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CLINICAL DECISION-MAKING IN PHYSIOTHERAPY FOR LOW-BACK PAIN IN PRIMARY HEALTH CARE

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CLINICAL DECISION-MAKING IN PHYSIOTHERAPY FOR LOW BACK PAIN IN PRIMARY HEALTH CARE

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Never, for “the sake of peace and quiet” deny your own experience or convictions

Dag Hammarskjöld, Markings 1963

To all musculoskeletal physiotherapists who daily make clinical decisions in treatment

ABSTRACT

Background and Aims: Low-back pain (LBP) is a complex and heterogeneous disorder commonly encountered at physiotherapy clinics, with most cases associated with an unknown cause (NSLBP). Identifying LBP subgroups for targeted treatment has been highlighted as a priority research task. It is unclear how various physiotherapy treatment options are selected and matched to patients with non-specific low back pain (NSLBP) in primary healthcare. The main purpose of this thesis was to explore physiotherapists' clinical decision-making in LBP, through the development and evaluation of a new decision-making treatment-strategy-based classification system (TREST) and through interviews with clinical physiotherapists (PTs) in primary healthcare.

Designs and participants: This thesis is based on four studies with diverse designs. **Study I**, a multi-case study with descriptive and pre-post-test experimental design, included one single physiotherapist and 16 patients with NSLBP and presents and describes a treatment-strategy-based classification (TREST) process. **Study II** investigates inter-examiner agreement between 4 experienced and Orthopaedic Manual Therapy (OMT) trained PTs (2 pairs) on the categorization of 64 patients with NSLBP to TREST subgroups and on 5 of its suggested subgroup criteria. **Study III** employs secondary logistic multiple regression analyses of the 128-examination data collected in Study II to examine the feasibility of subgroup criteria included in TREST. **Study IV** is a qualitative descriptive study exploring clinical reasoning in the decision-making and treatment of NSLBP in primary healthcare, through semi-structured interviews with 15 clinical PTs care in two different regions in Sweden.

Results: **Study I** describes the categorization of NSLBP into one of four treatment-based subgroups: *pain modulation*, *stabilization exercise*, *mobilization*, and *training* and the criteria for each subgroup. **Study II** shows substantial chance corrected inter-examiner agreement for the categorization to subgroups, whereas agreement on suggested criteria varied from fair (specific segmental signs, specific movement pattern) and moderate (uni-bilateral spinal signs, irritability), to almost perfect (neurological signs and symptoms). **Study III** identifies how the individual PTs applied criteria in the subgroup categorization and support feasibility of criteria: the presence or absence of neurological signs and symptoms, bilateral spinal signs and segmental signs as well as level of irritability and disability, in the categorization of NSLBP. In **Study IV**, decision-making was influenced by working approach at workplaces and healthcare priorities, disorder categorization and bodily examination findings, patients' capabilities and participation and physiotherapists' convictions and terms as well as their confidence in treatment and themselves, while insufficiency limited their decision-making. Treatment focuses on patient education and physical exercise as well as combining treatments and treating with atypical goals.

Conclusion: TREST can be reliably used by experienced OMT trained physiotherapists to categorize NSLBP to subgroups and inter-examiner agreement was moderate to almost perfect from three out of five examination items. Feasibility are supported for TREST subgroup criteria: neurological signs and symptoms; bilateral spinal signs; segmental signs; as well as level of irritability and disability. Decision-making was influenced by external circumstances (workplace and healthcare priorities), the disorder (categorization and bodily examination findings), patients (capabilities and participation), physiotherapists (personal convictions and terms, confidence in treatments and themselves, while insufficiency limited their decision-making). Treatment focuses on patient education, physical exercise and combined treatments.

SAMMANFATTNING

Bakgrund och syfte: Ländryggssmärta är vanligt förekommande, kan ibland ge en mycket nedsatt funktionsförmåga och dess orsak är oftast okänd. Ländryggssmärta behandlas ofta av fysioterapeuter och för en riktad fysioterapeutisk behandling har det av forskarsamhället framhållits som viktigt att kategorisera dessa patienter utifrån deras kliniska status. Syftet med avhandlingen är att beskriva och undersöka ett behandlings-strategi-baserat klassifikationssystem (TREST) där patientens kliniska status matchas till fyra olika fysioterapeutiska behandlingar, samt att utforska och beskriva fysioterapeutens kliniska resonemang och behandlingsbeslut vid behandling avländryggssmärta i primärvården.

Metoder och deltagare: Avhandlingen består av fyra delstudier med olika design. **Studie I**, en multi-fallstudie med en beskrivande och pre-post experimentell del, inkluderar 16 patienter med ospecifik ländryggssmärta, vilka kategoriseras av en fysioterapeut till en av de fyra behandlingarna. I **Studie II** undersökts inter-bedömarreliabiliteten (överensstämmelsen) när 4 erfarna sjukgymnaster (2 par) kategoriserar 64 patienter med ospecifik ländryggssmärta enligt TREST, samt undersöker överensstämmelsen för de föreslagna kriterierna i varje behandlingsgrupp. **Studie III** är en uppföljande analys av de 128 patientundersökningarna i Studie II, som genom logistiska multipla regressionsanalyser analyserar hur kriterierna för varje behandlingsgrupp tillämpades av var och en av de 4 fysioterapeuterna. **Studie IV**, en explorativ beskrivande kvalitativ studie som genom semistrukturerade intervjuer med 15 fysioterapeuter i primärvården från två olika regioner i Sverige, utforskar deras kliniska resonemang och behandlingsbeslut vid ländryggssmärta.

Resultat: **Studie I** beskriver en kategoriseringsprocess av patienter med ospecifik ländryggssmärta till en av fyra de behandlingarna *smärtmodulering*, *stabiliseringsövningar*, *mobilisering* och *träning*. I **Studie II** var överensstämmelsen mycket god mellan de två paren av fysioterapeuter när de kategoriserade patienterna till behandlingarna, medan överensstämmelsen för de föreslagna kriterierna varierade från låg (*specifika segmentella fynd*, *specifikt rörelsemönster*) och måttlig (*uni-eller bilaterala ryggfynd*, *irritabilitet*) till nästan perfekt (*neurologiska symptom och fynd*). I **Studie III** stöds tillämpningen av kriterierna: närvaro/frånvaro av ”*neurologiska symptom och fynd*”, ”*bilaterala ryggfynd*” och ”*specifika segmentella fynd*” samt grad av ”*irritabilitet*” och ”*funktionsförmåga*” i kategoriseringsprocessen. **Studie IV** visade att vilken behandling som ges påverkas av arbetsplatsens inriktning och hälso- och sjukvårdens prioriteringar. Kategorisering av ländryggsmärtan i sig och kroppsliga fynd styr behandlingsvalen och patientens kapacitet och deltagande är förutsättningar för behandlingen. Fysioterapeutens personliga övertygelser och villkor, deras tilltro till behandlingar och till sig själva påverkar den behandling fysioterapeuten väljer medan känslan av otillräcklighet begränsar behandlingsbesluten. Behandlingen fokuseras på patientundervisning och fysisk träning samt en kombination av behandlingar med atypiska mål.

Sammanfattning: TREST kan användas med mycket god tillförlitlighet av erfarna OMT fysioterapeuter, för att kategorisera ländryggssmärta till en av de 4 behandlingarna.

Överensstämmelsen är måttlig till god för 3 av 5 kriterier i TREST och tillämpningen av kriterierna ”*neurologiska symptom och fynd*”, ”*bilaterala ryggfynd*” och ”*specifika segmentella fynd*” samt grad av ”*irritabilitet*” och ”*funktionsförmåga*” stöds. Behandlingsbeslut påverkas av arbetsplatsen och primärvårdens prioriteringar, kroppsliga fynd, patientens förmåga och delaktighet, fysioterapeutens övertygelser och villkor, deras tilltro till behandlingar och till sig själva medan upplevd egen otillräcklighet begränsar besluten. Behandlingen har fokus på patientutbildning, fysisk träning och en kombination av behandlingar.

LIST OF SCIENTIFIC PAPERS

- I. Widerström B, Olofsson N, Arvidsson I. **Manual therapy and a suggested treatment based classification algorithm in patients with low-back pain: A pilot study.** J of Back and Musculoskeletal Rehabilitation 2007; 20 (2,3):61-92.
- II. Widerström B, Olofsson N, Arvidsson I, Harms-Ringdahl K, Evers Larsson U. **Inter-examiner reliability of a proposed decision-making treatment based classification system for low-back pain patients.** Manual Therapy 2012;17:164-171
- III. Widerström B, Olofsson N, Boström C, Rasmussen-Barr E. **Feasibility of subgroup criteria included in the treatment-strategy based classification system for patients with non-specific low-back pain.** Manual Therapy 2016; 23: 90-97
- IV. **Exploring physiotherapy clinical reasoning in the decision-making and treatment of non-specific low-back pain in primary health care.**
Widerström B, Rasmussen-Barr E, Boström C. Manuscript.

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LIST OF ABBREVIATIONS

CI	Confidence interval
CPG	Clinical practice guidelines
CPR	Clinical prediction rule
CS	Classification system
EBM	Evidence-based medicine
EBP	Evidence-based practice
HRQoL	Health-related quality of life
ICF	International Classification of Functioning, Disability and Health
ICD	International Statistical Classification of Diseases and Related Health
IFOMPT	The International Federation of Manipulative Physical Therapists
LBP	Low-back pain. Pain ache or discomfort, localised below the costal margin and above the gluteal folds with or without referred leg pain
LLLT	Low-level laser therapy
MDT	Mechanical Diagnosis and Therapy
MSI	Movement System Impairment classification system
NSAID	Non-Steroid Anti-inflammatory Drugs
NTPT	Neural tension provocation tests
OMT	Orthopaedic manual therapy
OSW	Oswestry low-back pain disability questionnaire
PCS	SF 36 subscale for physical health
PKB	Prone knee bend
ROM	Range of motion
SLR	Straight leg raise
TBC	Treatment-Based Classification system
TENS	Transcutaneous electric nerve stimulation
TREST	Treatment-strategy-based (classification system)
WCPT	World Confederation of Physical Therapy

1 INTRODUCTION

1.1 PREFACE

I have worked as a clinical physiotherapist in primary healthcare for many years, and the work presented in this thesis has its origin in my daily encounter with patients seeking care for low-back pain (LBP). For most of these cases the underlying cause of their pain is unknown and is therefore, diagnosed as non-specific LBP (NSLBP). Although heterogenic in nature, NSLBP is often in clinical trials randomized into two or more ‘treatment-arms’ without clear reference to individual differences or similarities in clinical status. Hence, results from such studies give limited information to clinicians on how treatment can be matched to the individual. As an alternative, patients can be categorized, based on their clinical presentation into subgroups linked to a treatment that is likely to be successful. Such categorization requires ways of thinking¹ and step-wise decision-making described in classification systems. This way of categorizing LBP symptoms and signs into subgroups likely to respond to a specific treatment caught my interest.

One classification system of special interest was the Treatment Based Classification System (TBC).²⁻⁶ This impairment based classification system has a clinical reasoning approach that is familiar to that used by musculoskeletal physiotherapists and included treatment selections, such as mobilizations and stabilization exercises, commonly used within musculoskeletal physiotherapy in patients with LBP. However, the TBC does not include treatment selections that can reduce pain in the initial phase of treatment, such as acupuncture, and includes treatment selections specific in nature, such as one specific manipulation technique for mobilization, and therefore lacks a necessary within-subgroup treatment flexibility for patients and physiotherapists, alike. Furthermore, the TBC does not describe a progressive treatment approach where patients can be recategorized as their status improves.

Identifying subgroups and by extension finding optimal treatment for each subgroup has been proposed as a research priority task. Accordingly, the starting point of this thesis was to use the TBC as a guiding principal to develop a readily and flexible classification system. Such a system should tailor care to the individual, include several commonly used and guideline-endorsed treatment selections and should not require extensive training or additional qualifications for physiotherapists in primary healthcare.

This work also reflects the empathic curiosity I hold for patients as well as my understanding of pain, disability and physical status associated with LBP and its treatment that my experience and specialization in musculoskeletal disorders have yielded.

1.2 FRAMEWORKS

1.2.1 Physiotherapy in primary healthcare in Sweden

Primary healthcare forms the foundation of the healthcare system in Sweden and is decentralized into 21 regions and organized by county councils, local authorities or municipalities. Team-based primary healthcare facilities with doctors, nurses, physiotherapists, and sometimes also occupational therapists, psychologists, and social welfare counsellors, are common. These can be publicly or privately operated, both being included in the social security system which encompasses all citizens and is primarily funded through national and local taxation. Primary healthcare in Sweden also includes privately-operated physiotherapy clinics where single physiotherapists or groups work, and are accredited by the local authorities. Patient fees are equal between publicly- and privately-operated centres in each region, but may differ between regions.⁷

Patients have direct access to physiotherapy which refers to patients being able to refer themselves to physiotherapy without a third-party referral, such as from physicians.⁸ Direct access and patient self-referral to physiotherapy are manifestations of professional autonomy and rely on the competencies and preparations that graduate physiotherapists are expected to have.⁹ Both publicly- and privately-operated physiotherapy clinics in primary healthcare are represented in this work.

1.2.2 Practice paradigms in musculoskeletal physiotherapy

A practice paradigm within physiotherapy is the physiotherapists shared sets of assumptions and values of practice.¹⁰ Based on the perceived importance of certain types of knowledge to be used in practice, the paradigm will influence clinical decision making, patient interaction and treatment delivery.¹¹ There are two main treatment paradigms in musculoskeletal physiotherapy, the biomedical model and the biopsychosocial model.¹²

The biomedical model originates from the 19th century and is based on the conclusion that all disease result from cellular abnormalities.¹³ In the biomedical model, pain is considered as an indicator of pathology and tissue damage with causative factors such as diseases, injury, overuse and immobilization. Within physiotherapy, the biomedical model defines disability and impairment as degrees of deviation from the 'normal,' and treatments are directed towards the neuro-musculoskeletal system with the aim of reducing pain and improving function.

The bio-psychosocial model was presented in 1977 as a descriptive model for understanding patients' experience of illness, with no guidance on treatment.¹⁴ It was later introduced to the management of LBP in order to understand LBP not as a physical disease, but rather as an illness including the patients' and society's reaction to pain.¹⁵ The persistence of pain is explained by psychological and social factors, other than the underlying pathology, and hence treatment aims at reducing pain behaviour and increasing healthy behaviour.¹⁶

It is suggested that best practice involves the integration of different paradigms and reasoning processes for comprehensive care.^{11, 16} The studies in this work primarily investigate and explore biomedical orientated practice in examining the influence of e.g. mobility and neurological signs, but also the influence that patient-reported perceived pain, symptom irritability and disability have on physiotherapists' clinical reasoning and decision-making.

1.2.3 Evidence-based clinical decision-making

Clinical decision-making, clinical judgment, problem solving or clinical reasoning are terms used interchangeably and defined as the professional context dependent cognitive process or thinking used in the evaluation and management of a patient.^{17, 18} Early work of the Evidence Based Medicine (EBM) working group stated that clinical decisions should be based on evidence from systematic critical assessment, experimentation and revision, with the gold standard level of proof being randomized clinical trials (RCTs).¹⁹ However, taking decisions on such evidence is rarely how clinical decisions are made in every day practice. There is inadequate evidence to support all dimensions of practice and decisions must be taken in the absence of clarity and certainty.²⁰ Not all health care research questions can be addressed through experimentation, and rather what is needed in many areas of health care is to seek an understanding of phenomena, for example through interpretative inquiry.²⁰ An updated version on how EBM should be used in Evidenced Based Practice (EBP), has emphasized that scientific evidence hierarchy alone is not sufficient and adequate to guide action.²¹ Sackett states that “without clinical expertise, practice risk being tyrannized by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient”.²²

For most clinicians summarizing evidence is overwhelming, and ensuring that clinician decisions are consistent with patient values is even more challenging.²³ In an updated version of EBP, clinical expertise (communication, interaction, experience and pragmatism) has been superimposed on the other components of EBP (research evidence, patient preferences and clinical state and circumstances).²¹ More recently a trans-disciplinary model (Figure 1) has disentangled clinical decision-making and suggested it as a fourth element that overlays the EBP components of best available research evidence, clinical expertise and patient preferences.²⁴ The main interest in this thesis has been to investigate and explore clinical decision-making treatment and its interaction with patient clinical status.

