referrals to imaging.

The median number of visits for treatment was five (range 1-41). In a recent study in primary care in the Netherlands, Bier et al. (224) investigated whether clinicians offer tailored treatment and an appropriate amount of treatment visits to patients with low back pain or neck pain according to their risk stratification, based on the SBT. They found that patients at low risk of poor outcome and in need of less treatment were overtreated, and patients at high risk of poor outcome, in need of an extended treatment and more treatment visits, were undertreated according to their prognostic profile (224). The authors conclude that there may be "substantial room for improvement" (224).

There is reason to believe that the same pattern may be seen in other primary care settings, including Swedish primary care. In this thesis, the SBT was not actively used as an instrument by the physiotherapists, and we do not know if the patients were treated according to a stratified care approach. We now have a first description of type of and number of interventions offered to patients in primary care in this context. Further studies are needed to investigate whether these interventions are tailored according to the patient's risk profile.

In WorkUp, we tried a new model where the patient, the health care professional and the employer met early in the rehabilitation process. The physiotherapists in this trial gave many occupational medical interventions, which is highly relevant for this patient group. Physiotherapists in the intervention group gave even more ergonomic advice, which strengthens the need for greater awareness of the importance of integrating occupational medicine interventions in the treatment of patients at risk of work disability in working age.

Methodological considerations

Strengths and limitations

The main strength of this thesis is that all participants were recruited in connection with the WorkUp trial – a prospective cluster randomised trial in primary care. The trial was conducted at a large number of primary care settings (32) linked to 20 different rehabilitation units in southern Sweden. A total of 67 physiotherapists included patients to the trial. All 20 units and physiotherapists were continuously supported by researchers and project coordinators throughout the project period. The study was pragmatic and closely linked to daily clinical practice in ordinary Swedish primary care, and was based on high-quality and thoroughly validated data, which further strengthens our conclusions. All four studies in this thesis were conducted in three different county councils, which represents approximately 20% of the Swedish population, and the characteristics of the people living in the region can be comparable to Sweden as a whole (225). This suggest that the results may be generalisable.

The predictive validity of the SBT was analysed in many different ways, which is a strength. We studied how the SBT risk groups and the SBT overall score could predict work ability and HRQoL outcomes, and we analysed the outcomes HRQoL and work ability, both on the continuous scale (Kruskal-Wallis) and as a dichotomised outcome (Chi-Square test for trend and logistic regression). The AUC was chosen, as this is a measurement that can be used to compare our results with other populations and settings (226).

The main limitation for all studies conducted in relation to WorkUp is that there is no record of all patients that applied for physiotherapy at the 20 different primary care rehabilitation units during the study period. Physiotherapists were asked to invite all patients that applied for physiotherapy for acute or subacute back and/or neck pain to participate in the study. If they were screened ≥ 40 points at ÖMPSQshort and did not meet exclusion criteria, they were included in the study. We cannot be certain that all patients were asked or if there were patients that were not invited, due to lack of time or other reasons. We must be aware that there might be a selection bias at baseline. In studies I and II, we also included patients that were not included in the WorkUp trial, but still screened with ÖMPSQ-short. For these patients we have limited information. This might impact the generalisability of some of the findings. Another limitation is that we did not have access to diagnosis for this group of patients. This had the consequence that we were not able to distinguish patients diagnosed with neck pain only and we conducted our subgroup analysis based on pain sites instead of diagnosis. For pain sites, we divided the population in two groups (BP and NP+BP) based on the answer on question number two in SBT, which is about comorbid neck pain. On the other hand, having neck pain with or without comorbid back pain is common (227) and thus makes the results of these studies applicable to a common clinical situation.

Participant classification to low or high risk for long-standing disability by the SBT and ÖMPSQ-short had moderate agreement, but there was also a disagreement. A larger proportion of patients were allocated to the high-risk group when using the SBT instead of the ÖMPSQ-short (53.7% vs 36.5%). This may be explained by the high-risk classification we used when we merged the medium and high-risk group for the SBT in our study. However, the reason why we merged the groups for SBT (medium + high) in the analysis was that patients with medium and high risk are those who will benefit most from physiotherapy (84).

In study II we also asked the patients not included in the trial about their work ability and health-related quality of life, by sending a questionnaire by post (n=124). Since we needed ethical approval for this, we were unable to send these questionnaires at 12-month follow-up. These patients (78/238) completed the EQ-5D and WAS questionnaires at median 22-month (range 16-27) follow-up. This means that about one third of the patients answered the questionnaire at almost one year later than the other two thirds. This could possibly have impact on how HRQoL and work ability were experienced.

In study III, we examined secondary patient-reported outcomes of the WorkUp trial. The power calculations made for the WorkUp trial were based on the primary outcome, which was work ability measured as sick leave (185). The power calculations indicated that slightly more than 500 patients were needed (259 patients in each treatment arm). Even though the recruitment period was prolonged by one year, the intended power for the primary outcome of the trial was not achieved. This may also have influenced the secondary outcomes.

The compliance for the workplace dialogue was that 91 patients (62.3%) took part in at least step 2, i.e. interview I (physiotherapist and patient) and interview II (physiotherapist and employer). We tried to maintain the intention-to-treat approach in our analyses. We also carried out an 'as-treated analysis' where those who did not receive at least step 2 were transferred from the intervention group to the reference group (37.7% of the patients in the intervention group). The as-treated analysis did not change the results. In the as-treated analysis, 91 persons were in the intervention group and 261 in the reference group.

