Chapter 01
General introduction
Content

1.1 Chronic low back pain
1.2 Interventions for chronic low back pain
1.3 Outcomes of interventions for chronic low back pain
1.4 Aims and Outline of this thesis
1.1 Chronic low back pain

Prevalence and incidence

Low back pain is a highly prevalent health condition globally and leads to individual suffering and a considerable burden for society. Recent research shows that, worldwide, low back pain is responsible for more years lived with disability than any other health condition [1,2]. Many people with low back pain have ongoing and recurrent complaints [3,4], and at a societal level there are substantial costs related to low back pain as a consequence of healthcare expenditure, disability insurance, and productivity loss caused by work absenteeism and work loss [5,6].

The mean global one-year point prevalence of low back pain is estimated to be 38.0% (±19.4) [7]. In the Netherlands, approximately 44% of the adult population experiences at least one episode of low back pain, and one in five (21%) report persistent back pain resulting in chronic low back pain (CLBP)[8,9], defined as low back pain lasting for more than three months [10] with substantial limitations in functional activities after one year [8,11]. Approximately 14% of the Dutch adult CLBP population is incapable of work [9]. Due to ageing and population growth, it is expected that the total number of CLBP-patients will increase.

In the Netherlands in 2007 the total cost of back pain to Dutch society was estimated to be €3.5 billion, which equates to 0.6% of the gross national product. This amount includes indirect costs such as productivity loss and costs incurred by society due to morbidity and mortality, which represent the majority of these total costs [5]. In 2007, more than 500,000 patients with back pain were referred to secondary or tertiary spine care and more than 30,000 underwent a surgical intervention for which the related costs were estimated to be 23 million euro. However, these numbers are likely to be underestimates, because research shows that despite initiatives to try to discourage the use of expensive diagnostic imaging in early stages, there has been no change in the amount of ineffective referrals to secondary care [5,12].

Symptom or diagnosis?

The CLBP population is heterogeneous and the term CLBP lacks diagnostic clarity. CLBP is an umbrella term, covering two main categories of lumbar spine disorders: degenerative and non-degenerative [13]. In clinical practice, an accurate patho-anatomical diagnosis of the cause of CLBP based on biomedical indicators can be made in only 10% of the patients (e.g. isthmic spondylolisthesis, lumbar spinal stenosis, lumbar disc herniation, scoliosis, spinal fracture, axial spondylarthropathy, neoplasm, Morbus Scheuermann) [14]. Hence, in the majority of patients, low back pain is a symptom referring to the location rather than reflecting a specific diagnosis [15,16]. Because in the vast majority of patients (90%) the aetiology is unknown [14], these patients are diagnosed as having degenerative low back pain and are often labelled as ‘non-specific’. However, the term ‘non-specific’ is thought to be meaningless [17] and therefore the term ‘degenerative lumbar spine disorder’ seems more appropriate (Figure 1.1).
Figure 1.1 Representation of the lumbar spine (A-B) and of a degenerative lumbar spine disorder (i.e. chronic low back pain; C)

(A) Schematic representation of the lumbar spine (A); 'normal' lumbar spine (MRI; B); 'degenerative' lumbar spine (MRI; C)

Aetiology and prognosis
The traditional model of clinical practice incorporates diagnosis based on aetiology, prognosis, and treatment of the condition or disease [18]. Aetiology refers to the study of causality of diseases [19]: the relationship between cause and effect. To describe aetiology in CLBP, in Western medicine the biomedical model, derived from Louis Pasteur's germ theory of disease, has been the dominant force. Following this model, it is assumed that CLBP is fully accounted for by deviations from the norm of measurable biological (i.e. somatic or patho-anatomic) factors. However, in the vast majority of CLBP cases no patho-anatomical diagnosis can be made. The model is also exclusive, since any symptoms that cannot be explained in biological terms are excluded from consideration, and thereby it leaves no room for the social, psychological, and behavioural dimensions. Yet, these aspects are important in chronic diseases and have led to a paradigm shift from purely biological to the bio-psychosocial model, which was introduced by Engel in 1977. Its scope is determined by the historic function of the physician to establish whether the person soliciting help is "sick" or "well" — and if sick, why sick and in which ways sick — and then to develop a rational programme to treat the illness and restore and maintain health [20].