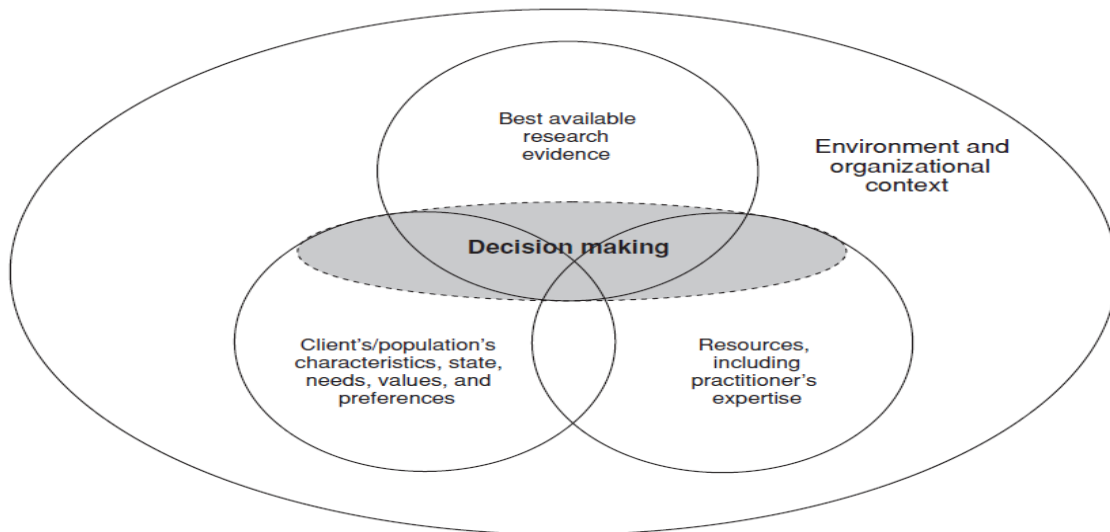


Figure 1. Trans-disciplinary model of Evidence Based Practice. Reproduced from Satterfield et al. 2009 ²⁴.(Reproduced with kind permission of the Milbank Memorial Fund www.milbank.org)

1.2.4 International Classification of Functioning, Disability and Health

According to the World Health Organization's International Classification of Functioning, Disability and Health (WHO-ICF) model,²⁵ the effect of LBP on the individual can be described from the perspectives of three components; body (biological), individual and society, synthesized into a bio-psychosocial model (Figure 2). In this model, LBP can cause loss of health due to impairments of body structures and functions, activity limitations and participation restrictions due to structural and/or physiological events, and be affected by personal and/or environmental factors. In this thesis the main concern has been on pain, body structure and function (impairments) and activity limitations (disability).

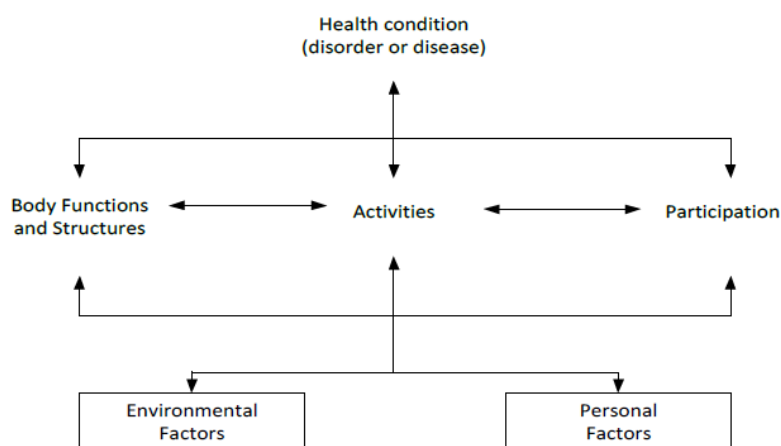


Figure 2 Interaction between the components of the ICF model²⁵ (Reproduced with kind permission from WHO under terms and conditions of non-exclusive license to use selected WHO published materials)

2 BACKGROUND

2.1 PHYSIOTHERAPY

Physiotherapy is an established health profession, and the World confederation for Physical Therapy (WCPT) describes physiotherapy as being “...concerned with identifying and maximising quality of life and movement potential within the spheres of promotion, prevention, treatment/intervention, habilitation and rehabilitation... which encompass physical, psychological, emotional, and social wellbeing”.²⁶ Within physiotherapy the understanding of human movement and function in relation to physical, emotional, existential and socio-cultural environmental factors is central.²⁷ The interaction between the physiotherapist and the patient is fundamental to all physiotherapy and relies on a complex interplay of technical skills, communicative abilities and reflective capacity of the therapist to respond to the patient.²⁸

2.1.1 Orthopaedic Manual Therapy

Orthopaedic manual therapy (OMT) is one subspecialisation area within physiotherapy with explicit focus on the evaluation and treatment of the musculoskeletal disorders. The International Federation of Manipulative Physical Therapists (IFOMPT) defines OMT as “...a specialized area of physiotherapy/physical therapy for the management of neuro-musculoskeletal conditions, based on clinical reasoning, using highly specific treatment approaches including manual techniques and therapeutic exercises” driven by “the available scientific and clinical evidence and the biopsychosocial framework of each individual patient”.²⁹ Manual therapy techniques include palpation techniques, thrust and non-thrust techniques (manipulations and mobilizations, respectively) and other hands-on treatment procedures such as massage, trigger point treatments, manual stretching and guided exercises.²⁹

2.2 CLINICAL REASONING

2.2.1 Clinical reasoning theories

Clinical reasoning may be defined as “a context dependent way of thinking and decision-making in professional practice to guide practice actions”.³⁰ The ability to identify small factors and fit them together is an important part of reasoning and judgment in clinical practice.³¹ Within musculoskeletal practice, as within other healthcare professions,³⁰ four commonly cited models of reasoning are *hypothetico-deductive*, *pattern recognition*, *clinical prediction* and *narrative*.

Hypothetico-deductive, *pattern recognition*, *clinical prediction* all derive from a cognitive science perspective^{32, 33} which has its roots in the positivist paradigm¹⁷ (section 2.6). Early work on clinical reasoning in physiotherapy suggested that the reasoning process was similar to that of physicians and was mainly concerned with the examination component and diagnosis.^{34, 35} This early work supported a hypothetico-deductive model, a backward

reasoning from a hypothesis of the problem followed by testing to rule out different answers.^{34, 35} This model has been challenged by the notion that treatment is a central and integrated part of clinical reasoning.^{18, 36} As a consequence models have been described where reasoning moves forward from a set of given information and observations, to modify or confirm hypotheses and present a treatment. *Pattern recognition* uses clinical status identification supported by previous clinical experience of a plausible treatment solution of the problem.³⁶⁻³⁸ *Clinical prediction* involves the identification of clinical variables that linked together suggest a specific and successful treatment selection.^{3, 4, 39}

In contrast, *narrative reasoning* originates from the interpretive/hermeneutic paradigm, and seeks to establish insight into the patient's perspective and story, rather than testing for "cause and effect".^{1, 40} Hereby narrative reasoning is distinguished from hypo-deductive reasoning in that "hypotheses" are validated by consensus between therapists and patients.⁴¹ In clinical practice narrative reasoning concerns the understanding of patients' stories of pain and/or disability and their subsequent beliefs, feelings and health behaviour.⁴⁰

It has been suggested that clinicians concurrently use these models to generate initial hypotheses and deductively test them through questioning and physical examination, recognizing prior experienced clinical patterns or identifying clinical variables that together suggest a treatment, and at the same time, forms an understanding of the patient's story.⁴² All the models described above have been presented as cognitive analytical processes with limited reference to the emotional component of clinical examination and decision-making where clinicians' empathy, gut-feelings, intuitions, and emotions play a role.^{41, 42} These emotional processes have been described as separated from, but co-existent with, the analytical processes.⁴²

2.2.2 Clinical reasoning in clinical practice

Clinical reasoning in clinical practice is specific to one's area of work and depends on the clinician's knowledge of a specific area,³⁰ without which decisions are prone to error.³⁸ Relevant knowledge within musculoskeletal physiotherapy includes; *facts* (e.g. anatomy, sources of pain); *procedures* (examination methods and treatments); *concepts* (e.g. disability, pain mechanisms,); *principles* (e.g. treatment selection and contraindications); and *patterns of presentations* (clusters of symptoms and signs). Furthermore, full competence in physiotherapy in general includes experience, intuition as well as social communication and manual clinical skills.^{18, 43}

In clinical practice clinical reasoning has been described as a way of thinking and taking action, labelled "clinical reasoning strategies", associated with diagnosis as well as management.¹ *Diagnostic* reasoning refers to the formation of diagnosis relative to physical disability and impairments and *narrative* reasoning to potential contributing factors and understanding the patients' stories. Reasoning on management are described as reasoning about determination and carrying out treatment (*procedure*), purposeful establishment and ongoing therapist-patient relation (*interaction*), a consensual approach to goal setting and

implementation of treatment (*collaboration*), thinking about content, method and amount of teaching in clinical practice (*teaching*), envisioning future scenarios and choice (*prediction*) and apprehension of ethical and practical dilemmas (*ethics*). These reasoning strategies are thought to interact with the above described analytical models of clinical reasoning.¹

2.3 LOW-BACK PAIN

2.3.1 Definition and prevalence

Low-back pain may be defined as “pain, ache or discomfort, localised below the costal margin and above the gluteal folds, with or without referred leg pain”.⁴⁴ LBP is a world-wide health problem with a life prevalence of approximately 80%, a global point prevalence of 9.4%⁴⁵ and one of the most common reasons for patients in the western countries to seek medical treatment.^{46, 47} Although often benign in nature,⁴⁸ LBP stands for individual suffering and extensive costs to society. Out of all 291 conditions in the Global Burden of Disease 2010 Study, LBP is ranked highest as a cause of years lived with disability and sixth in terms of overall burden.^{49, 50} In Sweden, statistics from 2016 show that musculoskeletal disorders are the second most common reason for sick leave,⁵¹ and back-pain being the most common among these disorders. For 2003, the expenditure of longstanding pain was estimated to 87.5 billion SEK, with 80 billion referring to loss of productivity and 7.5 billion SEK as direct healthcare costs.⁵² This indicates a need for research on how these patients may best be helped.

2.3.2 Pathology and diagnostics

Diagnosis is regarded as the primary guide to treatment and prognosis, and is considered the core component of clinical practice.⁵³ However, LBP treatment selection as being exclusively determined by diagnosis has been challenged by the biological, clinical and social factors influencing the likelihood of an individual’s future outcome.⁵⁴ Furthermore, diagnosis tells us very little about prognosis.⁵⁴ LBP is commonly triaged into pain due to 1) serious pathology, 2) nerve root involvement, and 3) non-specific LBP.⁵⁵ In most cases seen in primary health care LBP is not a sign of severe pathology and the exact cause of pain cannot be clarified.⁵⁶ While diagnostic imaging seems a logical way to clarification, studies have indicated that the source of pain cannot be identified by magnetic resonance imaging (MRI).⁵⁷ MRI has limited specificity in the assessment of a painful spine and limited diagnostic value in differentiating between painful abnormalities and aging modifications.⁵⁸ Furthermore, pain can also occur although lumbar anatomy is normal,⁵⁹ and in reverse, abnormal lumbar anatomy is not necessarily associated with pain.⁶⁰⁻⁶² These factors have put into question whether abnormal findings are clinically important in LBP and sciatica.⁶³ The use of early MRI scans has been shown not to alter patient outcomes and seems to be associated with persistent perceptions of poor health.⁶⁴⁻⁶⁶ Clinical practice guidelines (CPG) therefore recommended that diagnostic procedures should focus on suspected serious pathology and the exclusion of specific diseases⁶⁷ through the identification of “red flags”, i.e. age at onset <20 or >55 years, significant trauma, unexplained weight loss and widespread neurological changes.

2.3.2.1 *Non-specific and specific low-back pain*

Approximately 80% of LBP cases seen in primary health care are non-specific LBP (NSLBP).⁵⁵ This group includes patients with a cluster of signs and symptoms from the back, in different stages of impairment and disability.⁴⁵ Poorer prognosis with prolonged healing, chronicity, work absence and higher health-care costs have been reported for those with radiation of leg pain below the knee and with neurological findings, than with local pain only.⁶⁸⁻⁷² However, leg pain has been defined in diverse ways, from those with any leg pain to those with leg pain due to inflammation of the spinal nerve or its dorsal root or ganglion (radicular pain)⁵⁵ combined with numbness/tingling and muscle weakness along the course of a lumbar nerve and MRI-confirmed nerve root compression (radiculopathy)^{73, 74} In primary healthcare patients rarely present with severe nerve root involvement such as urinary retention, saddle anaesthesia or severe or progressive motor deficits.^{55, 75}

A specific low-back pain diagnosis is associated with a known and often serious pathology. In primary health care such specific diagnoses of LBP are rare, approximately in less than 10% of all cases.⁵⁵ These diagnoses, such as infection in lumbar disc or vertebra, tumours, inflammatory process and fractures, are coded in the International Statistical Classification of Diseases and Related Health Problems (ICD-10),⁷⁶ all these need medical diagnostics and treatment beyond the scope of this thesis. This thesis covers LBP with or without leg pain, where the cause has not been verified through diagnostic imaging and is therefore considered to be NSLBP.

2.3.3 **Pain definition and mechanisms**

The International Association for the Study of Pain's definition states that "pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".⁷⁷ This definition explains pain as multimodal complex experience,⁷⁸ which may be reinforced by belief, anxiety and depression, and avoids tying pain to physical origin, although pain most often has an adjacent physical cause. Pain can involve multiple neural sites; peripheral nerves, spinal cord and higher brain centres.^{78, 79} Pain is often the major symptom and of the greatest concern for the patient⁸⁰ and pain research has increased the understanding of the mechanisms behind how local and acute pain may transform to persistent pain.⁸¹ It has been proposed that musculoskeletal pain can broadly be categorized into three neurophysiological mechanism-based pain states: nociceptive pain (NP), peripheral neuropathic (PNP), and central sensitisation pain (CSP).^{78, 82 83}

Nociceptive pain refers to pain arising predominantly from somatic tissues (muscles, joints, discs, ligaments) in response to noxious (painful) stimuli. This painful stimulus is a result of inflammation or trauma of degenerative or systemic origin, or by ischemia secondary to repetitive/excessive mechanical loading (pressure or tension).⁸⁴ PNP refers to pain arising from dysfunction or lesions (e.g. compression, inflammation) within peripheral neural tissue

(peripheral nerve and dorsal root ganglion). This will lead to increased responsiveness and receptive field size due to neural hyperexcitability.⁷⁸

CSP refers to pain that is disproportionate to somatic tissue or peripheral nerve pathology, a result of aberrant processing/hypersensitivity in the central nervous system.⁸⁵ This can be due to increased excitation and/or reduced inhibition of central neurons.^{81, 86} These sensitisation mechanisms may lead to neighbouring uninjured areas being experienced as painful, and also cause innocuous (non-painful) stimuli to be experienced as painful.⁸¹

Most patients with LBP seeking primary health care can be categorized as experiencing nociceptive pain,⁸⁷ and approximately 10 % as having peripheral neuropathic pain,⁵⁵ but both nociceptive and neuropathic pain can develop into central sensitisation pain.⁸⁵ In clinical practice it is difficult to identify the predominant pain generator, pain state and underlying mechanism because many clinical tests have poor specificity and are unreliable.⁸⁸ In addition, there is often an overlap of pain states and coexistence of pain mechanisms at play.⁷⁸ Despite these limitations the patient history and physical clinical examination inform on the patients pain and disability, hereby providing an understanding and guidance in clinical decisions.⁵⁵

2.3.4 Clinical course and trajectories

The traditional notion that LBP is typically benign, self-limiting and transient with recovery or improvement within three months⁸⁹ has been reconsidered due to reports of 1-year recurrence being common.^{90, 91} Incidence of intermittent flares of symptoms seems to be a part of its natural history (development without actions taken).^{90, 91} The traditional temporal categorization of LBP as acute (<6 weeks), sub-acute (≤ 12 weeks) or chronic (>12 weeks), is based on the duration of the current episode.⁹² However, it has been shown that acute LBP is often a flare-up in a persistent condition.⁹³ Thus, temporal categorization has been questioned and deemed to be overly simplistic in using terms of recovery or chronicity only.^{94, 95} Rather the clinical course over time in most people with LBP is trajectories of either persistent or fluctuating pain of low or medium intensity.^{93, 95, 96} Principal trajectories of pain have been suggested with labels combining a descriptor of intensity, variability and change⁹³ (Figure 3) and have the potential of supporting clinical decision making and differentiating between treatments directed at an episode of intensive pain and disability and interventions intended for managing patients with persistent mild LBP.⁹³






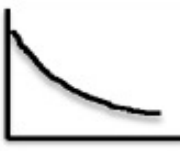

Principal pattern	Terminology for labelling	Suggested definition
INTENSITY		
	<i>Severe pain</i> <i>Moderate pain</i> <i>Mild pain</i> <i>Minor pain / Recovery*</i>	Mean scores 0-10 Numeric Rating Scale 5 to 10 4 to 5 2 to 3 0 to 1
VARIABILITY		
	<i>Persistent pain</i>	An individuals' pain intensity stays within mean +/-1-point (0 to 10 NRS) Pain reported >4 days per week
	<i>Fluctuating pain</i>	Variation in pain intensity exceeds 2 points, without periods of no pain (0) lasting ≥1 month**[27]
	<i>Episodic pain</i> <i>Single episode</i>	Experiencing more than one period of pain separated by periods with no pain (0) lasting ≥1 month** One period of LBP preceded and followed by periods with no pain (0) lasting ≥1 month
Change pattern (likely to be most relevant for clinical populations)		
	<i>Rapidly improving pain</i>	Marked decrease in pain intensity within 1 month
	<i>Gradually improving pain</i>	Marked decrease in pain intensity occurring gradually over more than 1 month
	<i>Progressing pain</i>	An overall pattern of increasing pain intensity

Figure 3 Illustration of Trajectories of pain from Kongstad et al. BMC Musculoskelet Disord 2016⁹³ (Reproduction permitted with credit to the original authors and source under the Creative Commons Public Domain Dedication waiver; <http://creativecommons.org/publicdomain/zero/1.0/>)

