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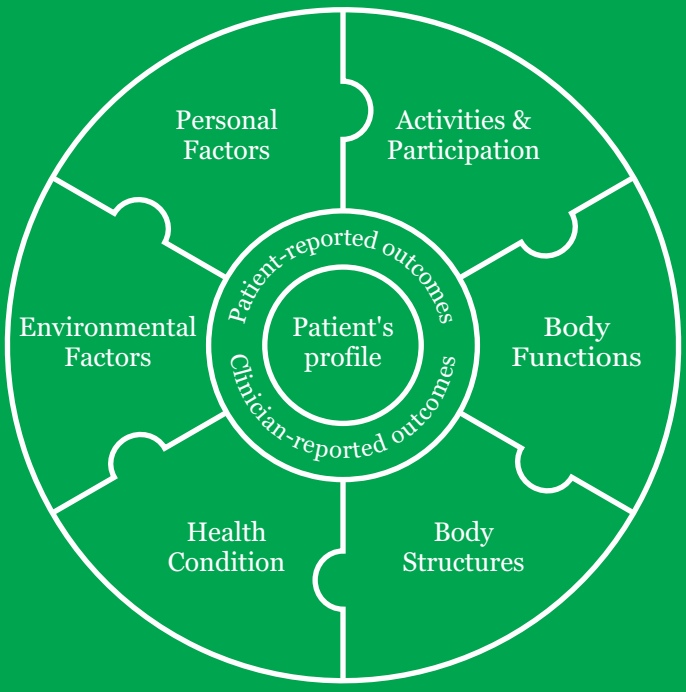
Biopsychosocial and patient-centred approach to assessment of patients with low back pain

– Development, implementation, field-testing and evaluation of the low back pain assessment tool



PhD dissertation
Charlotte Ibsen

Health · Aarhus University · 2020

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Supervisors

Thomas Maribo, Associate Professor, PT, PhD
Department of Public health, Aarhus University & DEFACTUM, Central Denmark Region, Aarhus, Denmark

Berit Schiøttz-Christensen, Professor, MD, PhD
Department of Regional Health Research, University of Southern Denmark, Odense & Spine Centre of Southern Denmark, Lillebaelt Hospital, Middelfart, Denmark

Claus Vinther Nielsen, Professor, MD, PhD
Department of Public health, Aarhus University & DEFACTUM, Central Denmark Region, Aarhus, Denmark

Mogens Hørder, Professor, MD, DMSc
Department of Public Health, Unit of User Perspectives, University of Southern Denmark, Odense, Denmark

Assessment Committee

Ellen Margrethe Hauge, Professor, PhD (Chairman)
Department of Clinical Medicine, Aarhus University, Aarhus, Denmark & Department of Rheumatology, Aarhus University Hospital Skejby, Aarhus, Denmark

Jan Hartvigsen, Professor, D.C, PhD
Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark & Nordic Institute of Chiropractic and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark.

Reuben Escorpizo, Clinical Associate Professor
Department of Rehabilitation and Movement Science, College of Nursing and health Sciences, University of Vermont, Burlington, USA & Swiss Paraplegic Research, Nottwill, Switzerland

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Charlotte Ibsen, August 2020

This dissertation is based on the following studies

I. "Keep it simple": Perspectives of patients with low back pain on how to qualify a patient-centred consultation using patient-reported outcomes.

Ibsen, C., Schiøttz-Christensen, B., Maribo, T., Vinther Nielsen, C., Hørder, M., Handberg, C.
Published: Musculoskeletal Care. 2019 August 20. doi: 10.1002/msc.1417

II. Assessment of functioning and disability in patients with low back pain – the low back pain assessment tool. Part 1: Development.

Ibsen, C., Schiøttz-Christensen, B., Vinther Nielsen, C., Hørder, M., Schmidt, A.M., Maribo, T.
Submitted: Disability and Rehabilitation, 9 March 2020 (in review)

III. Assessment of functioning and disability in patients with low back pain – the low back pain assessment tool. Part 2: Implementation.

Ibsen, C., Schiøttz-Christensen, B., Vinther Nielsen, C., Hørder, M., Maribo, T.
Submitted: Disability and Rehabilitation, 9 March 2020 (in review)

IV. Consultations facilitated by the low back pain assessment tool enhance use of patient-reported outcomes and shared decision-making. Results from a non-randomised controlled study.

Ibsen, C., Maribo, T., Vinther Nielsen, C., Hørder, M., Schiøttz-Christensen, B.
Submitted: Disability and Rehabilitation, 9 March 2020 (in review)

The studies are provided in appendices 1-4.

Abbreviations

ClinROs	Clinician-reported outcomes
ClinRO-LBP	Clinician-reported outcome instrument developed in this dissertation
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
i-PARISH	The integrated Promoting Action on Research Implementation in Health Services
LBP	Low back pain
NRS	Numeric rating scale
ODI	Oswestry Disability Index
Patient profile LBP	Patient profile developed in this dissertation
PEC	Patient evaluation questionnaire
PCC	Patient-centred care
PPI	Patient and public involvement
PROMIS	Patient-Reported Outcomes Measurement Information System
PROs	Patient-reported outcomes
PRO-LBP	Patient-reported outcome instrument developed in this dissertation
RCT	Randomised controlled trial
RMDQ	Roland Morris Disability Questionnaire
SDM-Q-9	Shared Decision-Making Questionnaire
SI-questionnaire	Successful implementation questionnaire
SpineData	Clinical registry implemented at the Medical Department of the Spine Centre
SpineData PRO	Patient-reported outcome questionnaire implemented at the Spine Centre, part of SpineData
VAS	Visual analogue scale
WHO	World Health Organization
WORQ	Work Rehabilitation Questionnaire

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English summary

Background

Low back pain (LBP) is a multidimensional symptom. Consequently, it is recommended to use a biopsychosocial and patient-centred approach to assess and manage LBP.