Studies on the prognosis of CLBP show frequent persistence of complaints [21] whilst an inverse relationship for the prognosis of a satisfactory outcome with symptom duration has been shown [22]. It is estimated that one to two years after the initial onset, 60-80% of patients consulting healthcare professionals still have pain and have not fully recovered [23,24]. Amongst patients with back complaints for more than three years, the chances of recovery are even smaller [22]. The literature demonstrates that persistence of CLBP is associated with pain, disability and psychological status at onset [22,25-27]. Many authors have emphasised bio-psychosocial influences on the development and persistence of CLBP [21,22,28,29]. However, the aetiology of CLBP remains largely unknown and the prognosis detrimental. Owing to this lack of diagnostic clarity, targeted interventions with successful outcomes remain a challenge.
1.2 Interventions for chronic low back pain

The failure to identify underlying causes is one of the reasons why a plethora of invasive and non-invasive interventions exist for the same symptom [30]. Therefore, practice variation exists amongst healthcare providers, and considerable uncertainty exists amongst major stakeholders as to which interventions are (cost) effective. For example, the rates of lumbar spine surgery vary largely within and between countries [31-34]. Despite decades of research and improved quality of clinical trials, the treatments offered to patients produce inconsistent results [35-41] and rarely show more than a small to moderate overall benefit [6,35,40,42-44]. Table 1.1 shows an overview of recently published systematic reviews and showing effect sizes for the main surgical and non-surgical interventions underlining these facts.

Surgical interventions

Various surgical interventions exist for CLBP. In the context of this thesis the focus is on most commonly performed surgeries for CLBP. These are spinal fusion surgery (two or more vertebrae are permanently 'fused' together [spondylodesis]) with or without decompression (relief of a compressed spinal nerve root), discectomy (removal of a part of the intervertebral disc), and disc replacement (replacement of the intervertebral disc by an artificial spinal implant). Figure 1.2 shows an example of a commonly performed procedure for spinal fusion surgery. Fusion surgery with or without decompression could be beneficial for a selected group of patients with CLBP, i.e. those with a specific diagnosis with an underlying 'biological cause' and who previously failed non-operative treatment (e.g. lumbar spinal stenosis, isthmic spondylolisthesis) [40,50,51]. However, for fusion surgery with or without decompression the effect sizes are not large and the overall quality of evidence is low. Current scientific evidence does not support superiority of surgery for CLBP compared to high-intensity conservative interventions to reduce pain intensity and restore functional ability [52]. Therefore, it is debatable whether any surgical, invasive intervention such as disc replacement or fusion surgery should be performed in patients without a clear diagnosis of the cause of their CLBP [53]. A nationwide survey amongst Dutch spine surgeons showed that no professional consensus could be identified in decision making on the treatment strategy for chronic low back pain, even in the group 'with presumed biological causes' [54]. To improve outcomes it has been recommended to identify subgroups of patients for whom spinal fusion surgery is an effective treatment [53-55]. Indeed, in a recently released draft version of the Dutch national guideline for instrumented lumbar spine surgery [56], this is regarded as an important recommendation to improve surgical outcomes, which is the subject of the third part of this thesis (Theme C; Chapter 9-11).

Non-surgical interventions

Various non-surgical interventions for CLBP in secondary care exist (e.g. invasive pain treatment [injections], functional restoration programmes, back schools, cognitive behavioural therapy, multidisciplinary bio-psychosocial pain management programme). In the context of this thesis the focus is on multidisciplinary bio-psychosocial pain management programmes. These multidisciplinary programmes may have benefits comparable to surgery for back pain caused by degenerative spine disorder, as demonstrated in a recent 11-year follow-up study of surgical trials [41]. A recent Cochrane review of 42 randomised controlled trials (RCTs) including 6,858 patients with CLBP showed that the effects of multidisciplinary bio-psychosocial programmes were of modest magnitude compared to usual care (moderate
quality evidence) and physical treatments (low quality evidence) in reducing pain and
disability in people with CLBP. For work outcomes, multidisciplinary programmes seem to
be more effective than physical treatment but not more effective than usual care [44]. Very
recently, the cost-effectiveness of a multidisciplinary bio-psychosocial pain management
programme including minimal interventional procedures (e.g. radiofrequency denervation)
for patients with CLBP was compared to the multidisciplinary programme alone (i.e. MinT
study [57]). The preliminary 12-month results of the MinT study show that adding minimal
interventional procedures is not more cost-effective [58]. At the Sint Maartenskliniek a new
combined physical and psychological (CPP) pain management programme was introduced
in October 2006 for patients with CLBP (Figure 1.3). The two-week intensive programme is
provided outside the clinic in a hotel setting, and three main components can be distinguished:
physical training, cognitive behavioural training including graded activity and graded
exposure, and education. To monitor the individual progress and to evaluate the programme
on a group level over time, participants are systematically followed for one year on patient-
relevant indicators (i.e. routine outcome monitoring). More detailed information on the CPP
programme is provided through the Internet [59]. A description of the treatment, including
who might benefit, has been reported in several published articles [60-62] that belong to
the first theme of this thesis (Theme A; Chapters 2-4). These results gave us the motivation
to further study and to determine which patients from the larger population of people with
CLBP should be referred to these multidisciplinary bio-psychosocial programmes, which is
in line with the recommendations in international guidelines [55,63,64] and in the previously
mentioned Cochrane review [44]. This is the subject of the third part of this thesis (Theme C;
Chapter 9-11).