2.4 MANAGEMENT OF LBP IN PRIMARY HEALTHCARE

2.4.1 Clinical guidelines

The evidence of intervention effectiveness is summarised in clinical practice guidelines (CPG). These summaries are based on RCT assessments of study-level averages and might assist decision-making, with advice applicable to populations of patients only.⁹⁷ One recent systematic overview of practice guidelines concludes that most guidelines targeting LBP not diagnosed as specific LBP recommend education, staying active, exercising, manual therapy, self-management options and pain medication as first-line treatments.⁹⁸ The review also concludes that patients with acute LBP should be encouraged to return to activity and may benefit from spinal manipulation, while management regarding patients with persistent LBP may include exercise, manual therapy, acupuncture and multimodal rehabilitation (combined physical and psychological treatment).⁹⁸ More recently the Danish national practice guidelines recommend information, advice to remain active, patient education, various types of supervised exercise, and manual therapy, but discouraged the use of acupuncture.⁹⁹ It is accepted that CPG recommendations of effectiveness alone are not sufficient to provide a good quality of healthcare, including physiotherapy.^{21, 100}

To be considered of good quality, health care should not only be effective: it should also be safe, efficient, accessible, patient centred/acceptable and equitable.¹⁰¹ It has been proposed that to improve the uptake of recommendations and enhance patient empowerment, the views and preferences of the patients need to be integrated in the next generation of high-quality guideline development process.⁹⁸

There is consistency in clinical practice guidelines (CPG) across countries that psychosocial factors (e.g. anxiety, depressive mood, fearful beliefs about movement),¹⁰²⁻¹⁰⁴ denoted as ‘yellow flags’, may be associated with a poor prognosis of LBP.^{67, 98} There is, however, considerable variation in the amount of details given about how to assess ‘yellow flags’, and subsequent therapeutic management.⁶⁷ The complexity of fear-avoidance has also been shown recently when patients hospitalized for LBP scored high on a fear-avoidance belief questionnaire, but did not indicate high fear-avoidance behaviour during their interviews.¹⁰⁵ It has been recommended that chronic LBP should be stratified by impact, i.e. combined measures of pain intensity, functional status and pain interference with normal activities, as a standard in future research.¹⁰⁶

2.4.1.1 Physical interventions

Overall, there is limited evidence for the effectiveness of most physical treatments for LBP.^{80, 107} Physical treatment options include for example, spinal manipulations/mobilizations, soft tissue techniques, various physical modalities (e.g. acupuncture, transcutaneous nerve stimulation and low level laser therapy) and physical exercise therapy.¹⁰⁸ Despite decades of research and improved quality of randomized clinical trials (RCT), physiotherapy treatments tend to produce small effects and often only in short term.¹⁰⁹ There are several reasons for this. Many RCTs do not reflect the complexity of clinical practice, looking at LBP as one

condition, examining single interventions, and measure outcome of simple recovery/non-recovery.^{93, 96} Furthermore, many patients with LBP have a favourable natural prognosis, hence control groups with minimal or no treatment in RCTs will also show significant improvement which may deflate the significance of treatment in studies.¹⁰⁹ Moreover, LBP symptoms may improve in a similar way following a wide variety of active as well as inactive treatments, indicating that factors other than the treatment might influence improvements.¹¹⁰

2.4.1.2 Psychological and behavioural interventions

The introduction of the bio-psychosocial view of LBP into public health research and practice has not reversed the trend of increasing numbers of cases with LBP and disability.^{49, 50, 111, 112} It is unclear whether the model itself is unsuccessful, or whether the health care community has failed to adopt the model successfully^{112, 113}

Systematic reviews show that psychological and behavioural treatment for chronic pain have at best modest effects in the short-term,^{114, 115} when compared to passive controls.¹¹⁶ These programmes are often costly, and cost-benefit as well as the time-benefit ratios are to be considered before enrolling a patient in such programmes.¹¹⁷ However, it is currently widely accepted that the development of LBP and in particular its maintenance is to be understood as multi-factorial, potentially related to combinations of physical characteristics as well as genetic, behavioural, psychological, anatomical and societal factors.^{67, 102, 118}

Multidisciplinary or multimodal bio-psychosocial rehabilitation, i.e. a combination of physical exercises and behavioural and/or psychological interventions, is recommended in the management of persistent pain,^{98, 117-119} specifically when there are significant psychosocial obstacles for recovery or when previous treatments have not been effective.¹¹⁹ These programmes target pain relief, regain of function, reduction in psychological distress, and improved work ability. Treatments are often group-based activities and include education about chronic pain, training in psychological techniques to better cope with pain, and interventions to improve the patient's physical health.⁵²

2.4.2 Clinical practice

2.4.2.1 Clinical physiotherapists' treatment decisions

Research at sites of clinical practice in various countries, investigating physiotherapists' clinical reasoning and decision-making in LBP have been reported. In Sweden, one study showed that physiotherapists' reasoning was related to case complexity, from easy to very complex, depending on the degree of involvement of psychological factors and help-seeking behaviour.¹²⁰ Another, found that problem-solving was central in the clinical encounters with patients and physiotherapists' professional and personal values may influence patients' access to health care, with a risk of unequal assessment and intervention as a consequence. In Portugal, a study found that reasoning was cognitive and biomechanical in nature and purely clinician centred, excluding patients from decision making.¹²¹ A study in the United Kingdom identified reasoning factors as, patient interaction and assessment, organization and

time constraints, safety and accountability, and most importantly the “gut-feeling”, as pertinent.¹²² In a study of physiotherapists in the United States, decisions were found to be made in relation to disorder origin and treatment-based, on either an experienced-or evidence-based approach.¹²³ A recent review synthesizing results from quantitative and qualitative studies concluded that treatment selections addressed biomedical factors and that treatment decisions were made on the basis of what would facilitate the relationship with and satisfy the patient and to what degree a patient would engage in treatment and/or self-management.¹²⁴

2.4.2.2 Clinical practice patterns and treatments in primary healthcare

Research from the site of clinical practice shows a plenitude of practice patterns in the management of LBP. These patterns can have focus on, for example, manual therapy (mobilizations/soft tissue techniques), on the Mechanical Diagnosis and Therapy (MDT-McKenzie) approach i.e. specific directional movements), or on exercises and function, regardless of their proven effects.^{48, 125-128} Rationales for this are multiple. Uncertainty in diagnosis and prognosis associated with LBP, pragmatism and individual experience of treatment efficacy,¹²⁹ convictions regarding the necessity of individualised treatment,^{97, 130} the use of combined treatments and the close commitment of physiotherapists to their preferred treatments are all in play.¹²⁸

The mechanisms through which physiotherapy interventions influence pain and disability in LBP are complex,^{28, 131} and their therapeutic effects are not fully understood.^{80, 107} However, in clinical practice musculoskeletal treatment selections are expected to have specific effects on LBP and are shown in the following:

Patient education and advice are reassurance and regimen based on the expected clinical course of recovery, self-care options and pain education, having effects on the patients ‘pain and worry’.⁹⁸

Physical modalities (electrical nerve stimulation (TENS), ultrasound, low-intensity laser (LLLT) and acupuncture) achieve short-term improvement in pain and can be useful adjuncts to other therapies.^{48, 132, 133} Mechanisms behind the analgesic effect of physical modalities are complex and unclear. Inhibition of nociceptive afferent input to the spinal cord (gate control theory), release of endogenous central and spinal opiates and neurophysiological effects on peripheral nerve function has been proposed as mechanisms of action.¹³⁴⁻¹³⁶

Manual therapy (e.g. massage, trigger-point procedures, mobilisations/manipulation and neuro-dynamic techniques) restore normal function to a joint/muscle or peripheral nerve.¹³⁷⁻¹³⁹ Manual therapy working mechanisms are unclear and are likely to have multiple effects that are not yet fully understood.¹⁴⁰⁻¹⁴² Early ideas concerning the effects of mobilizations/manipulations were predominantly mechanistic in nature, such as moving joint inclusions or disc fragments, dividing adhesions or repositioning sub-luxed vertebral segments.^{143, 144} Of late, theories have proposed that the repeated movements associated with manual therapy cause a decline of neural discharge due to inhibition of nociceptive afferent input to the spinal cord, resulting in hypoalgesia (diminished pain in response to a normally

painful stimulus) and improved muscle function.^{142, 145 146} Traction is one manual technique expected to benefit patients with LBP with radiating leg pain and concomitant neurological deficit.¹⁴⁷ The efficacy of traction for managing LBP has been put into question in systematic reviews.^{147, 148} Yet, there are patients that may benefit from traction and its usage among physiotherapist is common and is often supplemental to other interventions.¹⁴⁹

Neuro-dynamic techniques or neural mobilization, affect neural movement or movement of surrounding tissue, improve circulation and the diffusion of intra-neural oedema, and benefit patients with neural tissue mechanical sensitisation and improves pain intensity and disability in persistent NSLBP.¹⁵⁰⁻¹⁵²

Physical training or *physical exercise* has a moderate to high-intensity character and is focused on strength and endurance effects. Anticipated effects are improved spinal function, increased tolerance of spinal loading, prevented episodes of LBP and improved general fitness.^{153, 154} Although there is scientific evidence for short-time benefit of physical training,¹⁵⁵⁻¹⁵⁷ there is no evidence that one specific mix of exercises is more efficient than another. There are heterogeneous exercise characteristics in programme designs (individually designed or standard programme), delivery types (un-supervised home exercises, group, or individual supervision) as well as dose and intensity. This leaves the exercise selection to the treating physiotherapist and to the patients' ability and preference.^{98, 156, 158} Research shows that muscle alterations, such as reductions in cross-sectional surface area and fibre density, in LBP lead to muscle fatigue¹⁵⁹ and/or deficits in normal timing and recruitment (motor function) of the back muscles,¹⁶⁰ not always spontaneously resolved when symptoms alleviate.¹⁶¹ Furthermore, patients with recurrent LBP have been shown to exhibit altered and rigid postural control strategies.¹⁶²

Motor control/stabilisation exercises are guided low-intensity exercises focused on precision, motor timing and coordination expected to improve spinal control and tissue loading.^{163, 164} These exercises are specific and require attention and precision from the patient. The loss of a normal pattern of spinal motion and control is considered to cause pain and/or neuromuscular dysfunction,¹⁶⁵⁻¹⁶⁷ such as spinal repositioning errors, generation of increased loads and early muscle fatigue.¹⁶⁰ The exercise selection will be guided by the treating physiotherapist's experience and skill and by the patient's ability to perform the exercises accurately.

2.4.2.3 *Non-specific effects of treatment*

It is increasingly recognized that musculoskeletal physiotherapy also has effects attributable to non-specific factors.^{168, 169} One non-specific factor is the interaction between the physiotherapist and patient and is defined as the collaboration, warmth and support between the two.^{28, 170} One recent qualitative systematic review and meta-synthesis found good agreement between patients' and physiotherapists' perceptions of factors influencing this interaction.¹⁷¹ The factors both groups put forward were a mix; of interpersonal skills (empathy, friendliness, confidence); communication skills (active listening and

understanding); practice skills (easy explanations of the disorder, rationale of treatment and excellent technical abilities); individualized patient-centred care (specifically to their presentation, accounting preferences and abilities) and organizational factors (time, flexibility in care).

2.4.2.4 Patient treatment preferences

Evidence-based practice require clinicians to tailor evidence to people with different sets of problem, circumstances, concerns, values and preferences, in their treatment decisions.⁹⁷ For patient-centred care, patients should be involved in their treatment and information and treatment preferences should be shared between and understood by the patient and clinician, alike.¹⁷² In patient with LBP preferences for pain medication, exercises, manual therapy and acupuncture have been shown, on reasons of credibility, effectiveness, and individual fit, hence providing guidance on physiotherapy interventions from a patient perspective.¹⁷³ Patients wanted to obtain an explanation of their LBP, an understanding of the cause(s) beyond diagnostic labels from an empathic and expert clinician who could deliver a suitable treatment (or refer them on to someone else) and help them to negotiate the challenges of the healthcare system.^{173, 174} Similar expectations of professional physiotherapy management have been shown in a recent interview study including patients with musculoskeletal disorders.¹⁷⁵ Preferences were shown for individualized exercise, advice, and for a combination of various treatments, predominantly based on previous experience of physiotherapy and good effect. Home exercise was favoured on their simplicity and the treatment self-control such exercises provided, but was also considered easy to forget and “cheat” on, when tired after a day’s work. Preferences for passive treatments, primarily acupuncture, massage therapy or electrotherapy were also expressed, for reasons such as previously good effect on pain reduction and relaxation.¹⁷⁵

2.5 CLASSIFICATION SYSTEMS FOR LBP

2.5.1 Classification system development

The classification of any disorder can be defined as ordering disorder variables into groups with maximum between group heterogeneity and within group homogeneity.¹⁷⁶ Classification of LBP subgroups is defined according to a combination of criteria and can belong to specific theoretical dimensions such as patho-anatomical, signs and symptoms, psychological or social.¹⁷⁶ A top research priority is to develop reliable and valid subgrouping methods for the LBP population and hereby identify specific subgroups and consequently their specific physiotherapy management.¹⁷⁷ A specific research method framework has been presented in progressive stages for the development and validation of LBP classification systems. (Figure 4)^{178, 179} The stages have been labelled hypothesis generation, hypothesis testing and replication.¹⁷⁸ Hypothesis generation identifies a limited number of clinical variables that define a subgroup, and in addition, a plausible reason why patients in a given subgroup would respond to a given treatment. Hypothesis testing requires RCTs to test for the interaction between clinical variables and the selected treatment. The final stage requires RCTs in

slightly different study environment (patients, therapists, treatments or settings) of the original RCT, to confirm the results and ensure replication of findings holds outside the confines of the original trial.¹⁷⁸ The studies included in this thesis belong to the stage of hypothesis generation.

No decision-making tool can either replace individual clinical judgments or all decision-making needed in an individual case for adequate care. These decisions may be related to alternate physical treatments, further medical investigations, optimized drug treatment and/or cognitive-behavioural interventions, all of which may be required exclusively, in parallel or in sequence to physical treatment.

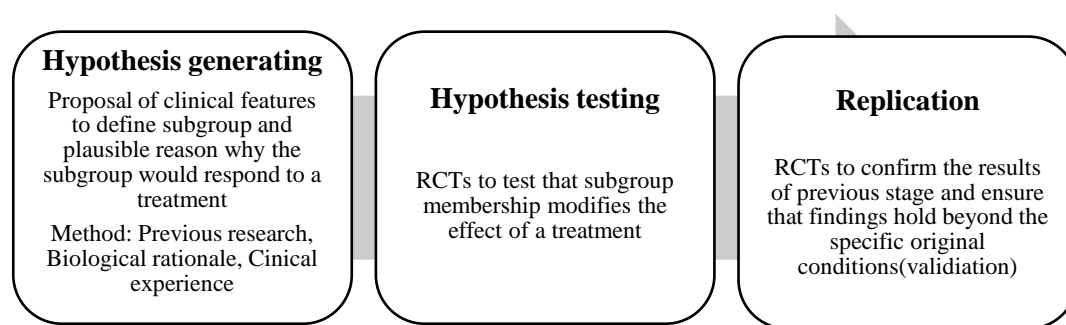


Figure 4 Conceptual phases of research for developing treatment based subgroups of low-back pain (Reproduced and adapted from Kamper et al 2010¹⁷⁸ with kind permission from Elsevier. License number 4197501101070)

2.5.2 Current low-back pain classification systems

Although LBP patients differ in impairment and disability, they exhibit similarities in clinical status that allow for categorization into subgroups with specific attributes (criteria).^{2, 83, 180} These criteria may derive from hypotheses, theories, clinical experience, expert opinion, and/or study results.¹⁷⁸ Various classification systems have been presented and include dimensions that are patho-anatomical,¹⁸⁰ biomechanical^{2, 181, 182} and bio-psychosocial.¹⁸³ These classification systems use different subgroups and have different aims for categorization, i.e. to identify underlying disorder mechanism,^{84, 180, 183} to target treatment^{2, 84, 180-183} or to identify prognosis.¹⁸⁴

The complexity of LBP and the different clinical reasoning approaches in each classification system provide a challenge of readily appliance in clinical practice, especially for novice practitioners.¹²³ One review concludes that the ideal classification system should have a small number of subgroups to ensure confident users with little training, and suggests that classification systems targeting treatments have the greatest potential to impact patient outcome.¹⁸⁵ Examples of such systems are movement system impairment (MSI) classification,¹⁸⁶ treatment-based classification (TBC),² the MDT-McKenzie approach,¹⁸⁷ and the Hall classification system.¹⁸² These impairment based classification systems focus on movement and pain, and categorize patients on judgments of the presence or absence of signs and symptoms.¹⁷⁶

There are conflicting results reported concerning inter-examiner reliability of current LBP classification systems^{5, 188-193} and they have yet not convincingly been shown to improve outcome.^{179, 192, 194, 195} Some report cautious evidence that targeted treatment to subgroups of patients with LBP may improve patient outcomes,^{3, 4, 196-199} while others have found no difference in patient outcomes for targeted and non-targeted treatment.^{194, 195, 200-203}

2.5.3 The Treatment Based Classification System (TBC)

The Treatment Based Classification System (TBC) is based on expert opinion and LBP is categorised into subgroups on basis of the patient interview and clinical examination. These subgroups are associated with an intervention believed to result in the best outcome for the patient.² Each subgroup is identified by a unique set of criteria and the six subgroups were labelled; *extension*, *flexion*, *lateral shift*, *immobilization*, *traction* and *mobilization* (Figure 5)