The International Classification of Functioning, Disability and Health (ICF) provide a biopsychosocial model and classification for describing functioning and disability. ICF is widely acknowledged, but implementation into clinical practice is lacking. To enhance implementation, ICF core sets have been developed, including a core set for LBP and a Rehabilitation set. ICF core sets tell what to measure but not how to measure. As a result, development of practice-friendly tools to facilitate the use of ICF core sets has been recommended.

Patient-reported outcomes (PROs) are considered a key component of patient-centred care. PROs used during the consultation turns the focus towards the patient's life experiences, identify information that may otherwise have been overlooked, enhance patient-clinician communication and facilitate shared decision-making. For PRO instruments to be patient-centred they have to incorporate the patient perspective; however, patients are rarely involved in the development of PRO instruments. Established LBP-specific PRO instruments mainly focus on pain and activity limitations; thus, they may not be adequate to assess functioning and disability as conceptualised by ICF. To cover the wide spectrum of biopsychosocial perspectives affecting patients with LBP, information from both patients and health professionals is recommended. A tool that combines information from patients and health professionals covering all components provided by ICF has not yet been developed. Therefore, we developed the LBP assessment tool including three features: a PRO instrument, a clinician-reported outcome instrument and a patient profile displaying the patient’s functioning and disability.

The aims of this dissertation were: 1) to explore the perspectives of patients with LBP to gain an understanding of how to qualify a patient-centred consultation using PROs, 2) to outline the evidence-based and systematic process used to develop the LBP assessment tool, 3) to assess the degree of successful implementation after three months and evaluate feasibility of the features in the LBP assessment tool and 4) to evaluate whether consultations facilitated by the LBP assessment tool can enhance use of patient-reported outcomes and shared decision-making.

Methods

Study I comprises focus group interviews with seven patients with LBP and we used the 'Interpretive description' method in the analysis.

Study II is a development study including the following elements: definition of construct and content, literature search, item generation, needs assessment, piloting and adaptations as well as design and technical production. The LBP assessment tool was based on ICF categories from the Comprehensive LBP core set and the Rehabilitation set.

Study III is an implementation study. We used the 'integrated Promoting Action on Research Implementation in Health Services' (i-PARISH) framework to assist the implementation. The implementation process comprised four key steps: feasibility-testing, training of health professionals, field-testing and feedback meeting. Field-testing provided data to assess successful implementation and feasibility of the tool.

Study IV is a non-randomised controlled study where 531 patients were allocated to either consultations facilitated by the LBP assessment tool (intervention group) or conventional consultations (control group). The groups were observed in the same setting but at different periods of time. Primary outcome was use of PROs during consultations. Secondary outcomes were use of a graphical overview presenting the individual patient's profile and shared decision-making. The primary and secondary outcomes were measured by a patient evaluation questionnaire.

Results

In Study I, three central themes emerged: simplicity, individuality and application. *Simplicity* symbolised keeping items to a minimum and avoiding item overlaps; *individuality* implied the need for self-identified concerns and *application* denoted that PROs should be used during the consultation.

In Study II, the development process comprised five steps. In total, 18 patients and 12 health professionals were involved in the development of the LBP assessment tool. The tool covered all ICF components. In Study III, feasibility-testing resulted in minor adaptations. Health professional training revealed that the LBP assessment tool was ready for field-testing. Field-testing included 152 patients and seven health professionals. In total, 79 % (n=138) of the patients reported that their PRO data were used in the consultation, whereas 69 % (n=134) were presented to their own data from the patient profile LBP. The LBP assessment tool was feasible to patients and health professionals. The feedback meeting showed that the tool supported health professionals to apply a biopsychosocial approach leading to a consultation based on the patient perspective.

In Study IV, 299 patients were allocated to the intervention group and 232 to the control group. In total, 235 patients from the intervention group (82 %) and 141 from the control group (61 %) completed the patient evaluation questionnaire. The intervention group reported a significantly higher use of their PRO data ($p<0.00$) and patient profile ($p<0.00$) compared with the control group. The intervention group also experienced to be more involved in decision-making ($p=0.01$).

Conclusion

This dissertation introduces the LBP assessment tool, which is the first evidence-based tool to address all ICF components and combine biopsychosocial perspectives provided by patients and health professionals for use in routine assessment. Firstly, perspectives of patients with LBP and health professionals from the Spine Centre of Southern Denmark informed the development of the LBP assessment tool. Secondly, the tool facilitated the implementation of ICF core sets in clinical practice among patients with LBP. Thirdly, the LBP assessment tool was found feasible for routine clinical practice by patients and health professionals. However, successful implementation was not reached after three months. Thus, more attention should be paid to facilitation and training of health professionals and a longer implementation time was also required. Finally, consultations facilitated by the LBP assessment tool enhanced the use of PROs and shared decision-making compared with standard care.