1.3 Outcomes of interventions for chronic low back pain

An important mechanism to improve interventions and with that the delivery of healthcare,
is to learn from practices proven to have the best outcomes in order to improve the overall 'quality of care' (i.e. benchmarking). The desired outcomes of interventions are the result of
a high-quality (infra) structure and process [65], reflecting the end result of care [66], and
are thought to matter most to patients and reflect all aspects of care [67,68]. The outcomes
of (spine) interventions could be regarded as a proxy for quality of care. Routine outcome measurement by means of well-designed outcome registries is challenging, but has well-documented benefits. For example, asking providers to systematically measure and report their outcomes has been shown to improve performance of the care delivered [67]. Furthermore, understanding and comparing outcomes facilitates continuous learning and improvement of the provider’s own strategies through benchmarking and learning from best practices. This type of continuous improvement and informed decision-making could be an important driving force for improving healthcare delivery by refocusing the system on ‘value’ (i.e. patient-related outcomes relative to costs [67,68]), especially in the area of low back pain where the current global burden of the condition, the practice variation, and growth in associated healthcare costs are unsustainable. The ability to define real-world ‘effectiveness’ (i.e. outcomes) of healthcare delivery is of utmost importance and gives the opportunity to assess the value of delivered healthcare, which is gaining in importance particularly within the realm of spine care [69,70].

**Measuring outcomes**

Human functioning and disability are central aspects of human life, and are key concerns in health and medicine. In numerous conditions, including CLBP, functioning or functional ability is not part of the disease process but is both a target and an outcome of health interventions. Therefore, the main health-related outcome domain used in the empirical and methodological studies of this thesis is functional ability. In CLBP, functional disability (i.e. disability) is characterised by pain of variable duration and by various activity limitations of daily life and participation restrictions. The health-related outcome domains that are relevant for patients with CLBP and clinicians include pain, functional ability, health-related quality of life [71-74], complications (including number of deaths) [73,74], repeat surgery (in spine surgery), work status, and analgesic use [74]. To evaluate these outcome domains over time and to achieve patient-centred care, patient-related outcomes such as patient-reported outcome measures (PROMs) are used. PROMs are used alongside the clinician-based measures (e.g. radiologic imaging, physical function tests) and aim to provide an objective measure of a subjective construct: that is, from the individual patient’s perspective and concerns in relationship to their health, healthcare and quality of life [75-77]. Well-designed PROMs have undergone rigorous testing and may be better validated, and as a result PROMs have greater
reproducibility than the so-called objective clinician-based measures [78,79]. PROMs provide a powerful, quantifiable and standardised research tool against which the effectiveness of healthcare interventions can be judged [77,80]. They facilitate comparison of results of different studies and also facilitate subsequent meta-analysis [79,81]. To evaluate individual patient care, PROMs can be used to support shared decision-making, communication and appropriate evaluation of individual treatment success [80].

To evaluate outcomes of interventions, generic or condition-specific PROMs can be used. Generic measures contain multiple concepts of health relevant to both patients and the general population, such as the MOS short-form 36 (SF-36) and the utility measure EuroQol 5 Dimensions (EQ5D) for CLBP. These measures support comparison of health between different patient groups, and between patient groups and the general population. Condition-specific measures are developed to evaluate the well-being of patients with a particular condition or disease. For example, in CLBP, functional ability is measured with condition-specific measures such as the Oswestry Disability Index and the Roland and Morris Disability Questionnaire [82]. However, limitations to the use of PROMs and the challenge to obtain sufficient follow-up responses are acknowledged. Some of these may be related to lack of data or lack of knowledge, and need further research. Such challenges include the myriad of (overlapping) PROMs used in evaluating interventions for CLBP [71], challenges of validation and understanding the association with long-term outcomes, and with that the predictive capacities of PROMs [83]. In this thesis, part B is dedicated to these challenges (Theme B; Chapter 5-7).