The further TBC evaluation and update in 2007⁶ presented a clinical prediction rule for patients likely to respond to manipulation,^{3, 4} and preliminary criteria for patients likely to benefit from stabilization exercises.²⁰⁴ The 1995 TBC classifications the directional preference exercises of extension, flexion, and lateral shift were merged to one subgroup labelled *specific exercises* and criteria for patients likely to improve with such exercises were updated.⁶ Furthermore, subsequent research had shifted the focus of reducing pain in patients with problems of maintaining spinal stability from *immobilization* of the spine, to the role of spinal muscles.^{205, 206} Hence the *immobilization* subgroup was relabelled as *stabilization*.⁶ (Figure 5)

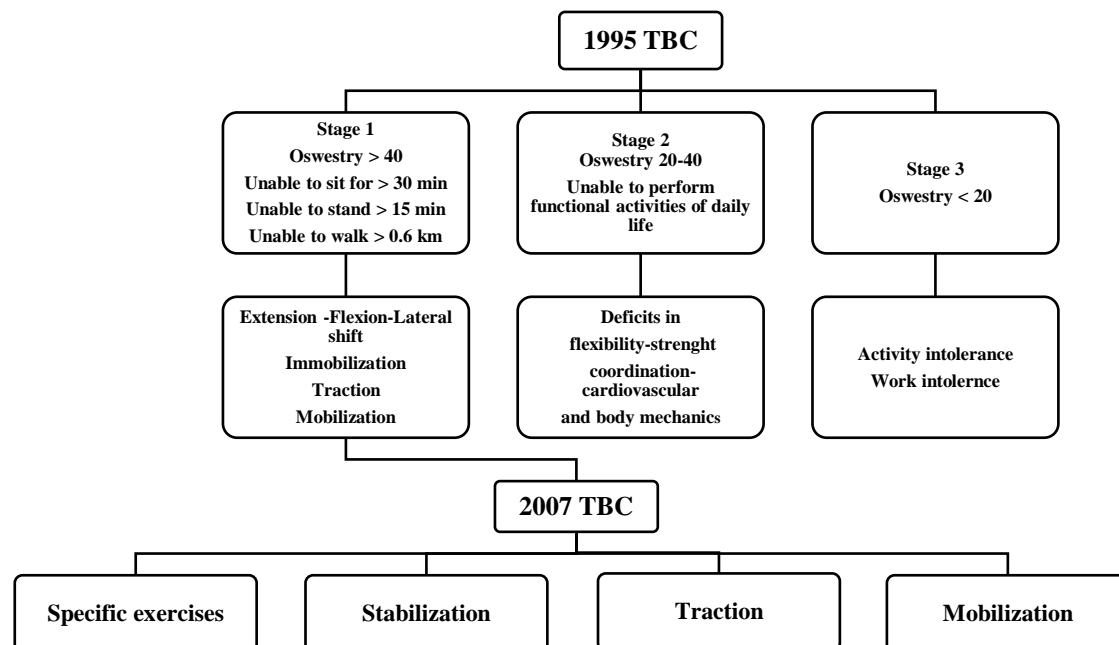


Figure 5 Illustration of the 1995 TBC² and the 2007 TBC update⁶

The original and updated versions of the TBC system have a clinical reasoning approach that is familiar to musculoskeletal physiotherapists, e.g. identifying mobility impairments, motor

control deficits, and centralization of pain with repeated spinal movements. What is more, it has clinical relevance in the inclusion of treatments commonly used in physiotherapy for LBP. However, single treatment options are recommended in subgroups. For example, traction is single treatment in one subgroup and one specific thrust manipulation is recommended in the manipulation subgroup.³ Such restrictions in treatment approach will lack a warranted within-subgroup treatment flexibility for patients and physiotherapists alike. Moreover, the approach does not explicitly include treatment options that target patients with an irritable clinical status. Neither of the TBC versions nor other classification systems presented at the time, had an approach where patients could be reclassified when their clinical status changed, such that disability and impairments had improved, and endurance and strength deficits did not meet patient's physical demands. These clinical limitations opened for a novel approach using the original TBC system as guiding principle.

In 2015 new ideas for a revised and updated version of the TBC system was presented.²⁰⁷ In this version the updated subgroups are labelled *symptom modulation*, *movement control* and *functional optimization* (Figure 6). This 2015 updated version presents a clinical reasoning process for patient presentations and treatment options that most closely resemble those of TREST. Moreover, it presents a replica of the TREST treatment-flow approach presented in 2007, a reclassification approach where patients can be reclassified as their clinical status alters,²⁰⁸ without reference to the work published on TREST²⁰⁸⁻²¹⁰. In a published letter to the editor of the journal in which the 2015 TBC update was published, this resemblance was highlighted (Appendix 1). This 2015 TBC version has not, to my knowledge, been further investigated.

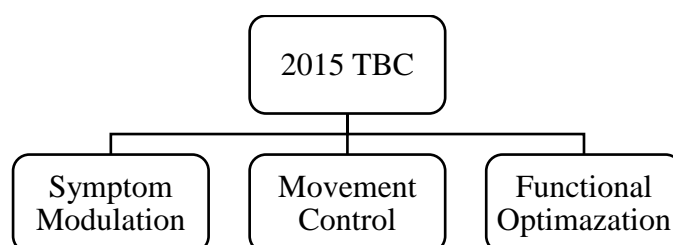


Figure 6 Illustration of the TBC 2015 update²⁰⁷

2.6 THE TREATMENT-STRATEGY-BASED CLASSIFICATION SYSTEM (TREST)

2.6.1 Theoretical and pragmatic framework

The formation of a new treatment-strategy-based classification system (TREST) started with a theoretical framework. This framework used two of the subgroups in the TBC system described above,^{2, 6} pain mechanisms⁸² and suggested mechanisms of action of various treatments (e.g. pain relief and improved mobility) and clinical experience. The framework has a primarily bio-medical approach and considers impairments (movement patterns, mobility, and motor control), pain mechanisms (nociceptive/ neuropathic pain, intensity and irritability) and limitations in activity/participation (disability). Furthermore, it aims to be

readily understood and applied by physiotherapists and considers circumstances associated with primary health care, not requiring extensive training or additional qualifications. Additionally, the framework included the novel idea of a “treatment flow”, where patients can be reclassified to receive a different treatment approach as their clinical status alters. This had at the time of development, to my knowledge, not been described previously in the classification literature.

The four classifications in the framework are labelled descriptively: *pain modulation*, *stabilization exercises*, *mobilization* and *training* (Figure 7). These labels refer to potential responders to tailored treatments in each subgroup. The suggested treatment selections included in each subgroup are used in clinical practice and have been investigated for effectiveness and cost- efficacy in numerous systematic overviews over the years.^{67, 98, 108, 155, 211-216} Case relevant individualized advice, regimen, ergonomics and simple home exercises are included as core treatment in all subgroups. The four treatment-strategy based subgroups in TREST have explicit aims referring to their expected specific effects (section 2.3.4.2) and the suggested treatment selections are as follows:

Pain modulation: to **reduce pain and enhance relaxation**, physical modalities, manual techniques (e.g. soft-tissue or low grade joint mobilizations), spinal traction or specific directional exercises,^{147, 187} are suggested. Neuro-dynamic treatment techniques can be considered in patients with neural tissue mechanical sensitisation.^{151, 152}

Stabilization exercises: to **increase or restore dynamic motor control**, individually dosed and selected stabilization/motor control exercises, carefully and progressively graded into loaded positions, are suggested^{167, 217}.

Mobilization: to **increase or restore spinal mobility**, individually dosed and selected active specific mobility exercises or passive mobilisation techniques^{137, 144} and/or a combination of the two,¹³⁸ are suggested.

Training: to **increase tolerance for spinal loading**, individually dosed and selected exercises with higher loading/ intensity and rapid progression, are suggested.¹⁶⁷ Programmes can include exercises targeting mobility, balance, fitness, strength and endurance, as well as extremity dissociation and control of trunk movement in complex whole-body movements.

The treatment-strategy-based approach is based on the idea that there are various exercises and techniques described and utilized that have a similar purpose, hence they can be grouped together and form treatment strategies. Given that the purpose and performance of a technique or exercise is targeted to the aim of subgroup treatment (i.e. pain relief, increase dynamic control of the spine, increase or restore spinal mobility or increase tolerance for loading) the technique/exercise selection is at the discretion of the physiotherapist and should be individualized to the patient.

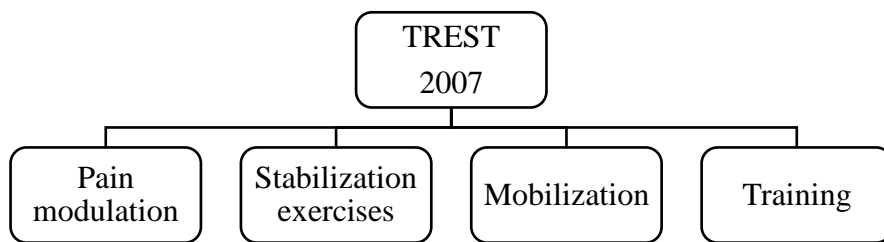


Figure 7 Illustration of the TREST subgroups ²⁰⁸

2.7 METHODOLOGICAL FRAMEWORK

2.7.1 Research paradigms

Research is conducted from various standpoints on what composes nature and being, what knowledge is and how knowledge can best be learned.²¹⁸ The physiotherapy profession aligns theoretically with both quantitative and qualitative research methodologies and three research paradigms important to physiotherapy research is shown below.

Within *the positivistic paradigm*, scientific knowledge is considered the true knowledge of the world as perceived through the observable phenomenon. Scientific data is observable facts that the passive and objective researcher collects and systemizes into objective and empirically verifiable knowledge. The positivist paradigm is presented in quantitative research and answers research questions that can be controlled, measured, and analysed with statistical methods with the aim to explain, predict or generalize. The sample size is typically large and sampling random.³¹

The *hermeneutic/interpretive paradigm* refers to theories on human experience and interpretation.²¹⁹ Experience and the outside world are seen as complex, context dependent, constructed and subjective and the researcher is an active participant in the development of knowledge.^{220, 221} The hermeneutic paradigm is presented in qualitative research and aims to explore, describe and understand the human experience and perspectives, with an overarching aim to develop ideas or theories. Qualitative research methods include systematic collection and interpretation of textual material derived from individual interviews, focus groups, observations, written documents or open-ended questions in surveys. The sample size is typically small, and respondents are selected so as to fulfil a given purpose.²²⁰

Pragmatism has been introduced as a paradigm, and is gaining recognition by researchers as a paradigm in itself.^{222, 223} Pragmatism is a philosophy that attends to the practical nature of reality, is outcome oriented and can address the practical nature of assessment and treatment of patients in a variety of settings.²²² As a research paradigm, pragmatism links concerns in practice directly to the research process, creating practice-based evidence that can effectively be used clinically.¹¹ Pragmatism is seen in studies that use mixed methods, the integration of qualitative and quantitative inquiry, bringing these paradigms together under a single

approach.²²³ Such studies might have advantages in the study of healthcare and results provide a depth of knowledge that would be difficult to achieve through either method in isolation and contribute to developing research that can inform evidence-based practice.¹¹

The studies herein have used quantitative (Studies I–III) and qualitative (Study IV) research methodologies and, as such, belong to the positivistic and interpretative paradigm, respectively.

2.7.2 Quantitative method

2.7.2.1 Reliability and validity

In the early stage of the development of any classification system, its construction and included criteria need to be tested for its reliability, the degree to which an instrument is free from error, and for its validity, the degree to which an instrument measures what it intends to measure.²²⁴

Reliability testing relevant for this thesis is the evaluation of whether the classification system can be applied reliably by different users, *inter-examiner reliability*, which in this thesis refers to the level of agreement between two examiners.^{225, 226} Inter-examiner reliability of a classification system concerns both the overall use of a system and its included criteria.⁵ Familiarization affects inter-examiner reliability positively and the required amount reflects the complexity, and in extension the applicability of the system.^{227, 228} Calculating the number of exact agreements (raw agreement), measured in percentage, is the simple approach to assessing inter-examiner reliability. However, raw agreement does not account for agreement just by chance and therefore a chance-corrected measurement for nominal and ordinal data e.g. Cohens kappa coefficient (κ), is needed.²²⁹ Yet, good inter-examiner reliability is not sufficient in order for a system to be considered valid.

The most relevant evaluations of classification system validity are considered to what extent one category can be discriminated from other categories (*discriminant validity*), the system's ability to predict subgroup membership determined by a previous validated system (*concurrent validity*), and the systems' ability to predict an outcome (*predictive validity*).¹⁷⁶ Direct classification system validation has not been involved in any of the studies in this thesis.

2.7.2.2 Feasibility

Any classification system has an underlying theory that can be studied for clinical applicability. In a full scale RCT of a subgrouping approach that leads to significant improvements in patients' disability, shows the implicit feasibility of the classification system at hand in clinical practice.^{184, 196} However, feasibility studies encompass any sort of study that can help to prepare for larger studies and assess whether ideas and findings can be shaped in order to be relevant and sustainable.²³⁰ Feasibility in the health research context is 'an assessment of the practicality of a proposed plan, idea or method' and can be labelled as "proof of concept".^{231, 232} In the initial phases of development of new methods such studies

can answer the main question “*Can it work*”.^{230, 233} Subgroup criteria included in a classification system can be evaluated for their feasibility in practice prior to larger study.²³⁴ Logistic regression analyses can identify the association between a) the application of clinical criteria in the categorization process and b) subgroup membership and infer to what extent the “theory” match the “operational patterns” (clinical practice). Studies exclusively investigating such applicability of NSLBP classification system criteria have, to my knowledge, not been reported in the literature.

2.7.3 Qualitative method

2.7.3.1 Qualitative data collection through interviews

The relevant qualitative method for this thesis is individual interviews for the collection of data for the understanding of clinical knowledge and reasoning, including thoughts, expectations, interaction and relations with patients.³¹ Interviews can be conducted in a more or less structured way. Semi-structured individual interviews are interviews where the informant answer pre-set open-ended questions formulated in an interview guide, a schematic presentation of questions or topics.²³⁵ This guide serves the purpose of exploring respondents systematically and comprehensively as well as keeping the interview focused. The questions in the interview guide should not be too many or too detailed. Questions can comprise keywords of the core question and have associated questions related to the central question.^{235, 236} The interview guide should be flexible, adapted to the situation and respondent, and should not necessarily be strictly followed.^{235, 236}

2.7.3.2 Content analysis

Content analysis has a long history and was first used to analyse hymns, newspaper articles and advertisements in quantitative way, counting specific words of interest.²²¹ Later, it is primarily used with a qualitative approach, describing variations in human experiences and beliefs.^{237, 238} Qualitative content analysis is one method for descriptive analysis where communication in interviews are transcribed into text, verbatim, aggregated and grouped, to describe and conclude the research question.^{237, 238}

Content analysis, according to Graneheim and Lundman,²³⁸ is used in this thesis and the analysis starts with reading through the whole unit of analysis (all data) to get a sense of the whole. Meaning units are thereafter identified, i.e. words, sentences or paragraphs that are related through content and context. These are then condensed preserving the core and then labelled into codes, which in turn are grouped into categories.^{237, 238} The categories should have content-characteristic names, be internally homogenous and externally heterogeneous.²³⁹ The research question and data determine whether the analysis is to comprise descriptions of the manifest content, close to text and what it says or interpretations of the latent content, what the text talks about i.e. distant to text but still close to the interviewees lived experience.²³⁸ The manifest content will result in categories. The latent content will yield further interpretation and abstraction into themes, and can be considered as a thread of an underlying meaning through meaning units, codes, and categories.^{238, 240}

2.7.3.3 Trustworthiness

Trustworthiness of results from qualitative research^{238, 241, 242} are expected to be respectively equivalent to criteria used within the quantitative research, *internal validity*, *reliability*, *objectivity*, *external validity*. Trustworthiness in qualitative inquiry relates to *credibility*, *dependability*, *conformability* and *transferability*.^{219, 238, 242} However, some argue that these concepts have not yet been carefully examined and for an increased comprehension and respect for qualitative studies concepts should remain consistent with those of the quantitative science community.^{241, 243, 244} Others state that when reporting findings from qualitative content, concepts linked to the qualitative research tradition should be applied.^{221, 238} In what follows both nomenclatures are used to describe concepts.

Credibility (internal validity) cover all parts of the research process and relate to the confidence how well data and analysis address the intended aim (problem relevance), how sampling was made (sampling relevance), and what knowledge the informants have given insight into (data collection relevance).^{219, 237, 238, 242}

Dependability (reliability) refers to what extent data changes and the researchers' decisions alter over time.^{219, 238} Describing the dialogue with co-researchers or a panel of peers is one way to avoid skewed data processing,²³⁸ demonstrate a link between findings and data through a detailed description of results,²³⁷ and illustrating how meaning units, condensations and abstractions are made as well as using authentic citations are all measures for readers to follow the analysing process.²³⁷

Conformability (objectivity) refers to neutrality or the extent to which the findings of a study are shaped by the respondents and not by researcher bias, motivation or interest.²⁴² Here, reflexivity is important and starts with the clarification of the researcher preconceptions, theoretical framework, perspective and pre-understanding of the topic to the readers.²²⁰ The failure to recognize one's preconceptions is a threat to reflexivity, but preconceptions are not the same as bias, unless the researcher fails to mention them.²²⁰

Transferability (external validity) refers to the possibility of transferring the findings to other settings and populations outside the study group.²³⁸ A clear and distinct description of context, data collection, sampling and characteristics of respondents, and analysis process, will give researchers reason to suggest transference of findings.²²⁰ However, no study, irrespective of method used, can provide findings that are universally transferable.^{220, 238}

2.8 RATIONALE FOR THIS THESIS

Clinical reasoning, a cognitive process preceding decision-making and treatment, is suggested to follow theoretical analytical models.^{122, 124} Research at sites of clinical practice has reported diversity of external, patient and physiotherapists factors in the clinical reasoning process in LBP. Yet, it is still unclear how physiotherapists match various treatments utilized in LBP to individual patients. Aspects that might guide and/or influence

clinical reasoning in the decision-making and treatment of LBP therefore need to be explored further.