In conclusion, the LBP assessment tool facilitated a smooth and positive consultation based on the patient perspective. Moreover, it supported health professionals to apply a biopsychosocial and patient-centred approach.

Dansk resumé

Baggrund

Lænderygsmerter er et komplekst symptom. Derfor anbefales det at anvende en biopsykosocial og patientcentreret tilgang til udredning, behandling og rehabilitering af patienter med lænderygsmerter.

International Klassifikation af Funktionsevne, Funktionsevnenedsættelse og Helbredstilstand (ICF) er en international biopsykosocial model og klassifikation til beskrivelse af funktionsevne og funktionsevnenedsættelse. ICF er anerkendt, men implementering i klinisk praksis er mangelfuld. For at øge implementeringen er der blevet udviklet ICF core set; inklusiv et core set til lænderygsmerter og et Rehabilitering set. ICF core set beskriver, hvad der skal måles, men ikke hvordan der skal måles. Derfor anbefales det, at der udvikles praksisvenlige redskaber til at lette brugen af ICF core set i klinisk praksis.

Patientrapporterede oplysninger (PRO) betragtes som en nøglekomponent i patientcentreret praksis. PRO data, der anvendes direkte i konsultationen, øger fokus på patienters livserfaringer, identificerer oplysninger, der ellers kunne være blevet overset, forbedrer patient-kliniker kommunikation og kan være med til at øge graden af fælles beslutningstagning. For at PRO instrumenter er patientcentreret, skal patientens perspektiv adresseres; patienter er dog sjældent involveret i udviklingen af PRO instrumenter. Etablerede lænderyg-specifikke PRO instrumenter fokuserer hovedsageligt på smerter og aktivitetsbegrænsninger, hvorfor de ikke vurderer funktionsevne og funktionsevnenedsættelse, som beskrevet ud fra ICF. For at dække det brede spektrum af biopsykosociale perspektiver, der påvirker patienter med lænderygsmerter anbefales det at indsamle oplysninger fra både patienter og sundhedsprofessionelle. Et redskab, som kombinerer oplysninger fra patienter og sundhedsprofessionelle, og som dækker alle ICF komponenter, er endnu ikke blevet udviklet til patienter med lænderygsmerter. Derfor udviklede vi lænderyg-udredningsredskabet, som er opbygget af tre features: et PRO instrument, et kliniker-rapporteret instrument og en patientprofil, som viser patientens funktionsevne og funktionsevnenedsættelse.

Formålet med denne afhandling var at: 1) udforske perspektiverne hos patienter med lænderygsmerter, for at få en forståelse af, hvordan man kan kvalificere en patientcentreret konsultation ved hjælp af PRO data, 2) skitsere den evidensbaserede og systematiske proces, der blev anvendt til at udvikle lænderyg-udredningsredskabet, 3) vurdere hvor vellykket implementering af lænderyg-udredningsredskabet er efter tre måneder samt evaluere gennemførbarheden af de tre features i lænderyg-udredningsredskabet samt at 4) evaluere, om

konsultationer, der faciliteres af lænderyg-udredningsredskabet, kan forbedre brugen af PRO data og fælles beslutningstagning.

Metode

Studie I bestod af fokusgruppeinterviews med syv patienter med lænderygsmerter. Forskningsmetodologien 'Interpretive description' blev anvendt til dataanalyse.

Studie II var et udviklingsstudie. Følgende elementer skulle adresseres i udviklingen af lænderyg-udredningsredskabet: definition af område og indhold, litteratursøgning, spørgsmålsgenerering, behovsvurdering, pilottest, justeringer samt design og teknisk produktion. Lænderyg-udredningsredskabet var baseret på ICF kategorier fra Comprehensive core set til lænderygsmerter og Rehabiliteringssættet.

Studie III var et implementeringsstudie. Vi anvendte implementeringsrammen 'integrated Promoting Action on Research Implementation in Health Services' (i-PARISH) til at understøtte implementeringen. Implementeringsprocessen bestod af fire nøgletrin: test af gennemførbarhed, undervisning af sundhedsprofessionelle, afprøvning i praksis og et feedback møde. Afprøvning i klinisk praksis leverede data til vurdering af graden af succesfuld implementering efter 3 måneder samt vurdering af redskabet gennemførbarhed.

Studie IV var et ikke-randomiseret kontrolleret studie, hvor 531 patienter blev fordelt til en konsultation der blev faciliteret af lænderyg-udredningsredskabet (interventionsgruppe) eller en konventionel lænderyg konsultation (kontrolgruppe). Grupperne blev observeret i samme kliniske praksis, men på forskellige tidspunkter. Primært outcome var brugen af PRO data under konsultationen. Sekundære outcomes var brug af den grafiske oversigt, der præsenterede den enkelte patients profil samt fælles beslutningstagning. De primære og sekundære outcomes blev målt ved hjælp af et patientevalueringsspørgeskema.