Patient-related outcome measures (both PROMs and clinician-based) need to be methodologically sound, that is they need to be based on good quality criteria (i.e. clinimetric properties). These criteria include: content validity, internal consistency, criterion validity, construct validity, reproducibility (agreement and reliability), responsiveness, floor and ceiling effects, and interpretability [84]. Score interpretation is a major challenge to the incorporation of PROMs into all settings; a challenge which is further confounded by growing evidence that patients and clinicians differ in their judgment of important change [85,86]. A patient’s interpretation of beneficial change or acceptable symptom state will be informed by his or her own definition of a ‘good outcome’. The tradition of reporting the statistical significance of score change does not necessarily translate into clinically meaningful change by the patient, the healthcare professional or other stakeholder. In fact, treatment success can be conceptualised in two ways: 1) relevant change or improvement, and 2) reaching an acceptable state. With the first concept, the emphasis is on whether or not an individual has relatively improved after an intervention, often expressed as reaching a minimal clinically important change, whereas with the second, the emphasis is on whether or not the achieved outcome is acceptable from the patient’s perspective [87], often expressed as reaching an absolute value. In this thesis, a chapter is dedicated to these concepts (Theme B; Chapter 8).

Collecting outcomes - Outcome registries

In systematic reviews, results of RCTs are pooled, analysed, and interpreted. In evidence-based medicine, RCTs are considered the gold standard for assessing the efficacy of interventions. However, some barriers for RCTs in spinal disorders are acknowledged, specifically when surgical procedures are involved. Examples are surgeon preferences, patients’ reluctance to randomisation, difficulties in blinding, high cost, the need for long-term follow-up and consequently the often high losses to follow-up, as well as the problem with cross-over [88].
Well-designed observational cohort studies, reflecting daily clinical practice, can reliably produce results similar to those of RCTs [89-91]. Such studies could be performed by means of an outcome registry. An outcome registry is an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s) [92]. In spine care, various national registries exist, such as the recently started Dutch Spine Surgery Registry in the Netherlands. Examples of large spine registries are the Swedish Spine Register (SweSpine) [93], the Spine Tango Spine Surgery Registry of Eurospine (the Spine Society of Europe) [94,95], and the multicentre adult spinal deformity database in the United States [96]. Recently published studies showed that the results of spine registries seem to be in concordance with those of the published RCTs [91,97-99]. When well designed, registry data can be used to reliably identify optimal treatments, to understand variations in treatment, and to describe care patterns, including identifying appropriateness of care and disparities in the delivery of care. Furthermore, when introducing new health interventions in healthcare, outcome registries are needed to continuously monitor the quality of the healthcare delivered to improve health outcomes [100,101] and, ultimately, to increase the value of the care delivered (i.e. outcome per unit cost [67]) [67,68,70,101,102]. In this thesis the impact and methodology of spine outcome registries are studied (Theme B; Chapter 5).

**Predicting outcomes**

It is assumed that with more precise targeting of interventions, patient outcomes improve and so too the efficiency of the healthcare. Classifying the heterogeneous CLBP-population into more homogeneous subgroups, based on their profiles, would support patient triage and guide treatment, as much as any classification system in healthcare aims to do. To distinguish patient profiles, several outcome-based classifications for decision making exist and some aim to identify profiles based on patho-anatomy and biomedical indicators [103]. Some classifications are based on the prognostic course of back pain, e.g. those aimed at the risk of chronicity [104], whilst others aim to identify patients likely to respond favourably to particular interventions [105]. All of them have been developed and studied as a guide for non-surgical interventions applied in primary care [106]. Although these attempts have been made, and some of them seem to be successful [104], the optimal classification system still remains elusive and large numbers of patients consult secondary or tertiary spine care medical specialists to help them solve their CLBP-problem. Different patient profiles might be identified which are likely to benefit from different recommended interventions [39, 44,50,55,63,106]. Ideally, these profiles are based on aetiological and prognostic evidence and on evidence of indicators modifying the effects of interventions. As a challenge, the major recommendation for future research has been to focus on classification systems, which guide the right patient to appropriate surgical or nonsurgical interventions. The rationale is that this has the greatest potential for improving outcomes [106]. A research programme of the spine unit in Sint Maartenskliniek has focussed on the development of such a classification system, and the third theme of this thesis is dedicated to this challenge (Theme C; Chapter 9-11).
1.4 Aims and Outline

The ultimate aim of this thesis is to contribute to the body of knowledge on outcomes of interventions for CLBP and to identify outcome-based subgroups characterised by different patient profiles within the heterogeneous CLBP population.