Low-back pain is a global health problem and is the greatest cause of years lived with disability. Neither considerable bio-medical research aiming to elucidate the aetiology and origin of LBP,^{57, 60-63, 245} nor research aiming to clarify psychosocial components of back pain¹¹⁴⁻¹¹⁶ have been successful in fully explaining patients' experience of pain and disability.¹¹⁴⁻¹¹⁶ Patients with LBP is often encountered at physiotherapy clinics and is a heterogeneous disorder with various symptoms, signs, severity and duration. Consequently management comprise a range of physiotherapy interventions,¹⁰⁸ and practice patterns.²⁴⁶ Classifying LBP into subgroups based on subgroup specific criteria have potential to facilitate clinical decision-making, guide treatment and impact outcomes.^{185, 197} Various classification systems have been presented in the literature²⁴⁷, some are reliable and valid^{3, 5, 248}, but not necessarily readily applied in clinical practice and convincingly improved outcomes have not been reported. Hence, at the time this work started the literature revealed neither classification systems that had a warranted clinical flexibility in treatment selections in resemblance with clinical practice, nor systems that were easy to use and did not require extensive familiarization or specific equipment and included commonly used treatment selection in physiotherapy.

Various designs and methodologies are used in this thesis to present, describe and investigate a decision-making classification system and explore clinical reasoning in the decision-making and treatment for LBP in primary healthcare.

3 AIMS

The overall aim of the work presented in this thesis was to develop, describe and examine a treatment-strategy-based classification system (TREST). A further aim was to explore physiotherapy clinical reasoning in the decision-making and treatment in patients with NSLBP in primary healthcare. The studies included covered the following specific aims:

Study I

To describe a categorization process of patients with LBP for physiotherapy treatment, present a treatment flow and report on short-term outcomes.

Study II

To examine the inter-examiner reliability of experienced physiotherapists' ability to independently categorize patients with LBP into one of the four subgroups *pain modulation*, *stabilization exercise*, *mobilization* and *training*, and examine the inter-examiner reliability on five patient physical examination items: the presence or absence of 1) neurological signs and symptoms 2) specific movement pattern, 3) specific segmental signs 4) uni-or bilateral signs and 5) the level of symptom irritability

Study III

To examine the feasibility of TREST sub-group criteria; 1) neurological signs and symptoms 2) specific movement pattern, 3) specific segmental signs 4) uni-or bilateral signs and 5) level of symptom irritability; 6) pain intensity, and 7) disability; in the categorization of patients with NSLBP into one of the subgroups *pain modulation*, *stabilization exercise*, *mobilization* and *training*.

Study IV

To explore and describe physiotherapists' clinical reasoning in the decision-making and treatment of NSLBP in primary healthcare.

4 METHODS

4.1 DESIGNS, PARTICIPANTS AND SETTINGS

4.1.1 Study designs

The four studies included in this thesis use various designs (Table 2). Study I, is a multi-case study with two parts. The first part has a descriptive design, and describes a categorization process of LBP. The second part has a pre-post-test experimental design to observe patient treatment outcome. Study II, investigates inter-examiner reliability, employing a mixed independent and simultaneous examiner design. Sample size (≥ 47) was determined by a power-calculation using a power of 0.80, $\alpha = 0.05$ and cut-off level of >0.6 for un-weighted kappa coefficient, using subgroup categorization as main outcome. Study III is a cross-sectional study using secondary analyses of data collected in Study II, examining the feasibility of sub-group criteria included in the decision-making algorithm (TREST). Study IV has a qualitative descriptive design and explores clinical reasoning in the decision-making and treatment of NSLBP through semi-structured interviews. All the studies were carried out in Sweden, at physiotherapy out-patient clinics with direct access to physiotherapy included in the Swedish primary healthcare system.

Table 1 Overview of design, participants, data sources and analyses in Studies I-IV.

Statistics	Study I	Study II	Study III	Study IV
Design	Multiple subject case study; descriptive and pre-post-test experimental	Inter-examiner reliability	Observational cross-sectional with secondary analyses on data in Study II	Exploratory descriptive qualitative
Participants	1 PT 16 patients	4 PTs 64 patients	4 PTs 64 patients (128 observations)	15 PTs
Data sources	PTs judgments on patient assessments and self-reported Borg's CR 10 ¹ , ODI ² and SF 36	Checklists of PTs categorization and judgments on examination items. Patient reported Borg CR 10 ¹ and ODI ²	Checklists of PTs categorization and judgments on examination items. Patient reported Borg CR 10 ¹ and ODI ²	Semi-structured interviews
Analysis	Descriptive statistics	Descriptive statistics Raw agreement, Student's T-test, Mann-Whitney U test, Chi-Square, Fischer's exact test, Cohen's Kappa: un-weighted and linear weighted	Descriptive statistics, Chi-square, One-way ANOVA, Non-parametric one-way ANOVA, Logistic regression	Qualitative manifest content analysis

¹ The Borg CR 10 scale measurement of pain intensity ² Swedish version of the Oswestry Low-back pain Questionnaire

4.1.2 Participants and settings in Studies I-III

In *Study I, II* and *III*, participants were a convenience sample of adult, consecutive, consenting patients seeking physiotherapy treatment for a primary complaint of LBP. Study III included the participants in Study II in a secondary analysis (Table 2). Those included had with non-specific LBP regardless of duration, with or without radiating pain to the lower extremities and had no difficulty understanding the Swedish language. Exclusion criteria were previous back surgery, pregnancy, and known neurological or rheumatic disease.

The single examiner in **Study I** was an experienced, clinical specialist in OMT with master's degrees in Physiotherapy and OMT, working in private practice in a smaller city. The two pairs of volunteer physiotherapists in **Study II**, and subsequently in **Study III**, were all experienced, with various levels of OMT training, working in two different private practice clinics, one suburban and one urban in greater Stockholm.

4.1.3 Participants and settings in Study IV

Study IV included fifteen physiotherapists, both novice (≤ 5 years of experience; $n=6$) and experienced (> 6 years of experience; $n=9$), working in private practice, or privately or publicly employed. Seven physiotherapists worked in the same number of clinics in one sparsely populated region and eight physiotherapists in four clinics in a larger city in Sweden.

4.2 DATA COLLECTION AND ANALYSES

4.2.1 Data collection and outcome instruments

In Studies I, II and III there were baseline data, age and symptom duration, orally obtained during the patient interviews, and in addition two self-reported instruments were used. The Borg CR 10 scale²⁴⁹ was used to assess pain intensity and the Swedish version of the Oswestry Low-back pain Questionnaire (ODI)²⁵⁰ was used to measure disability. In addition, the Physical Health Score in the Swedish version of the SF 36²⁵¹ was used in Study I. All three self-reported instruments are considered reliable and valid in a population of LBP²⁵² and these were also used as outcome measurements in Study I.

4.2.1.1 Patient assessment procedure in Study I and II

In **Study I**, patient assessments followed the physiotherapists' everyday procedure. In **Study II**, assessments were at the discretion of each of the four physiotherapists, but specific examination items were outlined in a checklist to be completed. The patient assessment focused on the following:

The *patient interview* focused on symptoms; pain (area, nature); history of symptoms, patient activity limitations, earlier treatment and treatment response,⁴³ general health and level of irritability. Level of symptom irritability^{253, 254} was determined to be mild, moderate or high, using two questions; 1) how easily are your symptoms aggravated by activity? and 2) how long does it take for your symptoms to subside after aggravating activity?

The observation of *active movements* focused on posture and movement impairments. Assessment concerned altered mobility due to pain and whether painful movement patterns could be identified²⁵⁵ denoted as present or not (Table 3). A normal movement pattern is when flexion, extension, lateral flexion and rotations are performed smoothly and around respective axis of rotation and in respective movement plane. If patients showed an aberrant movement pattern in extension, and/or forward-and side-bending, active stability tests were performed. These tests evaluated the active control of the lumbar spine were at the examiner's discretion and could include test in various body positions such as single active straight leg raise in lying,^{256, 257} single-leg balance in standing or single-leg-hip flexion in sitting.²⁵⁸ These tests were observed and deemed by individual physiotherapists as performed with poor (positive) or good control (negative) of the spine.

Table 2 The movement patterns used in the judgements of the observation of active movements in Studies I and II/III

Aberrant	Specific	Multidirectional
<ul style="list-style-type: none"> • Deviation during movements and/or • Painful arc and/or • Reversed lumbar-pelvic rhythm and/or • Thigh-climbing 	<ul style="list-style-type: none"> • Pain and limitation in a flexion/opening/tension/divergence pattern (flexion and lateral- flexion to the opposite side from the pain) or • Pain and limitation in an extension/closing/compression/convergence pattern (extension and lateral-flexion to the same side as the pain) 	<ul style="list-style-type: none"> • Pain and limitations in all movement directions

The *passive movement assessment* evaluates spinal segmental mobility (range/quality) and associated pain response. Segmental mobility signs were denoted as hypo-mobile, normal or hyper-mobile. The signs, mobility and associated pain, were denoted as 1) unilateral, 2) bilateral or 3) bilateral but predominantly unilateral.^{137, 259}

A *peripheral neurological assessment* was performed in patients with radiating pain to the lower extremities. It included nerve conduction tests, i.e. passive and active tests that identify altered reflexes and /or sensation, motor disturbances (muscle strength). These tests were denoted as positive or negative (“normal”). In patients with radiating pain but normal nerve conduction, were tests of the mechanical movement of the neurological tissues as well as their sensitivity to mechanical stress (tension) or compression (palpation) assessments were performed.^{150, 260} These neurodynamic tests were: slump test²⁶¹ (a seated “slumped” position and cervical flexion as the knee is extended and the ankle is dorsiflexed); straight leg raise (SLR = passive hip flexion with knee extended in supine); prone knee bend (PKB = passive knee flexion with hip extended in prone); and palpation of neural tissue (sciatic and femoral nerves).²⁶² All these tests were denoted positive or negative (“normal”).

4.2.1.2 Patient assessment and systematic bias (Study II)

In **Study II**, patient assessment procedure had to consider systematic bias. Therefore, were the physiotherapists in each pair assigned as number 1 or 2, changing for every other patient (Paper II, Figure 2). To minimise patient variability and ensure that the physiotherapists were given the same information, both physiotherapists were present during the patient interviews and active movement testing, but only examiner number 1 questioned the patient and instructed on active movements. As active movements may change with repeated assessment, these were carried out once. The passive and peripheral neurological assessments were performed separately in direct sequence, by each physiotherapist without the other physiotherapist being present

4.2.1.3 Familiarisation with the decision-making algorithm

The two pairs of physiotherapists included in **Study II** were familiarised with the algorithm during a single approximately three-hour session at each clinic. The procedure was outlined, and the main subgroup characteristics and possible treatment selections in each subgroup were explained and discussed. The physiotherapists were instructed to maintain their everyday examination procedure. This was important as the study aimed to reflect everyday clinical practice, in which a strict unanimous examination protocol is not likely to be utilized.

4.2.1.4 Subgroup criteria (Studies I-III)

The resulting judgements from the patient assessment (patient interview, active- passive movement and neurological testing) in **Study I** were selected as clinical criteria on basis of the guidance on treatment selection these can provide. This selection was made by the primary investigator (BW). The criteria in each subgroup are a combination of judgmental determination of the presence or absence of these of signs and symptoms and was labelled with reference to five clinical judgments on the presence or absence of *neurological signs and symptoms*, *specific movement pattern*, *specific segmental signs*, *uni-or bilateral signs* and *irritability* of symptoms. Musculoskeletal symptom irritability refers to judgments on how easily pain is provoked by activity (movements) and how long it takes for pain to subside and are intended to avoid symptom exacerbation following treatment and consequently affect the vigour of treatment and self-care options.¹⁴⁴ In **Study II** these five items were set as pre-determined subgroup criteria¹⁷⁶ and each item was examined for the inter-examiner agreement. In **Study III** a secondary analysis of the data collected in **Study II** identified how the physiotherapists applied these five pre-determined subgroup criteria, and in addition, patient-reported *pain intensity* and *disability*, in the categorization of patients with NSLBP into one of the TREST four subgroups.^{176, 263} The combination of subgroup criteria is shown in Table 3.

Table 3 The clinical criteria in each of the TREST subgroups

Clinical Criteria	Pain modulation	Stabilization exercises	Mobilization	Training
Neurological symptoms	Positive = radiating pain, weakness, numbness,	Negative	Negative	Negative
Neurological signs	Positive = altered reflexes and /or sensation, and/or muscle strength. Positive NTPT ¹	Negative	Negative	Negative
Movement pattern	Multidirectional	Aberrant ²	Specific ³ Restricted	Specific ³ Restricted
Segmental signs ⁴	Inconclusive	Hypermobility	Hypomobility	Hypomobility
Uni-or bilateral signs	Bilateral	Bilateral	Unilateral	Bilateral
Irritability	Moderate/ High	Moderate/High	Low/Moderate	Low
Pain intensity	Moderate/High	Low/Moderate	Low/Moderate	Low
Disability	Moderate/High	High/Moderate	Low/Moderate	Low

¹Neural tissue provocation tests (Straight leg raise, Prone Knee Bend, seated Slump position, and nerve palpation)

²Painful arc, thigh climbing, deviations³ Flexion/tension pattern or Extension/compression pattern ⁴Judgments on mobility and associated pain

4.2.1.5 Interview procedure, pilots and clinical vignette development (Study IV)

Interviews in **Study IV** were semi-structured, face-to-face and audio recorded, performed by the primary investigator (BW) at the workplace of each physiotherapist. Question areas were identified within the author group and open-ended questions were developed into an interview guide (Paper IV, Table 2). The interview guide and interview situation were tested in three individual pilot interviews with three clinical physiotherapists in primary healthcare not included in the main study. Adjustments to the interview guide, such as rephrasing questions slightly, were made following the review of pilot interview audio recordings.

The interviews explored clinical reasoning in the decision-making and treatment of NSLBP and in three diverse descriptions of NSLBP. Theses descriptions, i.e. vignettes (Appendix 2) were developed from literature^{84, 87, 256, 258, 264-266} describing NSLBP and from results of Studies I–III.²⁰⁸⁻²¹⁰ Each vignette aims to represent diverse NSLBP disorders without directions on patho-anatomic source or diagnosis. The vignettes were reviewed for clinical relevance and consistency by three clinical physiotherapists, with various musculoskeletal post-graduate training, not included in the main study. *Vignette I*, represents a patient with irritable neuropathic pain, conduction deficits, and high disability. *Vignette II*, represents a patient with nociceptive bilateral pain, moderate irritability, motor control deficits and

moderate disability. *Vignette III*, represents a patient with nociceptive unilateral pain low irritability, mobility deficits, and low-moderate disability.

This thesis presents the method, analysis and results of the part of the interviews before the vignettes were introduced to the informants. The part of the interviews where the vignettes were introduced remains to be analysed in another study not included in this thesis.

4.2.2 Analysis

4.2.2.1 Studies I, II and III

An overview of the statistical methods used in this thesis is given in Table 2.

The analysis of descriptive and first part of **Study I** was conducted through an inductive approach looking for similarities and differences in the 16 included patients' clinical statuses categorized into one of the four treatments *pain modulation*, *stabilization exercises*, *mobilizations* and *training*, after which a tentative hypothesis was developed, illustrated in a step vice decision-making algorithm. The second part of **Study I** compared individual ratings from patient-reported instruments for pain, disability and physical health, at baseline and at discharge. No comparisons were made between patients. For pain intensity minimum clinical important change was set at $\geq 30\%$ difference in the patients' ratings, as recommended for assessing individual patients.²⁶⁷ For disability (ODI) improvements were set to at least six points or a 50% improvement in patients' ratings.²⁰⁴ The scores on the Physical Health Score in SF 36 were presented as point values at baseline and on discharge and compared to the Swedish population mean.²⁵¹

Analyses in **Study II** compared the differences in distribution of patients to subgroups and in patients' baseline characteristics, at the two different clinics. Agreement between the physiotherapists in each pair was calculated as observed agreement (raw agreement= %) and as the un-weighted kappa coefficient (κ) and corresponding 95% confidence intervals (CI) for categorical variables (subgroup, specific movement pattern, specific segmental-, neurological- and uni- or bilateral symptoms and signs). The aggregated results of the two questions on irritability were transferred to one ordinal variable scored 1–5 and the linear weighted kappa coefficient (κ_w) was calculated. Kappa values were interpreted according to Landis and Koch as; ≤ 0.20 poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1.00 almost perfect agreement.²⁶⁸

In **Study III**, univariate analyses examined whether patient baseline characteristics (age; gender; duration of symptoms; pain intensity; and disability) directed subgroup categorization and determined the occurrence of predetermined subgroup criteria in each subgroup. Four separate multivariate logistic regression analyses were applied in two models. The first model identified the association between a) physiotherapists judgments on subgroup criteria in addition to patient reported measures of pain intensity and disability (independent variables) and b) the use of theses judgments in the categorization of NSLBP into the TREST four subgroups (dependent variables). The independent variables were dichotomized. In the

second model, patient-reported measures were excluded, in order to analyse whether this exclusion changed results. Results were presented as odds ratios (ORs) and corresponding 95% confidence intervals (CIs).