Resultater

Fokusgruppeinterviews med patienterne (Studie I) identificerede centrale temaer: enkelhed, individualitet og anvendelse. *Enkelhed* symboliserede at holde antal spørgsmål på et minimum og undgå overlap af spørgsmål; *individualitet* indebar behovet for at kunne beskrive områder af betydning for den enkelte patient og *anvendelse* betød, at PRO data skulle bruges under konsultationen. I udviklingsstudiet (Studie II) omfattede udviklingsprocessen fem trin. I alt var 18 patienter og 12 sundhedsprofessionelle involveret i udviklingen af lænderyg-udredningsredskabet. Redskabet dækkede alle ICF-komponenterne. I implementeringsstudiet (Studie III) medførte gennemførbarhedstesten mindre justeringer. Undervisning og træning af de

sundhedsprofessionelle viste, at lænderyg-udredningsredskabet var klar til afprøvning i klinisk praksis. Afprøvningen inkluderede 152 patienter og syv sundhedsprofessionelle. I alt 79 % (n=138) af patienterne rapporterede, at deres PRO data blev brugt i konsultationen, mens 69 % (n=134) fik vist deres egne data fra patientprofilen. Patienter og sundhedsprofessionelle fandt lænderyg-udredningsredskabet var anvendeligt. Feedbackmødet afslørede, at redskabet understøttede de sundhedsprofessionelle i at anvende en biopsykosocial tilgang, hvilket førte til en konsultation der var baseret på patienternes perspektiv. I det ikke-randomiseret kontrolleret studie (Studie IV) blev 299 patienter fordelt til interventionsgruppen og 232 til kontrolgruppen. I alt 235 patienter fra interventionsgruppen
(82 %) og 141 fra kontrolgruppen (61 %) udfyldte patientevalueringsspørgeskemaet. Interventionsgruppen rapporterede en signifikant højere anvendelse af deres PRO data (p<0,00) og anvendelse af patientprofilen (p<0,00) sammenlignet med kontrolgruppen. Interventionsgruppen oplevede også at være mere involveret i fælles beslutningstagning (p=0,01).

Konklusion

Denne afhandling resulterede i lænderyg-udredningsredskabet; det første evidensbaserede redskab der adresserer alle ICF-komponenter og kombinerer biopsykosociale perspektiver fra patienter og sundhedsprofessionelle, der skal anvendes i rutinemæssig udredning af patienter med lænderygsmerter. For det første bidrog patienter med lænderygsmerter og sundhedsprofessionelle fra Rygcenter Syddanmark til udviklingen af lænderyg-udredningsredskabet. For det andet faciliterede redskabet anvendelse af ICF core set i klinisk praksis, hvilket medfører at redskabet har potentiale til at levere internationalt sammenlignelige data om funktionsevne og funktionsevnenedsættelse blandt patienter med lænderygsmerter. For det tredje fandt patienter og sundhedsprofessionelle lænderyg-udredningsredskabet anvendelig i klinisk praksis. Imidlertid opnåede vi ikke succesfuld implementering efter tre måneder, hvilket indikerede at der var behov for mere facilitering, undervisning og træning af sundhedsprofessionelle samt længere implementeringsperiode. Endelig viste det sig at i de konsultationer, der blev faciliteret af lænderyg-udredningsredskabet var der et øget brug af PRO data og fælles beslutningstagning sammenlignet med standard konsultationer.

Det konkluderes, at lænderyg-udredningsredskabet lykkedes med at facilitere en god og positiv konsultation baseret på patientens perspektiv, samt at redskabet understøttede de sundhedsprofessionelle i at anvende en biopsykosocial og patientcentreret tilgang.

1. Motivation for this PhD dissertation

"Stop seeing low back pain solely through a medical lens"

Professor Nadine Foster, Nordic Back Pain Seminar 2018

This quotation fits well with the idea of this dissertation, although my motivation to make this dissertation began long before I learned about the quotation. I was motivated by the aspiration to provide a concrete tool to facilitate a biopsychosocial and patient-centred approach to patients with LBP. I wanted to contribute with new knowledge to the existing body of evidence on LBP, and ultimately contribute to the research efforts towards reducing the substantial impact LBP has on patients' lives, their relatives and communities as well as healthcare and social systems.

Worldwide, LBP is a prevalent and burdensome symptom for individuals and society [1,2]. It is widely acknowledged that LBP is a multidimensional symptom influenced by different factors [1], which are unique to each patient [3]. To deal with this heterogeneity, a biopsychosocial and patient-centred approach has been recommended to assess and manage LBP [1,4]. In 2001, World Health Organization (WHO) presented the International Classification of Functioning, Disability and Health (ICF), which is a biopsychosocial model for describing functioning and disability [5]. Despite agreement to apply a biopsychosocial and patient-centred approach, the biomedical approach to managing LBP is still predominant in current clinical practice [6]. Consequently, tools to enhance implementation of the biopsychosocial approach into clinical practice are warranted [7]. However, a tool that combines the biopsychosocial and the patient-centred approach has not yet been developed for patients with LBP.

The planning of this dissertation began in 2014 when Associate professor Thomas Maribo (main supervisor) introduced me to Professor Berit Schiøttz-Christensen (co-supervisor). For years she had encouraged health professionals, managers and organisations within LBP to shift from a biomedical to a biopsychosocial and patient-centred approach. Unfortunately, her great effort had not yet gained acceptance and we discussed how we could facilitate implementation of the biopsychosocial approach into clinical practice. ICF constituted the basis for our discussions [5]. ICF recognises that functioning is a dynamic interaction between a person's health condition, environmental factors and personal factors. This understanding illustrates the complexity of LBP. To support a patient-centred approach, we also wanted to facilitate patient involvement by using patient-reported outcomes (PROs) and shared decision-making during the consultation with patients with LBP [8,9]. Initially, we investigated the content of established LBP-specific PRO instruments according to ICF. We published our results in 2016, and the main conclusion was that the investigated PRO instruments covered 33% of ICF [10]. These findings were in accordance with

previous studies, concluding that LBP-specific PRO instruments primarily focus on pain and activity limitations rather than on functioning and disability as conceptualised by ICF [11,12].