Outline of this thesis

The thesis consists of three related themes (A-C) with a total of twelve chapters, including the General introduction and the Summary and General discussion. In Chapter 1, the General introduction, an overview of CLBP as the topic of this thesis is given and this sets the scene for the studies described in themes A-C, including (systematic) literature reviews, empirical, and methodological studies. The thesis follows the chronological framework of the research programme, which is the basis for this thesis. First, a combined physical and psychological (CPP) programme was evaluated and a subgroup of patients benefitting from this programme was identified (Theme A). Subsequently, methodological considerations were studied regarding outcomes and outcomes assessment (Theme B). Finally, through a literature search and a formal consensus procedure, indicators contributing to treatment outcome were identified. These indicators were used to develop a classification system for patient triage to surgical and non-surgical interventions (Theme C).

THEME A: Introduction of a combined physical and psychological programme (Chapter 2-4)

This theme includes empirical studies in which, amongst others, continuous outcome monitoring is performed after introduction of a new intervention for patients with CLBP — the intensive combined physical and psychological (CPP) programme as provided by RealHealth NL.

The overall research question of this part is twofold:
1. Does the novel CPP programme for CLBP improve patient outcomes and reduce healthcare consumption?
2. Is it possible to identify a subgroup of patients that benefits most from the novel CPP programme so that selection criteria can be optimised?

The specific study aims:

• To evaluate the outcomes of a new intensive CPP pain management programme for CLBP patients and whether this is reflected in the use of healthcare services (Chapter 2).
• To evaluate the stability of the two-year follow-up results of a short, intensive cognitive behavioural pain management programme. The emphasis is on evaluating daily functioning, the use of healthcare services, and the use of pain medication two years after the intervention (Chapter 3).
• To determine the factors which predict a successful 1-year outcome from this new intervention with the goal of refining the selection criteria (Chapter 4).

THEME B: Outcomes assessment (Chapter 5-8)

This theme includes a literature study with a qualitative survey, and empirical and methodological studies to clarify the ambiguity of and recommendations to standardise outcomes assessment in secondary or tertiary level spine care.
The overall research question of this part is threefold:
1. What is the current value and methodology of spine outcome registries in clinical practice?
2. Which patient-related outcome measures should be used for outcomes assessment for degenerative lumbar spine disorders?
3. Which criterion can be used to define a successful outcome of interventions for patients with degenerative lumbar spine disorders?

The specific study aims:
• To evaluate the available evidence for the effects of introducing and using spine registries on patient-related outcomes, and to provide a set of methodological recommendations to improve spine registries (Chapter 5).
• To propose a set of patient-related outcomes for use in daily spine care and for research purposes (Chapter 6).
• To translate and adapt a patient-reported outcome measure in the functional outcome domain, the Oswestry Disability Index (ODI; version 2.1a), into the Dutch language and to investigate the validity and internal consistency of the translation (Chapter 7).
• To estimate the score on the ODI version 2.1a corresponding to a ‘patient acceptable symptom state’ (PASS) in patients undergoing surgery for degenerative disorders of the lumbar spine (Chapter 8).

THEME C: Prediction of outcomes (Chapter 9-11)
This theme includes a literature study and empirical studies in which the development and validation of a new triage tool is studied for secondary or tertiary spine care specialists.

The overall research question of this theme:
1. Is it possible to develop a triage tool for CLBP, which enables valid and reliable identification of patient profiles that supports triage of the patients to a spine surgeon or to non-surgical specialists?

The specific study aims:
• To develop a decision tool for secondary or tertiary spine care specialists to decide which patients with CLBP should be seen by a spine surgeon or by non-surgical medical specialists (Chapter 9).
• To provide preliminary insight into the factors considered by CLBP-experts when deciding whether or not to refer a patient to spinal surgery (Chapter 10).
• To identify patient profiles which are associated with and predictive for treatment ‘response’ or ‘non-response’ when referred to either a surgical intervention or a non-surgical intervention (Chapter 11).

In the Summary & General discussion, Chapter 12, the results of the studies performed and described in the previous chapters are discussed and their implications for generalisability of the study results, for research, and for clinical practice are considered. In Key points thesis an overview of this thesis is shown by summarising per the themes ‘What is already known on this topic’ and ‘What this thesis adds’.
<table>
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<th>Diagnosis</th>
<th>Comparison</th>
<th>Outcome</th>
<th>Effect size (SMD)</th>
<th>95% CI</th>
<th>Remark</th>
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<td>Good result at 1.5 - 2 yr</td>
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<td>0.07 - 0.43</td>
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CLBP, chronic low back pain; SMD, standardised mean difference; CI, confidence interval; PT, physical therapy; multidisc., multidisciplinary; prgm., programme; yr, year; ODI, Oswestry Disability Index
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General introduction

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