4.2.2.2 *Study IV*

The analysis followed manifest content analysis as described by Granheim and Lundman²³⁸. All authors read through the transcribed material so as to gain an overall impression. The data was then organized into units of analysis based on the content. One unit covered the first part of the interview, without the vignettes. The second covered the part where the vignettes were used and were subsequently excluded from the present analysis, and this is yet to be analysed.

Meaning units, defined as words, phrases or sentences with a common meaning were identified through cautious exclusion of parts not corresponding to the aim of exploring and describing physiotherapists' clinical reasoning and decision-making in treatment of NSLBP in primary healthcare. Condensation and coding of meaning units were carried out with minimal interpretation, in keeping with the text and in words used by informants (Paper IV, Table 4). The coding process was made with OpenCode 4.0.²⁶⁹ Codes were then grouped into categories, inductively and iteratively from the data, and categories with similar meaning were in turn grouped together and labelled to cover the content of categories included. The analysis included researcher triangulation with co-authors with experiences and skills dissimilar to those of the primary investigator. Throughout the process, we moved back and forth through the steps iteratively as well as going back to the full transcriptions of interviews (Paper IV, Table 3). Another input in the analysis process was a review of preliminary subcategories carried out within a research group that included peers with experience from various areas in the musculoskeletal field.

4.3 ETHICS

4.3.1 Ethical approvals and considerations

The studies were approved by the Regional Ethical Review Board in Umeå (Study I) and in Stockholm (Study II, III). An ethical statement without objections, from the Regional Ethical Review Board in Stockholm, was obtained for Study IV. Permissions from primary care officials was obtained prior to Studies I, II and IV.

All participants in included studies were given written information about the study at hand, prior to their written or oral consent to participate. No data could be linked to any individual and all participants could withdraw at any time without giving any reason. The convenience sample of patients Study I and II (III) was at first visit at the clinics informed by secretarial staff about the study, that participation or not would not affect their upcoming treatment and asked whether they agreed to participate. The primary investigator (BW) was aware of the patients' identities in Study I, but blinded to patients' identities in Study II (III). Patients in all studies were given codes in the research protocols and following analysis.

Physiotherapists in Studies I and II followed their normal examination procedure and no untried tests or treatments were introduced. The risk of inflicting bodily harm during clinical testing and treatment were not higher than every day clinical practice in Study I. In Study II there was a risk of symptom exacerbation as the passive examination and neurological examination were repeated twice. However, the benefit of being thoroughly assessed balanced this risk. In Study IV, informants' identities were handled with confidentiality throughout the research process by giving informants a code and number in the transcriptions.

There are limited direct short-term benefits for participants in the current studies. Patients were given greater attention than in usual care which might render short-term positive effects. Improved outcomes were shown in patients in Study I, but such improvements are not necessarily different to those seen in everyday clinical care. However, patients and physiotherapists alike contribute to an increased understanding of how LBP can be categorized that, by extension, can improve the rehabilitation of this patient group. For participants in Study IV possible benefits are related to the opportunity of reflection on one's work and professional development, and results might be of significance for healthcare and education providers.

5 RESULTS

5.1 STUDIES I, II AND III

5.1.1 Study I

The result of the descriptive part of **Study I** is a treatment-strategy-based classification algorithm (Paper I, Figure 1). This algorithm illustrates the categorization process of patients with NSLBP into one of four subgroups; *pain modulation*, *stabilisation exercise*, *mobilisation* and *training*. Patient reported disability and pain intensity and the judgmental determination of the presence or absence of clinical signs and symptoms important in treatment selection decision-making were identified. A combination of the presence and absence of these signs and symptoms formed the criteria for each subgroup (Paper I, Figure 1). The distribution of patients to the subgroups that the categorization process resulted in is shown in Figure 8.

The *pain modulation* subgroup recognizes patients with unstable clinical status where activity easily provokes symptoms. Patients may present peripheral neurological signs and symptoms of neuropathic pain²⁶⁶, increased neural mechano-sensitivity¹⁵⁰, irritable symptoms¹⁴⁶, and high levels of pain and disability.

The *stabilisation exercises* and *mobilization* subgroups were adapted from the TBC system and were partly given new content. In TREST, *stabilization exercises* cover the sub-group of patients who have nociceptive mechanical pain⁸⁴ due to decreased capacity of controlling segmental movements. This decreased capacity results in suboptimal tissue loading manifested by e.g. fluctuating back symptoms due to minimal perturbations, aberrant active movements and excessive segmental mobility.^{204, 217} *Mobilization* covers patients with nociceptive mechanical pain⁸⁴ due to movement restrictions caused by lumbar hypo-mobility, without distal neurological signs and symptoms (muscle weakness, sensory loss, diminished reflexes) and/ or neural mechano-sensitivity (e.g. positive SLR).

The *training* subgroup recognizes patients with stable and low intensity nociceptive pain symptoms, low irritability and disability and who seek physiotherapy to increase function and prevent recurrence.^{153, 154} It also cover patients who have been in one of the other subgroups and have improved to the extent that physical training, including strength, endurance and coordination exercises, can further improve their function.

Two patients were excluded during the study, one due to progressive symptoms and one due to a pregnancy unknown at the time of inclusion. Results from the remaining 14 patients and the second part of **Study I**, showed short-term individual improvements: change of at least 30% difference in pain intensity in 13/14 patients; in physical health in comparison with Swedish mean in 12/14 patients; and disability at least 50% or 6 points in 8/14 patients following the individualised treatment patients received according to assigned subgroup. (Paper I, Figure 3 and 4).

A treatment flow-chart demonstrated that most patients were transferred to the *training* subgroup when their clinical status improved while a minority remained in their initial subgroups throughout the study (Study I, Figure 2).

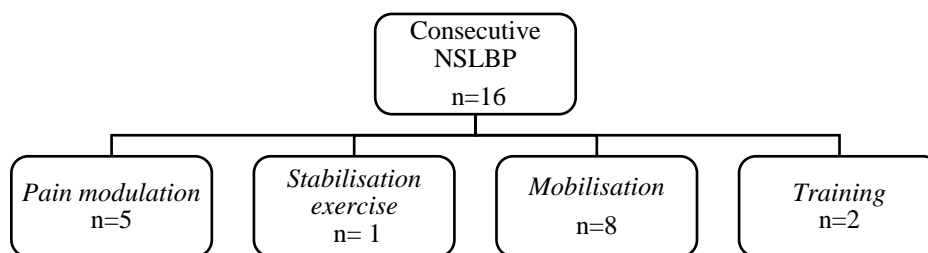


Figure 8 Distribution of patients to subgroups in Study I

5.1.2 Study II

The results of **Study II** show that experienced OMT physiotherapists given a short 3-hour familiarization with TREST had substantial chance-adjusted agreement on subgroup membership (80%, κ 0.72; 95% CI 0.59- 0.85), but had varied agreement on the signs and symptoms suggested as criteria in subgroups. Agreement was fair for judgments on the presence or absence of spinal segmental signs (67%, κ 0.28; 95% CI 0.03–0.53) and movement pattern (68%, κ 0.38; 95% CI 0.15–0.53), moderate for uni/or bilateral spinal signs (62%, κ 0.42; 95% CI 0.23–0.60) and disorder irritability (82%, κ_w 0.41; 95% CI 0.25–0.56), and almost perfect for peripheral neurological signs and symptoms (92%, κ 0.84; 95% CI 0.70–0.97). The distribution of patients to subgroups that the categorization process resulted in is shown in Figure 9.

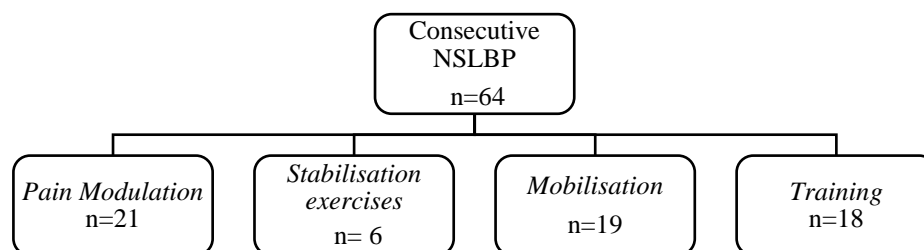


Figure 9 Distribution of patients to subgroups in Study II

5.1.3 Study III

Results from the univariate and multiple logistic regression analyses in **Study III** show how the individual physiotherapists in **Study II** applied patient reported baseline characteristics (age, gender, disability, pain intensity and disorder duration) and their judgements on selected criteria of signs and symptoms in the categorization of patients with NSLBP into one of the four subgroups *pain modulation*, *stabilization exercise*, *mobilization*, and *training*. There were no significant differences in age, gender or patient-reported pain intensity across subgroups.

The presence of neurological signs and symptoms and a high disability score (ODI >30) increased the odds five and eight times, respectively, of being categorized to *pain modulation* (OR 5.5; 95%CI 1.9–16 and OR 8.5; 95% CI 3.2–20, respectively). The presence of bilateral signs increased the odds of being categorized to *stabilization exercise* almost 6 times (OR 5.6; 95% CI 1.1–29) and the presence of “specific segmental signs” increased the odds four times of being categorized to *mobilization* (OR 4.0; 95% CI 1.2–14. A high disability score (ODI >30) reduced the odds 5 times of being categorized to mobilization (OR 0.2; 95% CI 0.1–0.6) and the presence of “neurological signs and symptoms” reduced the odds 5 times of being categorized to *training* (OR 0.2; 95% CI 0.1–0.4) (Paper III, Table 4). When patient self-reported pain and disability were excluded from the regression analysis, an irritable disorder increased the odds three times of being categorized to *pain modulation* (OR 3.0 95% CI 1.2–7.4). Summary of results is shown in Figure 10.

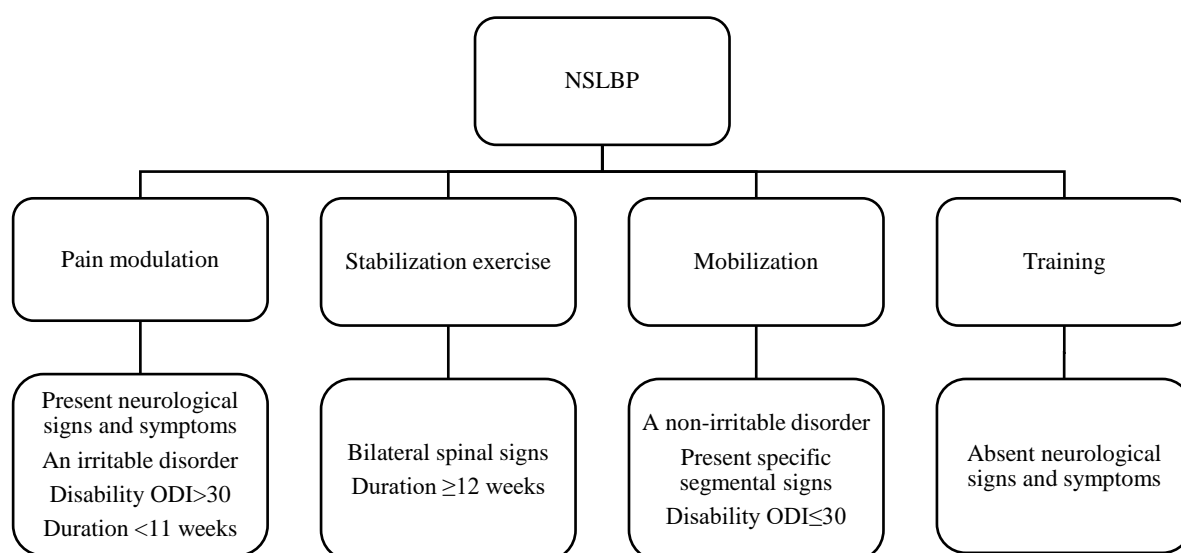


Figure 10 Illustration how the clinical criteria were applied by individual physiotherapists in the categorization into TREST subgroup in Study III.

5.1.4 Study IV

The analysis of physiotherapists’ clinical reasoning in the decision-making and treatment of NSLBP in primary healthcare provided ten categories, derived from twenty-eight subcategories. (Paper IV, Table 5) The ten categories are described without citations below.

Work place and health care priorities affect

Various external circumstances in relation to work place and healthcare organization were highlighted. Treatment selections requiring short treatment time, prioritizing new patients and reducing follow up visits were measures taken to handle work load by informants. Patients geographical distance from healthcare centres was resolved with home exercises and

telephone follow ups. Treatment series were experienced as being limited rather by financial resources and limited access to training facilities than by patient needs. Specific treatment approaches advocated at work places influenced practice and future practice pattern. The experienced physiotherapists stated that extensive exercise programmes, using equipment such as pulley machines, had changed towards to a few targeted exercises using none or simple equipment (e.g. balls or rubber bands) that patients could use at home. Home exercise programmes had also been altered, and now included a small number of specific exercises that were more thoroughly followed up.

Categorization a first step

Differentiating between and allocating patients to cognitive categories was part of the informants' clinical reasoning process. Patient differentiation included the exclusion signs and symptoms needing medical revision as well as psychological distress needing interventions beyond the competence of the physiotherapist. Psychological distress associated with pain and symptoms was considered as something that could be differentiated from mechanical pain and could be addressed with physical activities and exercises with the support of the physiotherapist. Pain categorization included reasoning as to whether pain was driven by peripheral or central mechanisms and whether peripheral nerve tissue was involved. Painful movements were categorized as being regional (the whole lumbar spine) or segmental and whether the range of motion was altered or not.

Bodily examination findings designate treatment

Judgments on specific bodily examination findings were stated as being decisive for specific treatment selections. Restricted mobility should be treated with mobilizations, signs of lumbar instability with exercises targeting stability, muscle fatigue with exercises, signs of muscle tension with soft tissue techniques, and local discogenic pain with specific extension oriented movements as described in the McKenzie approach (MDT). It was thought that acuteness with high pain intensity and/or neurological symptoms required caution, not provoking pain and finding alleviating body positions. The level of irritability, i.e. how easily pain is exacerbated and the timeframe for pain to subside, was viewed as pertinent for the perceived tolerance for treatment.

Patient capabilities prerequisite

The patients' usual physical demands were important for how treatment would be suggested and applied. Patients' life situation advised the extent of treatment and the amount of self-management that could be expected. It was considered that focus should be altered from the experience of pain towards increasing physical activity in patients with persistent pain. There was ambiguity among informants on the influence of patients' age might have on treatment. The expected diagnoses in different age categories were considered to be influential on treatment.

Patient participation fundamental

Several aspects related to the patients affecting decision-making and treatment were expressed. Patients' motivation, understanding and expectations were considered pertinent for how treatment could be implemented and essential to patient participation. Patient education with explanations of how pain can arise and persist was important in treatment. Explanations were one way to reduce patients' anxiety and empower them to self-management and exercise. Ways proposed to enhance patient participation were to be responsive to patients' narratives and to gain their trust. Individualized treatment was considered to be crucial, and a dialogue with patients on treatment selections was highlighted as one way to get patients participating and compliant to the treatment regimen.

Physiotherapist's personal convictions and terms rule

Informants stated how their personal convictions affect treatment decisions. Preconceptions were expressed that treatment decisions could be made by the physiotherapist solely to which patients adhered. The physiotherapist's self-image of being an independent and physically active person affected their views that patients also needed to be active and independent, without clear reference to whether this was something that the patient had said. Patients' expectations of and motives for passive treatments, such as acupuncture, were viewed with scepticism and could be questioned. Passive treatments were avoided or conditioned by requirements for additional active exercises and self-management. It was said that the rehabilitation was explicitly the patient's responsibility and not the physiotherapist's.

Confidence in treatment selection and oneself

Informants felt confident about the patient encounter and when to treat and when not to. They were likely to use treatments that the patient had experienced as helpful previously and wanted the patient to revisit them for follow ups on treatment response. Confidence in hydrotherapy as effective for reducing fear of movements and improving mobility, modalities effective for reducing pain and manual therapy as effective in improving hypomobility, were mentioned. Informants were convinced of the effectiveness of physical exercise and explicitly that of motor control exercises. Intuition was considered part of experience and was by some preferred to that of the findings of physical examination as guidance in treatment decision-making. The experienced informants recognized clinical patterns in patients, and were likely to use treatment options they regarded as successful in similar cases previously.

Insufficiency limits decision-making

Low back pain was experienced as a complex and challenging condition and feelings of uncertainty and lack of competence and skills were expressed. There was a wish for improved guidance by evidence, to be well-informed and do the right thing. Some took part in science, while others said that work load hindered them from staying up-dated on current scientific findings, which was considered as an insufficiency. General physical exercise was considered to be supported scientifically, while manual techniques, traction, modalities, were

by some considered unproven, either scientifically or in their own experience. Novice physiotherapists articulated shortcomings in clinical reasoning during undergraduate training and a wish for more support and supervision by colleagues. Some stated that they had attended post-graduate courses but later lost interest, while others said that they had not been given an opportunity to attend post-graduate courses. Informants expressed scepticism regarding some treatment approaches such as Orthopaedic Manual Therapy (OMT) and McKenzie (MDT), and their rationales. There was a low awareness of decision-making tools and those aware of them considered them to be potentially supportive, but they were mostly seen as limiting and static in clinical practice.