As a direct consequence of our previous findings [10], discussions and the existing body of evidence, we decided to develop a new ICF-based assessment tool to facilitate a biopsychosocial and patient-centred approach to patient with LBP. It was also essential to implement, field-test and evaluate the tool in routine clinical practice. We named the tool the *LBP assessment tool.*

2. Introduction

2.1 Low Back Pain

LBP is a very common symptom experienced by approximately 80 % of the general population at least once during their lifetime [1,2]. Globally, LBP is ranked as the leading cause of disability [1,13]. In 2015, LBP accounted for nearby 60 million years lived with disability; an increase of 54 % since 1990 [2]. Disability caused by LBP is highest among people at working age and in Europe, LBP is the most common source of sick leave and early retirement [2,14]. Estimates from Denmark show that 880,000 people live with LBP [15]. Additionally, LBP is the most common cause of sick leave, it accounts for approximately 6 % of the total early retirement benefits, and it is also the most frequent reason for contacting the general practitioner [15].

Patients with LBP report disability such as reduced activity and participation in everyday life, affecting both social and work life. Moreover, LBP may have psychosocial consequences such as anxiety and depression [1,16,17]. Consequently, LBP impacts extensively on the everyday life of patients and their relatives, communities as well as healthcare systems [1,13]. Thus, healthcare systems face challenges due to the major financial burden of LBP as a major public health issue [1].

In most patients, a specific cause of LBP cannot be identified [18]. In a small number of patients with persistent LBP a serious cause can be identified [1,19]. Thus, there is growing evidence that LBP is a multidimensional symptom characterised by a complex interaction between biological, psychological, social, environmental and personal factors [1,7,20]. The contribution of these factors is unique to each patient [3,7]. Consequently, assessment and management of patients with LBP should be considered within a biopsychosocial and patient-centred approach instead of the more traditional biomedical approach [4,21,22]. The biopsychosocial and the patient-centred approaches are both rooted within the holistic perspective and emphasise the importance of active involvement of patients in their own care [22]. In the following, the biopsychosocial as well as the patient-centred approach will be presented in more detail.

2.2 The biopsychosocial approach

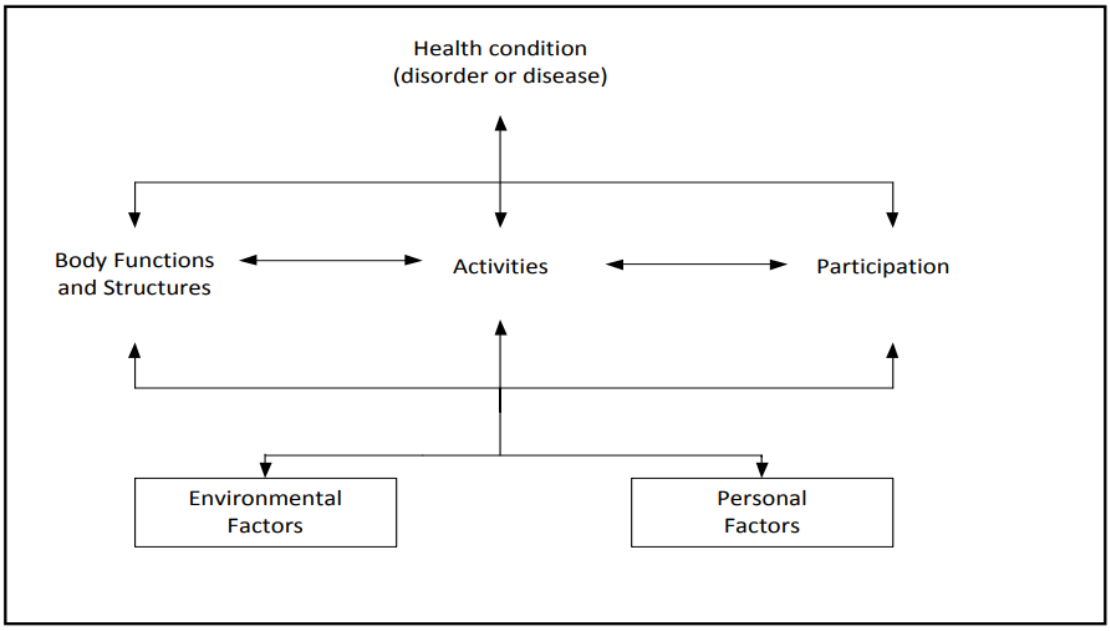
The biopsychosocial approach was introduced in the 1970s to extend the traditional biomedical model [23]. The biopsychosocial approach is based on a holistic view where illness and health are considered as interactions between biological, psychological, and social factors important to the individual patient [23,24]. In 1987, Waddell presented the biopsychosocial model of LBP, suggesting that LBP should be understood in a broader sense [25]. The biopsychosocial model of LBP thus marked an essential change in the understanding of LBP [25]. Nevertheless, widespread

acceptance and implementation of the model into research and everyday clinical practice is lacking [7,26]. The biopsychosocial model has evolved during the years and in 2001, WHO introduced the ICF biopsychosocial model of functioning and disability [5].