In study IV, we developed a treatment protocol based on clinical and research experience. The aim of the protocol was to cover and represent commonly used interventions in primary care physiotherapy. At the time of planning the trial, no validated protocol was available. When the trial started, physiotherapists did not record procedure codes in the medical records, but today this is common procedure. It would have been a strength if the treatment protocol had been based on an existing protocol that included official procedure codes. However, we believe that we managed to convert the different treatment alternatives we provided to the physiotherapists in the treatment protocol into procedure codes and into five relevant treatment categories according to Abbott et al. (7).

In study IV we also saw that the recorded treatment periods were long (md 43 days, range 1-411). This is somewhat surprising, since the study population had acute or subacute pain, and treatment periods should have been shorter. We have reasons to believe that the recorded treatment length also included the follow-up at three, six and twelve months, which added several months to the treatment period recorded.

Summary and conclusions

This thesis has deepened the knowledge on health care interventions in primary care for working-age patients with acute or subacute back and neck pain. The Swedish STarT Back Tool (SBT), a brief screening tool designed for tailored interventions based on risk stratification/triage, has been validated for individuals with acute or subacute back and neck pain in primary care. Long-term effects of a workplace dialogue (CDM), as an add-on to structured physiotherapy on self-reported function, health-related quality of life and work ability have been evaluated, and the broad spectrum of interventions used by primary care physiotherapists for patients with back and neck pain in working-age have been described.

- The correlations between the SBT and the ÖMPSQ-short scores were moderately strong for individuals with acute or subacute back and/or neck pain, and the SBT was feasible to use in clinical practice. We therefore suggest that SBT can be used in primary care to identify individuals with both back and neck pain at risk of long-term pain and disability.
- We found that the SBT also can be used to identify patients at risk for a poor long-term health-related quality of life and/or work ability in a population with acute or subacute back and/or neck pain
- We found no effect of the CDM, as an add-on to structured physiotherapy, on self-reported function, health-related quality of life, and work ability (point prevalence) at the 12-months follow-up. All self-reported outcomes improved over time in both the intervention and the reference group.
- Patients with neck and back pain at risk of work disability were offered many different types of interventions, with physical exercise being the most frequently used treatment category. Patients in the intervention group received more occupational medicine-oriented interventions than patients in the reference group.

Clinical implications

- It is important to use screening tools in primary care in order to tailor interventions and manage with limited resources. Recent studies have shown that using the SBT together with matched treatment is cost-effective and can optimize treatment for patients with back pain. We found that the SBT is a clinically useful tool that can be used for patients with both back and neck pain. It can be used to allocate patients into low-, medium- or high-risk strata/groups of long-term pain and disability and can also be used to identify patients at risk for a poor long-term health-related quality of life and/or work ability outcome.
- SBT may help clinicians to prioritize between different treatment pathways, steer away from overtreatment of patients with a good prognosis and direct a more extensive package of treatments to patients at high risk of poor outcome. This has potential to save both time and costs and improve clinical outcomes for patients with back and neck pain in primary care.
- Early interventions and interventions involving the workplace are important in preventing work disability. In the WorkUp trial, we found no effect of the CDM, as an add-on to structured physiotherapy, on self-reported function, health-related quality of life and work ability (measured as a point prevalence). Although we found no impact of CDM on self-reported measures in this study, our earlier analysis of the primary outcome of the trial (actual absence from work) showed a positive effect from adding CDM to structured physiotherapy. This finding from the earlier primary outcome analysis together with the cost-effectiveness, is regarded be sufficient to justify the introduction of the CDM more widely in primary care settings.
- In general, physiotherapy interventions are not in detail described. For the safety of the patient, and for health care it is important to register the interventions provided for patients in primary care. In the WorkUp trial we found that physiotherapists offered many

different types of interventions for patients with back and neck pain. To be able to evaluate the effects of different physiotherapy interventions, physiotherapists need to better describe and register what type of interventions that are offered to their patients.

Future research

There is a need to study in more detail the extent and suitability of different physiotherapy interventions in primary care for patients with back or neck pain. This includes studies where the SBT is actively used in primary routine care as a risk stratification tool, and where physiotherapy treatment is tailored according to SBT risk groups. These studies should include self-reported outcomes and register data on sick leave and also outcomes on health care and drug consumption.

We also need to gain further knowledge on the relationships between self-reported outcomes on work ability, presenteeism and sick leave. The long-term effects of the WorkUp trial will be evaluated using health care register data on sick leave, health care consumption, and costs.

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Physiotherapy in primary care for working-age patients with early back and neck pain



Malin Forsbrand is a registered physiotherapist with a Master of Science in Physiotherapy. She works in primary care, at Karlskrona Rehabcenter in Sweden, and has many years of experience in the care of individuals with back and neck pain from many different primary care centers. She also has a Credential Exam in Mechanical Diagnosis and Therapy.

Back and neck pain is very common, and is a troublesome condition for the individual and costly for society. There is need to better target the optimal intervention to the right person in order to optimize resources. Therefore, we have validated the STarT Back Tool in Swedish primary care, a brief questionnaire that can be used to identify patients at risk for long-term back pain and disability designed to tailor interventions. We found that it is a useful tool that can be used for patients with both back and neck pain. It can be used to allocate patients into low-, medium or high-risk groups of long-term pain and disability and can also be used to identify patients at risk for a poor long-term health-related quality of life and/or work ability outcome.

To prevent work disability, we need more knowledge on what interventions can promote work ability. Therefore, we have also studied if a structured workplace dialogue can promote self-reported function, health-related quality of life and work ability, in addition to structured physiotherapy. Although we found no impact of the workplace dialogue, earlier studies have shown less absence from work when adding a workplace dialogue to structured physiotherapy. The broad spectrum of interventions used by primary care physiotherapists for patients with back and neck pain in working-age are also described.



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