Focused on education and physical exercise

Informants used various treatment selections in NSLBP. Patient education and advice included individualized information and instructions on ergonomics, posture and resting positions as well as explaining anatomy and pain models. Different modes of physical exercise were stated as central in treatment, with stabilizing/motor control exercises explicitly as the main mode of physical exercises. However, it was also highlighted that such exercises could increase movement avoidance in patients and that accurately performed strengthening exercises, e.g. squats and dead lift, should rather be used. Treatment progression was described as going from simple to more complex exercises, in more challenging positions and with increased loadings. Ambiguity was expressed regarding both home and supervised exercises. Other treatment selections were extension oriented exercises according to the McKenzie approach (MDT), manual therapy, body awareness therapy and modalities.

Combined treatments and treat with atypical goals

Mixing manual techniques, exercises and/or modalities was stated as being a successful working approach. Patients were helped and satisfied with a combination of treatments and most informants did not want to devote themselves to a specific method. Modalities could be used not only for pain relief, but could also work as a second-best treatment when other treatments had failed, or to gain time to elaborate on patient problems, or further as a starting point and gate-way to active treatment. Massage could be used as one way to strengthen therapist-patient relationship.

In summary: The external circumstances of working approach at the workplace and health care priorities influences the decision-making in treatments offered to patients with NSLBP in primary healthcare. The first step categorization of the NSLBP disorder itself as well as bodily examination findings designate to treatments. Patients' capabilities and participation constitute the prerequisites for treatment. Physiotherapists' personal convictions and terms, as well as their confidence in treatments and in themselves decide treatment selection, while their perceived insufficiency limits the decision-making in treatment, that primarily focuses on patient education, physical exercise and combined treatments, sometimes with atypical goals (Figure 10)

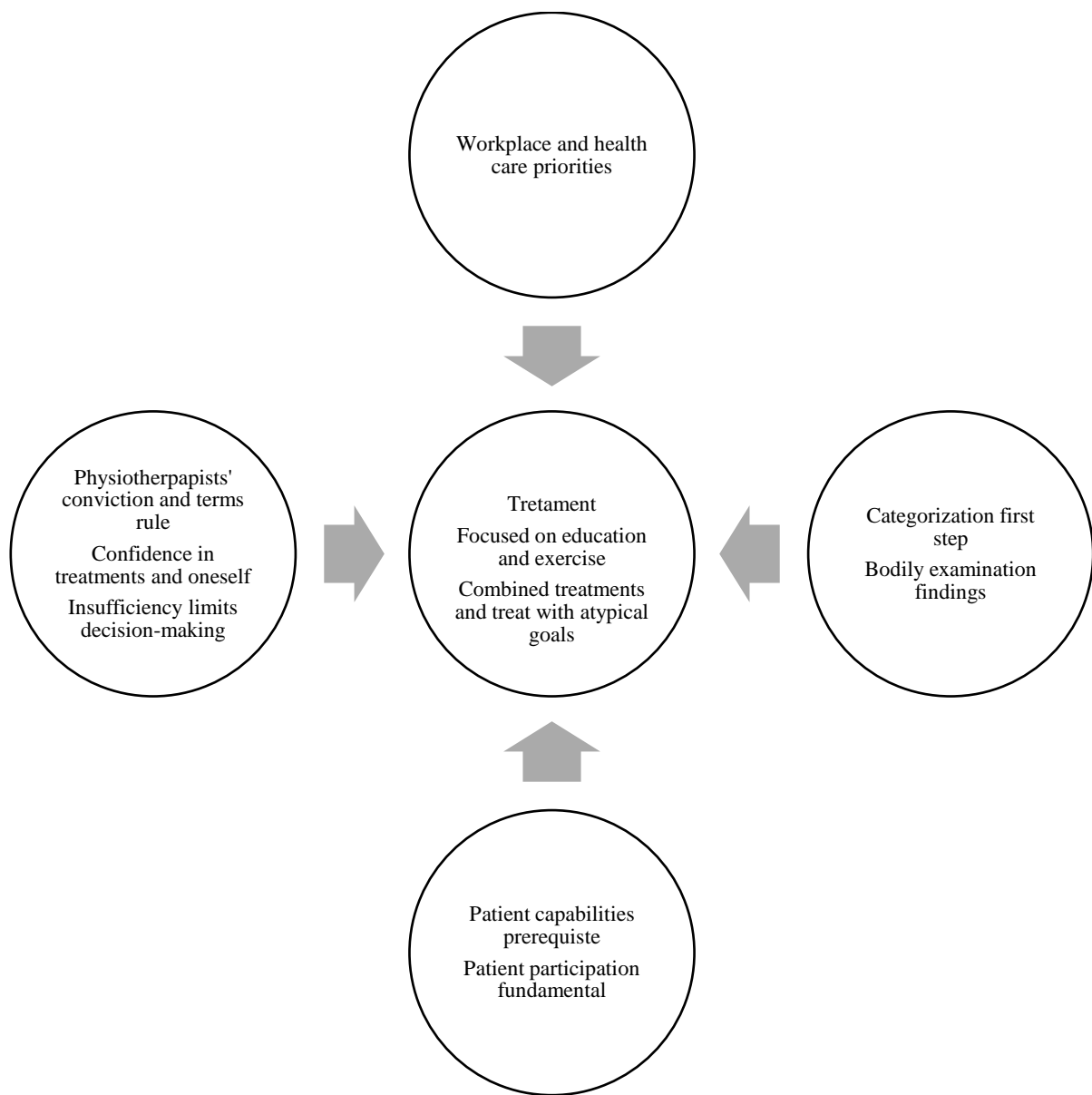


Figure 11 Illustration of the ten main categories which describes the clinical reasoning in the decision-making and treatment of NSLBP in primary healthcare.

6 DISCUSSION

6.1 LOW-BACK PAIN AND PHYSIOTHERAPY

Low back pain is a heterogeneous disorder with various symptoms, signs, severity and duration, and is often encountered at physiotherapy clinics. Within primary healthcare in Sweden, patients can self-refer to physiotherapy and will be introduced to a variety of treatments depending on physiotherapist's skills, experience and preferred treatments. To date there is no consensus on how to best target treatment to the individual patient. The work in this thesis is based on the potential benefits that categorizing LBP into subgroups potentially has on facilitating decision-making as well as guiding and matching treatments to patients and by extension, improve outcomes. The work has used previous research on the TBC system, biological rationale and/clinical experience in forming a practice-derived hypothesis²³⁰ and had the aim of developing and investigating this hypothesis in real-world settings, and what's more, exploring physiotherapists' clinical reasoning and decision-making in the treatment of NSLBP in primary healthcare.

6.2 MAIN FINDINGS IN STUDIES I-IV

This work presents and describes a categorization approach in which a combination of clinical symptoms and signs build the criteria of four treatment-strategy-based subgroups, *pain modulation*, *stabilization exercise*, *mobilization* or *training*, in a theoretical treatment-strategy-based classification system (TREST). This categorization approach was readily and reliably applied by experienced OMT trained physiotherapists, whereas the agreement between them on suggested important examination items in the TREST categorization approach, varied from fair to almost perfect. The feasibility of these examination items and patient reported pain intensity and disability in the categorization process was supported for the judgements on "presence or absence neurological signs", "an irritable or non-irritable disorder", "high or low disability", "bilateral spinal signs" and "presence or absence of specific segmental sign". Clinical reasoning and decision-making LBP among physiotherapists in primary healthcare involves aspects of external circumstances (workplace and health care priorities); the disorder (categorization and bodily examination findings); patients (capabilities and participation); as well as physiotherapists (personal convictions, confidence and insufficiency); and treatment was primarily focused on patient education, physical exercise and combined treatments.

6.2.1 The TREST classification system

The TREST subgroups are comprehensible in being descriptively labelled by designated treatments. It has been suggested that an ideal system should have a small number of subgroups, so as to ensure confident users with minimal training.¹⁸⁵ The four subgroups in TREST are comparable to other systems targeting impairments and treatment. The McKenzie system (MDT)¹⁸⁷ has three primary subgroups (derangement, dysfunction and posture), while Movement System Impairment classification system (MSI)¹⁸¹ has five (rotation- extension, extension, rotation, rotation-flexion and flexion), the 2007 TBC⁶ system has four

(manipulation, specific exercise, stabilization and traction) and the 2015 TBC ²⁰⁷ update has three (symptom modulation, movement control and functional optimization). However, the TREST has some potential clinical advantages. It includes information from all parts of the physiotherapy patient assessment and provides flexibility from the perspective of patients and physiotherapists ²⁷⁰ by the suggested wider concepts of treatment (treatment strategies) in each subgroup. However, it is to date unknown whether TREST and the inclusion of treatment-strategies has acceptance among physiotherapists and patients, or whether it will improve patient outcomes.

Within evidence-based practice, treatment should be endorsed by scientific evidence, summarized in clinical guidelines.²¹ There are, however, concerns about flaws in guidelines including poor literature review methodology, limited involvement of stakeholders and unclear editorial independence and the potentially negative impact of such guidelines on the care and health outcomes of patients.²⁷¹ Notwithstanding these, a recent systematic review of high-quality clinical guidelines for chronic NSLBP concludes that advice, education, self-care options, exercises, manual therapy and multimodal rehabilitation (cognitive/behavioural approaches and exercise for patients with high levels of disability or significant distress) are endorsed across guidelines, and that massage and acupuncture are recommended in most.⁹⁸

The TREST include guideline-endorsed treatments for NSLBP in its subgroups.^{98, 272} There is scientific support for the inclusion of *mobilization* and *physical exercise*, although the exact application of these are unknown and should be chosen in consideration to people's specific needs, preferences and capabilities.²⁷² There is scientific support for the treatment selections of acupuncture and massage in *pain modulation*, other modalities are discouraged.⁹⁸ There is no or limited scientific support reported in recent guidelines and reviews for the inclusion of *stabilization exercises*^{98, 272, 273} Yet, modalities and stabilization /motor control exercises are commonly used in clinical practice for reasons that include the experience and expertise of the treating physiotherapist, stated as important in EBP.^{21, 24, 172} There is, however, a need to gain more knowledge in the clinical reasoning and decision-making regarding how these treatment selections might be matched to patients' clinical status.

6.2.2 Inter-examiner reliability and feasibility of TREST

6.2.2.1 Inter-examiner reliability of the categorization and examination items

The investigation of whether TREST could reliably be used by clinical physiotherapists other than the developer showed substantial agreement between the two pairs of experienced and OMT trained physiotherapists in the categorization of patients into one of the four subgroups in TREST. Substantial inter-examiner agreement across other classification systems has been shown in studies of different cohorts of examiners.^{5, 188, 193, 209, 227, 228, 274-277} However, the guidelines for the interpretation of Kappa values, among which Landis and Koch is one set, are all arbitrary²⁶⁸ and it is difficult to compare kappa values from different studies as the interpretation of the magnitude of the kappa coefficient can be influenced by prevalence, number of categories, and bias.^{225, 229}

It is well established that familiarity increases inter-examiner reliability.^{227, 228} However, most studies on inter-examiner agreement of categorization to subgroups have used physiotherapists who are very familiar with the system investigated, and hence agreement values might be overestimated.^{5, 188, 189, 275} The amount of familiarization needed when introducing a new system reflects its complexity and has a bearing on the readily implementation into clinical practice.^{227, 228} The three-hour familiarization of the TREST and yet the substantial agreement on categorization is promising for its feasibility in practice. However, reliable sub-group categorization is not sufficient for a reliable classification system. It must contain examination items that can reliably be used by different examiners and the resulting inter-reliability values on examination items in TREST, varied from fair to almost perfect.²⁰⁹ This concurs other studies also showing that agreement on clinical tests is difficult to reach and may require strict protocols and sufficient training time for consistency.^{278, 279} Given the limited familiarization of the TREST that physiotherapists was given in the present study gives reason to expect potentially increased kappa values with study designs that include more training time.

6.2.2.2 Feasibility of clinical criteria

Further analyses were needed to identify how individual physiotherapists applied their judgements on examination items and patient-reported pain intensity and disability, suggested as clinical criteria in subgroups, in the categorization of patients in Study II.²¹⁰

Disability, measured by the ODI score which identifies functional activities and their association with pain, was shown to be important to physiotherapists in providing useful information on treatment selection. This is in line with recommendations that NSLBP should be considered in relation to its interference with normal life.¹⁰⁶ Furthermore, the presence of neurological signs and symptoms^{69, 71} were used together with high irritability so as to categorize patients for treatments suggested in *pain modulation*. It reasonable to expect that mechanical stimuli, such as exercises or mobilizations, were considered inappropriate treatment options in such a clinical status. This consideration is also supported in pain research, showing that mechanical loading may trigger dysfunctional pain response and the development of sensitization.^{81, 280}

The association between the “bilateral spinal signs” and the subgroup *stabilization exercises* must be interpreted with caution given the small number of examinations in this subgroup (n=12). This subgroup may be better elucidated by an additional inclusion of clinical variables identified as being indicative of poor movement control performance^{204, 258} as well as by validated specific questions regarding subjective symptoms of clinical spinal instability.²⁸¹

The presence of specific segmental signs, low irritability and disability were used to classify patients for treatments suggested in *mobilization*. This shows that physiotherapists considered patients to have a necessary tolerance to the mechanical stimuli induced by mobilizations. This is interesting, as the presence of specific signs alone have been found to be un-reliable

and hence questionable as clinical criteria.^{209, 278, 282} The combination of assessment findings is supported by the notion that treatment decisions cannot be made on a single test or out context of a full clinical picture.²⁶³ However, other ways of establishing spinal mobility to identify patients in need of mobilization treatment should be explored.

The association between subgroup *training* and the absence of neurological signs and symptoms is logical. Interestingly, the training subgroup had large proportion of patients with high irritability, in contradistinction to the suggested criteria. Given that assigned patients had an absence of neurological deficits, it might be that physiotherapists judged the irritability as tissue-mediated (nociceptive) and not centrally mediated pain,^{84, 265, 266, 283} and therefore best treated with exercises addressed to target these tissues. Although exercise therapy has been found to be beneficial in persistent pain, it should be appropriately and individually tailored and applied with adequate recovery strategies.²⁸⁰ The clinical reasoning regarding sub-groups of patients who might benefit from physical exercise as first line treatment needs to be explored further.

The criteria of pain intensity and presence/absence of specific movement pattern were not associated with any of the TREST subgroups and were hence un-supported. This means that judgement on these criteria did not influence patient subgroup membership. Although, self-reported pain intensity is of the greatest importance for patients and, therefore, pertinent to monitor and target in treatment,²⁸⁴ the physiotherapists still considered the ODI score as more useful in the categorization process. High scores on self-reported pain have recently been shown not to be associated with the selection to multimodal rehabilitation.²⁸⁵ It might be that self-reported pain-intensity is of more value as an outcome measure than decisive for treatment approach. The variable presence/absence of a specific movement pattern was new to the physiotherapists in the study which might have had an influence on results.²⁰⁹ Although differences in movement patterns have been found between individuals with and without LBP, there are no consistent reports of improvements and changes in movement quality following movement based treatment.^{286, 287} In contrast, the evaluation of specific movement patterns has been described as being crucial for treatment selection.^{190, 228, 286, 287} This indicates that, for future use in the TREST more information is required regarding movement quality testing.

6.2.3 Physiotherapists' decision-making

How patients are selected to the various physiotherapy treatments of NSLBP in primary health care is unclear,^{285, 288} and the highlighted aspects provide an understanding how treatments are matched to patients in clinical practice. The most commonly used treatments in primary healthcare in Sweden have been reported to be advice and physical exercise.¹²⁶ This was supported by our informants who focused their treatment on advice, education and physical exercise. A recent review synthesizing results from quantitative and qualitative studies concluded that physiotherapy treatment for NSLBP is primarily bio-medically oriented.¹²⁴ There is, however, reason to expect that our informants used a bio-psychosocial orientation, using such as pain mechanisms and guidance of patients' perceived capabilities in

the modification of treatments and in building trusting relationships with patients. All these aspects have been stated as being essential in clinical practice.¹¹³

Also essential to physiotherapy practice is measuring impairments (e.g. stiffness and weakness) and functional abilities (e.g. sitting, walking)^{11, 25} The highlighted bodily examination findings that designate patients to specific treatments demonstrate the importance the informants put on physical findings e.g. hypomobility, hypermobility, muscle fatigue and muscle tension, that directly designated the patient to specific treatment selections of active mobilization exercises, stabilization/motor control exercises, physical exercise and soft tissue techniques, respectively. These aspects are of interest for the further development of TREST. The importance of altered mobility is already included in TREST, whereas muscle findings are not. The role of explicit muscle findings in TREST subgroup criteria needs further consideration.

While previous studies have shown that patient treatment expectation affect treatment selection,^{124, 289} our informants stated, on the one hand, responsiveness to patients' expectations, but on the other, questioned and conditioned passive treatment preferences. Plausible reasons for this might be the informants' focus on physical exercise as well as their personal conviction, that patients should be independent and active. These notions made them prone and responsive to preferences of active treatment and the fact that passive preferences were considered negatively and something that should be avoided. Categorization into "good" and "bad" patients, with "bad" associated with the passive nature of the patients and a poor outcome, has previously been found to influence communication and practice.^{120, 290} Such influence of physiotherapists' professional and personal values on clinical practice has led to questions as to whether these might also influence patients' access to healthcare.^{124, 289, 291} Interestingly, our informants sometimes used massage and modalities to strengthen relationships with patients as well as an opportunity to contemplate on the patient's condition and to encourage patients to participate in active physical exercises.