2.2.1 The ICF biopsychosocial model

ICF builds upon the biopsychosocial model of functioning and disability but it also provides a comprehensive, universal and internationally accepted classification for framing and describing functioning and disability [5]. ICF is part of the WHO family of international classifications, such as the International Classification of Diseases (ICD) [27]. ICF has moved the concept of disability away from just being a result of a specific health condition to now recognise it as the interaction of a person's health and functioning combined with environmental and personal factors [5] (Figure 1).

Figure 1. The ICF diagram; Interaction between ICF components [5]



ICF is organised in two parts and each part has two components [5]. Part 1 -'functioning and disability', are umbrella terms covering the components 'body functions', 'body structures' and 'activities and participation'. They are the result of a dynamic interaction between a person's health condition and contextual factors, which forms Part 2. Part 2 - 'contextual factors' comprise the components 'environmental factors' and 'personal factors'. The dynamic interaction between the components of ICF means that changes in one component may potentially modify one or more of the other components [28]. Each component is structured in various domains, which each contain several ICF categories which are the units of the classification [5]. The structure and categories of ICF is illustrated in Table 1, using the domain *b2 Sensory functions and pain* as an example.

Table 1. An example of structure and categories of ICF

Part 1	Functioning and disability
Component	Body functions and structures
	Body functions
Domains	b1 - b8
	b2 Sensory functions and pain
ICF categories	
2nd level	b280 Sensation of pain
3rd level	b2801 Pain in body part
4th level	b28013 Pain in back

Each ICF category has a short definition, except for the component 'body structures', comprising inclusions and exclusions to clarify the content. Although 'personal factors' are recognised in ICF they are not classified; they relate to the individual 's life and living such as age, gender, health conditions, habits, education and lifestyle [5].

Even though ICF is widely accepted, its applicability in everyday clinical practice is still limited [29,30]. This can be due to the comprehensiveness of the ICF classification with more than 1450 ICF categories [31]. To facilitate implementation of ICF in clinical practice, ICF core sets have been developed [32].

2.2.2 ICF core sets

ICF core sets are shortlists of essential categories from the entire ICF classification describing functioning and disability [32]. Condition-specific ICF core sets such as the LBP core set [33], and context-specific core sets such as the Rehabilitation set [34] have been developed. Comprehensive and brief versions are provided for the condition-specific ICF core sets. Comprehensive core sets include ICF categories with extensive descriptions to be used for multidisciplinary assessments. Brief core sets comprise the most essential categories and serve as a minimum standard for describing functioning. All categories contained in ICF core sets are 2nd level categories (Table 1).

The LBP core set

The LBP core set was developed in 2004 by experts from 15 countries [33]. The experts decided which categories to include in the LBP core set followed by a formal decision-making and consensus process, integrating results from three preparatory studies [35-37]. In total, 78 categories were selected for the Comprehensive LBP core set, of which 35 were included in the brief core set [33]. The 78 categories included 19 categories from the component 'body functions', 5 from 'body structures', 29 from 'activities and participation' and 25 from 'environmental factors' [33].

The content validity of the LBP core set is supported by the literature and the included categories comprehensively cover the aspect of functioning relevant to both patients [38,39] and health professionals [40-42]. Furthermore, the LBP core set appears to broaden the perspective of participation and environmental factors in the assessment [43]. Evidence also supports the structural validity of the LBP core set to be used as a measurement instrument by health professionals [44-46]. Two recently published studies showed that patients with LBP were able to provide reliable ratings on operational items regarding activity and participation using categories from the LBP core set [47,48]. However, further research is needed to investigate patients' rating of other ICF components such as the 'environmental factors component [47] in addition to the overall application of the LBP core set in routine clinical practice [39].

The Rehabilitation set

The Rehabilitation set was developed in 2016 [34] and serves as a generic minimum set of categories to describe functioning in the context of rehabilitation and disability across various health conditions and along the continuum of care [34]. The Rehabilitation set was based on secondary analyses of existing data sets using regression analyses and expert consultations [34]. In total, 30 categories were included in the Rehabilitation set, of which 9 were from 'body functions' and 21 from 'activities and participation' [49].

Due to its novelty, literature on the Rehabilitation set [34] is relatively sparse [50-55]. Three studies have described development of 'simple, intuitive descriptions' of ICF categories to inform widespread implementation of the Rehabilitation set [52,54,55]. One study developed operational items, including specific questions and response options [50] and another study presented a clinical assessment schedule [51]. A recent study provided a four-step approach based on the Rehabilitation set, which may serve as a model when planning the documentation of functioning using ICF as a reference in research and clinical practice [53]. These studies are the first stepping stones towards application of the Rehabilitation set in clinical practice, although further research is needed [52].

ICF core sets as measurement instruments

An ICF core set defines *what to assess* [56], not *how to measure* [57]. Therefore, ICF qualifiers to record the extent of functioning or disability in a given category ranging from 0 "no problem" to 4 "complete problem" were presented [5]. However, concerns about the reliability and validity of ICF qualifiers have been raised [58,59]. Moreover, ICF categories alone are not operational items and may thus be difficult to assess and use in everyday clinical practice. Consequently, further specification of ICF categories in a user-friendly language, including operational items and response options, is required to promote their use in routine clinical practice [52,54,55].