It has been proposed that musculoskeletal physiotherapy should acknowledge how clinicians' feelings, emotions and physical responses may play a part in the decision-making, especially in cases perceived as being difficult and challenging.⁴² Our informants considered NSLBP to be complex and cited insufficiency due to shortcomings in clinical reasoning skills and the lack of continued postgraduate education, which limited their decision-making. This shows that physiotherapists' lifelong learning is essential as well as a need for emphasis on clinical reasoning skills already during undergraduate education. Furthermore, there is a need for workplace organization where novice physiotherapists are supported at the outset of their professional life. In contrast, informants expressed confidence in their encounters with patients, in some treatment selections as well as in their intuition or gut feeling. Intuition and/or gut feeling has been suggested as being separate reasoning methods, but co-existent with other reasoning methods.⁴² However, our informants suggested intuition as being equivalent to experience and intuition seemed mixed with analytical reasoning.

Informants' decision-making and treatments seemed to concur with the previous findings of being primarily experienced based.¹²³ For instance, mobilizations were regarded as effective in improving hypomobility and physical exercises was considered having an overall effectiveness. Physical exercise was the single treatment considered to be supported by scientific evidence. It was not acknowledged that clinical practice guidelines recommendations in persistent NSLBP also include education, advice, manual therapy, self-management, acupuncture and multimodal rehabilitation.^{98, 99}

It was confirmed in our study that external circumstances of finance constraints, previously highlighted in research¹²² influenced clinical reasoning and practice. In contrast, the previously highlighted influences of safety and national policy or directives on decisions were not mentioned.¹²² Instead the advocated treatment approach at workplaces was influential on treatment selection and the perceived low priority of persistent NSLBP in primary healthcare limited treatment periods for these patients.

6.3 METHODOLOGICAL CONSIDERATIONS AND LIMITATIONS

6.3.1 Development and investigation of TREST

6.3.1.1 Development

It been advocated that clinical studies on NSLBP should be conducted on patients seeking care.²⁹² Participants in Study I were a mix of referred and self-referred patients with NSLBP, something that is normal for Swedish conditions. Not excluding patients with radiating pain to the lower extremities, cover most patients seen by physiotherapists in primary healthcare and these patients are comparable to those reported in the same context in other studies.²⁹³ To be able to justify the subgroups individual ratings of pain, disability and physical health, at baseline and at discharge were compared, without comparisons between patients. However, this experimental design means that conclusions on treatment outcome cannot be inferred.

There are examples of classification systems where single physiotherapists have used their experience in addition to various amount of support from previous research in the development of respective systems.^{183, 186, 294} To maintain consistency of treatment approach, one single physiotherapist classified and treated all patients in the development of TREST, indicating bias. However, this pilot study was to propose clinical features to define subgroups of NSLBP and present plausible reason why the subgroup would respond to one specific treatment. Such hypothesis-generating studies can use methods that include previous research, biological rationale and/or clinical experience.¹⁷⁸ The development of TREST used a mix of these methods. The TBC system and subsequent research of two of its subgroups, mobilization and stabilization, were used as a guiding principle.^{3, 4, 204} The two new subgroups, *pain modulation* and *training* were empirically formed using biological foundations of pain mechanisms, descriptions of LBP as rationales as well as guideline support for physical exercise in the management of LBP.^{55, 58, 81, 82, 84, 265, 266 98, 108} A shortcoming of the TREST is that it does not explicitly consider psychosocial-or behavioural

aspects in the reasoning process and treatment selections. Although, the aspects highlighted by informants adds to the understanding of all the considerations taken in the decision-making in treatments, it is still unclear whether alternate treatment selections will be added to TREST.

6.3.1.2 Inter-examiner reliability and feasibility testing

There are several methods for examining agreement on judgments from physical examinations. These include repeated examinations on the same day, on separate days, concurrent examinations or using videotaped examinations.^{5, 188, 191, 227, 295, 296} For practical reasons and to avoid fluctuations in status from day to day and thus considering status as being as stable as possible, we used examinations on the same day. A use of videotape examinations would reduce patient variability, but may only be feasible for one part of the examination procedure, the observation of active movement tests. Furthermore, the external validity and value in clinical practice of such studies are limited, as evaluations of movements performed on videos are not carried out under ordinary clinical conditions.

Participating patients in the study comprised a mixture of referred and self-referred consecutive adults, primarily women, average middle-aged, with moderate self-scored pain intensity, hence representative of individuals commonly seeking physiotherapy treatment for NSLBP in primary care.^{297, 298} In comparison, the experienced OMT trained physiotherapists cannot be considered representative of most physiotherapists working in primary healthcare. The reason for using such trained physiotherapists was that the examination protocol included items that require manual experience and skill. The inclusion of a novice pair would have provided more information on how readily and reliably the TREST could applied. The method used in an examination of the inter-examiner reliability of another classification system, where ten physiotherapists, randomly assigned into pairs, would have been the ideal method.¹⁹³ However, such method has obvious logistic difficulties.

The secondary analyses in Study III, used logistic multivariate regression analyses to identify feasibility of subgroup criteria. Any such secondary analysis will use a priori set data and sample size, with 95% CIs representing estimates compatible with original data.²⁹⁹ The secondary analyses provided some CIs that were broad, suggesting imprecise estimates. However, estimates were interpreted rigorously such that only those that did not include a null value (OR =1) were regarded as representing an association, although it may be inappropriate to interpret such estimates as evidence of the lack of association.³⁰⁰ However, the accuracy of these judgments and subgroup categorization is unknown since no investigation of treatment outcome was carried out.

6.3.2 Aspects of decision-making

6.3.2.1 Physiotherapists experiences and thinking

There are different ways to investigate and explore clinical reasoning. These ways could be surveys, observations, focus or individual interviews, or a mix of these.^{1, 121, 289-291, 301, 302}

Qualitative research methodology and individual interviews are suited for the exploration of tacit clinical knowledge and thoughts held by physiotherapists. Although the resulting sample size is within the recommended for individual interviews,²³⁵ additional informants could have provided other aspects of clinical reasoning and decision-making. However, individual interviews highlighted various aspects of reasoning and clinical practice which provided variations in the data.

All clinics were primary healthcare out-patient physiotherapy clinics, included in the Swedish healthcare system, with direct access to physiotherapy. To cover a diversity in practice and perspectives on the research question, warranted in content analysis,²³⁸ variations in settings, working conditions, experience and geographical areas was sought. Yet, it is still possible informants from other settings could generate alternative aspects which could add to the findings.

The interviewer, an experienced clinical physiotherapist in primary healthcare, had a pre-understanding of the informants' work and conditions. This understanding made the interviews comfortable without the need of thorough descriptions of circumstances or explanations of language used. Although such familiarity can lead to un-reflected mutual understandings, it can also be an asset, as it facilitates judgements on the face validity of analytical decisions.³⁰³ Informants might also have felt uncomfortable being interviewed by an experienced colleague, although such feelings might have been mitigated by the interviewer being a novice to the research interview situation.

6.3.2.2 *Theoretical extrapolation of physiotherapists' decision-making*

There is reason to believe that the clinical reasoning used by the informants in our study is congruent with theoretical clinical reasoning models described.³⁰ Diagnostic reasoning associated with pain mechanisms and tissue pathology in the differentiation and categorization of NSLBP and expressed efforts to understand and interpret the patients' narratives. These approaches seem to follow "hypo-deductive reasoning"³³ in combination with "narrative reasoning".^{10, 40} The inclination for using previously successful treatments in the treatment of patients with an experienced recognizable clinical pattern demonstrates the use of "pattern recognition reasoning".^{18, 36} Some examination findings were considered to directly suggest specific treatments and can be considered as traces of the "clinical prediction model".^{3, 4}

There is also reason to expect that informants' thinking and actions concerning physiotherapy management follow the clinical reasoning strategies described.¹ Informants' concern for patients' abilities in the determination of treatment as well as being responsive to patients and building trusting relations with and empowering patients to participate in treatment demonstrate reasoning strategies of *procedure*, *interaction*, and *collaboration*. Reasoning strategies about *teaching* were demonstrated by the emphasis on patient education and reasoning about *ethics* was shown by the perceived impact that healthcare priorities and limited financial resources have on treatment. Reasoning on *prediction* was not apparent in

our data, apart from reasoning on the importance of self-management for the prevention of recurrent LBP. The components in the evidence-based decision-making model²⁴ seems to be applied by informants in their decision-making, although not to the equal extent that is described by the model

6.3.3 Internal validity

Internal validity refers to the confidence one can place in the cause-effect relationship in a study.³⁰⁴ Study I used a consecutive sample without randomization, a small sample size and a pre-post-test experimental design. These are limitations of the study meaning that no conclusion can be inferred as to whether the categorization approach improves outcomes. However, the aim of this second part of the study, with a pre-post-test experimental design, was not to investigate the treatment outcome as such, but to follow up on individual response to intervention, and to guide the progressive treatment-flow.

Since it is unrealistic to expect physiotherapists to examine patients in exactly the same manner in clinical practice, ordinary examination procedure without strict protocols was used at the discretion of the physiotherapists in Studies I and II (III). In Study II this makes it possible to measure the normal variability in examinations and judgments. However, OMT training includes a specific examination procedure, and it may therefore be expected that examinations were performed in a similar manner. The examination procedure of changing primary examiner for every other patient and performing passive and peripheral neurological assessments in sequence was outlined with an account taken of examiner bias and patient convenience and variability. Clinical review bias, i.e. the availability of clinical information from patients to physiotherapist prior to the physical examination, infer bias³⁰⁵ However, patient history is a routine procedure in the physiotherapy assessment and a central part in evidence-based decision-making and research on clinical decision-making need to be carried out in the same way.¹¹

As active movements may change with repeated examination, these were carried out once. This single-active-movement examination enabled the judgments to be based on the same information, but still to be independently interpreted. In contrast, each examiner separately performed the passive movement examination and the peripheral neurological examination. The response to these tests may also change with repeated examination, but, for independent interpretation, these hands-on tests must be performed individually. The physiotherapists were blinded to each other's judgments. However, this mixed simultaneous and independent examiner design could potentially have overestimated the Kappa values, as inter-examiner reliability studies require independent examiners who fully repeat the examination.²²⁵ It was therefore surprising that the inter-examiner reliability was not higher than fair for the item "presence of specific movement pattern", showing that the interpretation of active movements may differ between physiotherapists despite concurrent observations.

The other item collected from the part of the examination where both physiotherapists were present "level of irritability" had a moderate weighted kappa value. Feedback from the

physiotherapists after completion of the study showed that the irritability concept was new to them and not used routinely prior to the study. The moderate kappa values give reason to expect the information was independently interpreted and may have been influenced by novelty rather than the simultaneously given information. Furthermore, the answers from this item were put in a table with five categories, in which not all categories were used. Since raw agreement was high (82%), the explanation of the moderate agreement might, therefore, be a prevalence bias situation of limited variation resulting in incorrectly low kappa values.²⁷⁹

Trustworthiness in qualitative research is for the reader to decide and findings need to be presented in a way that allows the reader to look for alternative interpretations.²³⁸ Credibility refers to the confidence in how well data and analysis address the intended aim, how sampling was made, and what knowledge the informants have given insight into.^{237, 238} The method of sampling and resulting variation in gender, experience and working conditions and semi-structured interviews, allowed for a variety of individual thoughts and experiences.²³⁸ The condensation of meaning units and coding with minimal interpretation and the illustration of authentic citations give insight into how categories were created and refers to the dependability (reliability) readers can infer on findings.^{237, 238} Being an experienced and clinical specialist in musculoskeletal physiotherapy might inadvertently have led to bias in data collection and refers to the conformability (objectivity) of findings. However, such bias might have been lessened by the researcher triangulation method that was part of the analysis process. The other researchers' theoretical and methodological knowledge differed from that of the interviewer and provided a broader outlook of the experiences and thoughts that informants expressed in the interviews. However, since all researchers are female and physiotherapists, a male perspective as well as input from another healthcare professionals might have provided alternative interpretations. Therefore, preliminary categories were discussed in a research group where participants were male peers as well as peers with experiences from other fields within musculoskeletal physiotherapy.

6.3.4 External validity

External validity refers to whether research findings obtained from a small sample can be extrapolated to a whole population. For this, subject sampling and setting are of great importance. For this reason, the studies included physiotherapists in settings who would normally perform the assessments under study, using ordinary flexibility and time limits during assessments. Further, studies included patients who would normally present a variability and who would normally go through such assessments. However, physiotherapists were experienced and trained in OMT, and therefore results can only be extrapolated to physiotherapists with similar characteristics. Examiner autonomy is of concern for the external validity of inter-examiner reliability studies.²²⁵ For this, Study II did not include the developer among the examiners. Other studies of classification system inter-examiner reliability have used developers' judgements as the "gold standard",^{190, 227, 228, 275} which means that such studies examine the ability of following the developers' judgements rather than agreement on independent judgements.

External validity or transferability of qualitative studies refer to the clarity and distinct description of context, data collection, sampling and characteristics of respondents and analysis process.²³⁸ The study describes what is unique to a Swedish context. All informants but one, were trained in Sweden and the study was carried out in a Swedish context where physiotherapy is a part of the social security system and patients have direct access to physiotherapy. Whether findings can be applied to physiotherapy clinical practice where informants are trained elsewhere, and healthcare is organized differently, is unknown. Yet it's possible that findings of the study may be relevant and extracted to other contexts as well as to other health care professionals.

6.4 IMPLICATIONS

The TREST classification system presented has potential advantages for stakeholders. Since it aims to guide parts of the decision-making physiotherapists use, is based on ordinary physiotherapy examination procedure and includes known treatments that do not require expensive equipment or specific tools, it might be interesting to and used by clinical physiotherapists working with spinal pain. TREST also seeks, by extension, to find optimal physiotherapy treatments for each sub-group, and might, therefore, be beneficial for patients with NSLBP. To date, there is support that experienced OMT-trained physiotherapists reliably can apply TREST in the categorization of NSLBP in clinical practice and that some of its subgroup criteria can be used reliably as well as evolving understanding of how clinical criteria included in TREST can guide treatment decisions. Yet, there is no evidence the TREST classification approach can improve treatment outcomes and therefore the clinical implications are to date limited.

The exploration of decision-making among physiotherapists in primary care has highlighted various aspects of clinical reasoning in the decision-making and treatment of NSLBP. The aspects that influence treatment selections, primarily focused on education and physical exercise, cover a spectrum of aspects of the disorder, patients, physiotherapists and external aspects. These findings might be of significance for education and healthcare providers as well as physiotherapists professional reflection in their everyday clinical practice. The findings will furthermore have implications for the future development of TREST, although it is to date unclear exactly in what manner.

6.5 FUTURE RESEARCH

The TREST is in its derivation/explanatory phase and the investigations and findings of the studies included in this thesis have implications for further research. Clinical decision-making is fundamental to the physiotherapy treatment of patients with NSLBP. Future research could, therefore, continue to identify clusters of signs and symptoms that may identify subgroups for targeted physiotherapy treatment. Here, the continued analysis of the vignettes that were used in the interviews is of value. Furthermore, the patients' perspective and voices have not been explored in any of the studies included and need to be considered and integrated in the continued development of TREST.

Rather than adapting physiotherapy practice to the existing research evidence, there is a need of better fitting physiotherapy research design with a clear practice orientation to effectively inform practice.¹¹ Therefore, the cause-effect between subgroups in TREST and treatment outcome as well as ascertaining patients and physiotherapists' acceptance of TREST need to be investigated. If such validity of TREST in the decision-making and treatment in NSLBP can be shown, further research might target how TREST could successfully be implemented in everyday clinical practice.

7 CONCLUSIONS

The results and findings of the work in this thesis present and describe:

- an individualized treatment-strategy based classification system (TREST) for subgrouping NSLBP for physiotherapy treatment with a progressive treatment flow.
- a differentiation in clinical status of NSLBP in each of the four subgroups; *pain modulation, stabilization exercise, mobilization and training*, based on patient interview, physical assessment and evaluation of pain intensity and disability.
- that the categorizing approach of the TREST can reliably be applied by experienced OMT-trained physiotherapists.
- that three of the TREST clinical criteria, “neurological signs and symptoms”, “unilateral signs” and “level of irritability”, show a moderate to almost perfect inter-examiner reliability.
- that two of the TREST clinical criteria, “specific movement pattern” and “specific segmental signs”, show fair inter-examiner reliability, and therefore, need to be clarified or reconsidered.
- support for the feasibility of the TREST clinical criteria “presence or absence neurological signs”, “irritable or non-irritable disorder”, “high or low disability” “bilateral spinal signs” and “presence of specific segmental signs” in the categorization into subgroups.
- that the external circumstances of working approach at the workplace and health care priorities influences the decision-making in treatment offered to patients with NSLBP in primary healthcare. The initial categorization of the NSLBP disorder itself and bodily examination findings designate to treatments. Patients’ capabilities and participation constitute the prerequisites for treatment. Physiotherapists’ personal convictions and confidence in treatments and themselves decide treatment selection, while their perceived insufficiency limits the decision-making in treatment, that primarily focuses on patient education, physical exercise and combined treatments.

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