2.3 Patient-centred approach

Worldwide, patient-centred care (PCC) is high on the political agenda and is one of the six core domains[1] [60] of high quality healthcare [60,61]. The Institute of Medicine has defined PCC as: "*Providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions*" [60]. PCC originates from a holistic approach and underpins application of a biopsychosocial rather than a purely biomedical perspective [62]. Furthermore, the most important attribute of PCC is the active involvement of patients in the care process [22]. Implementing PCC has several benefits for both patients and health professionals [63-66]. PCC innovations have shown improved patient-clinician communication, higher patient satisfaction, adherence to treatment and improved health outcomes [65-67]. For health professionals, PCC may facilitate a more effective addressing of the patients' needs [68]. Despite the known benefits of PCC, the concept is not fully implemented [63]. One of the main challenges is that many health professionals do not work in a patient-centred way, failing to listen to patients' concerns and to discuss treatment options [64,66].

The growing interest in developing a more patient-centred approach in healthcare systems [61] has resulted in increased attention to the use of patient-reported outcomes (PROs)[69]. PROs are considered a key component of PCC due to their focus on patients' life experiences [61,70,71].

2.4 Patient-reported outcomes

A PRO is defined as *"any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else*" [72].

PROs are measured by PRO instruments, which are often standardised questionnaires [73]. Originally, PRO instruments were developed for research purposes to measure treatment effectiveness [71]. However, there is a growing interest in using PROs directly during the consultation to support management of the individual patient [74-76]. PROs can provide new information that may otherwise have been overlooked [74], enhance patient-clinician communication and facilitate shared decision-making [69,77-79]. Additionally, filling in questionnaires prior to a consultation may enable patients to reflect on their own symptoms, to identify issues and prioritise the issues they wish to share with health professionals during the consultation [71,80]. Moreover, PROs can be used as a tool to increase the awareness of health professionals to patient concerns when PRO data are presented prior to or during the consultation.

[1] The Institute of Medicine (IOM), includes the following six aims for the health care system: 1) Safe; 2) Effective; 3) Patient-centered; 4) Timely; 5) Efficient and 5) Equitable [59]

This attention can facilitate that health professionals explore and discuss these concerns [81] and use the information to refer patients to other services or to change the treatment or rehabilitation plan [71].

Regardless of the potential benefits of PROs, evidence shows that implementation has not yet been successfully accomplished in clinical practice [82]. Therefore, focus has been on identifying factors to facilitate successful implementation of PROs [71,83-87]. A recent systematic review identified the necessity of investing time and resources, preparing the organisation, training staff in the use, validity and value of PROs as well as investing in systems to support the implementation process [82]. Furthermore, feasibility-testing prior to launching PRO systems [88], to appoint a facilitator to lead the implementation as well as feedback meetings with health professionals were found to be essential elements of the implementation process [82]. Finally, graphical presentation of PROs has been shown to facilitate interpretation of PRO data, and thus facilitate application in clinical practice [86].

2.4.1 Development of PRO instruments

For PRO instruments to be patient-centred they have to truly incorporate the patient perspective [89].Originally, selection and development of PRO instruments used in routine clinical practice and research have been dominated by historical preferences or by the perspective of health professionals and researchers [90]. It is worth emphasising that conventionally developed PRO instruments are unlikely to be able to assess the aspects that matter most to patients [89]. Therefore, the literature highlights the importance of involving patients in PRO development [91,92].

When involving patients in the development of PRO instruments, the result may be more meaningful to patients and better reflect the challenges of their daily life compared to PRO instruments developed by health professionals or researchers [93-95]. Patients' viewpoints are crucial because the patients themselves have the experience of living with their disease; this information is unknown to health professionals [96]. Furthermore, evidence has shown discrepancies between patients and health professionals in their assessment of important health outcomes [97,98]. Patients report how their everyday life is affected by their condition, while health professionals base their assessment on the patient's physical health status [97]. This underlines the importance of patient involvement in development of PRO instruments [93].

Evidence suggests that conducting focus groups or individual interviews with patients as a starting point in development of PRO instruments leads to a better understanding of the patient perspective, domain clarification and item generation [99]. However, it has been argued that collaborative forms such as patient and public involvement (PPI) are needed to truly ensure that

PRO instruments capture the patients' perspectives [93]. PPI is a topic of increasing interest and relevance in health research and it is defined as: *'research being carried out with or by members of the public rather than to, about, or for them'* [100]. PPI in the development of PRO instruments shifts the view from patients being participants in research to patients being more actively involved in research such as being a member of a research team [100]. However, the value of using PPI in development of PRO instruments to advice on the process and guide the research is not widespread [91,101,102]. A scoping review synthesised patient involvement in the development of PRO instruments [91]. It included 189 studies describing the development of 193 PRO instruments [91]. There was no reporting of patient involvement in more than a quarter of the included studies. In more than a half of the studies, patients were involved in item development and in half of the studies patients were involved in pilot-testing. In one out of ten studies, patients were involved in determining which outcomes to measure. The scoping review showed that the level of patient involvement in the development of PRO instruments varied considerably, and that this lack of involvement impacted on the ability of the instrument to reflect the patient perspective [91]. In addition, the scoping review reported that the extent of patient involvement did not increase between 1980 and 2014 [91]. The scoping review recommended further attention to patient involvement in the development of new PRO instruments [91]. Three of the 198 studies concerned LBP-specific PRO instruments [103-105]. One out of three studies reported patient involvement in item development [104]. Accordingly, patient involvement in the development of LBP-specific PRO instruments is sparse.

2.5 Assessment of functioning and disability in patients with LBP

Assessment of functioning and disability is an important starting point for understanding a health condition and its impact on daily life [106-108]. This is also important in LBP as the complexity of the symptom underlines the need for a systematic and comprehensive assessment of multiple domains to target all facets [109,110]. Using both the status of functioning (ICF) and medical information (ICD) can provide a more complete picture of a patient's health status [107]. Specifically, it has been shown that a functioning assessment based on ICF compared to a conventional medical assessment provided a broader and more complete care plan and it reflected the patient's self-reported concerns in more detail [111]. Furthermore, it has been reported that information on participation and activity limitations provided by patients increased the assessed work limitations compared with information about the medical history alone [112]. Overall, more insight into detailed information on functioning status covering a wide spectrum of biopsychosocial perspectives provides a strong base for decision-making [58,111]. To gain a comprehensive biopsychosocial description of functioning and disability in patients with LBP, it is necessary to obtain information from both patients and health professionals [113] and the variation gained by these two perspectives [114].

2.5.1 LBP-specific PRO instruments

To identify and collect data regarding LBP-related symptoms, PROs are often used in addition to clinician-reported outcomes (ClinROs). The ClinRO is an evaluation in which an authorised health professional is the assessor [115].

The current gold standard for self-reported physical functioning in patient with LBP [116] is the Roland-Morris Disability Questionnaire (RMDQ) [103] and the Oswestry Disability Index (ODI) [117]. The RMDQ was originally intended for use in primary care but has been used in a variety of other settings [118]. Items for the RMDQ were derived from the Sickness Impact Profile [119]. The first version of ODI was developed in a specialist referral clinic for patients with chronic LBP. Interview with patients were a part of the development [117]. However, no cognitive interviews with patients were included in the development of the two instruments [117,119]. Also, several concerns regarding the content and structural validity of the two instruments have been reported [116,118,120,121]. Different versions have resulted in poor standardised used, which hampers comparison between studies [116,121,122]. Finally, RMDQ and ODI were developed before release of ICF and their main focus is pain interference rather than functioning and disability as conceptualised by ICF [10,11]. Accordingly, it has been recommended to develop new self-reported instruments to operationalise the ICF model and taxonomy [123]. To facilitate patient perspectives on functioning and disability as described by ICF, a LBP Core Set Self-Report Checklist was developed and tested [47,48]. This checklist is limited as it only consists of the 'activities and participation' components [47]. Thus, tools combining information from patients and health professionals covering all ICF components have not yet been developed for patients with LBP.

2.6 Summary of introduction and knowledge gaps

In summary, LBP is a multidimensional symptom that remains a major global public health problem. Evidence recommends a biopsychosocial and patient-centred approach to assess and manage LBP, reflecting a holistic approach and emphasising the importance of active involvement of patients in their own care. At the same time, implementation of the biopsychosocial and patient-centred approach into routine clinical practice has not yet been accomplished. In 2001, the ICF biopsychosocial model was presented. ICF provides an internationally accepted model and classification for framing and describing functioning and disability. To enhance the use of ICF in routine clinical practice, ICF core sets have been developed, including a LBP core set and a Rehabilitation set.

PROs are considered a key component of patient-centred care. Evidence shows that direct use of PROs during the consultation is sparse and that current LBP-specific instruments lack the involvement of patients in the development process. Furthermore, the literature questions the

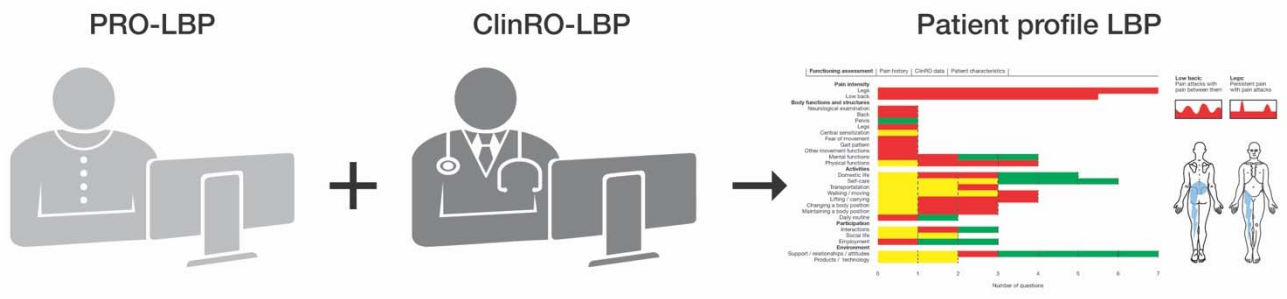
validity of the most frequently used LBP-specific PRO instruments. It is an additional drawback that they do not cover all aspects of functioning and disability as conceptualised by ICF.

To target all facets of LBP, a systematic and comprehensive assessment including assessment of multiple domains is essential; consequently, information from both patients and health professionals is needed. However, tools combining information from patients and health professionals, thus covering a wide spectrum of biopsychosocial perspectives as provided by ICF, have not yet been developed for patients with LBP. This dissertation aims to bridge this knowledge gap by introducing an assessment tool specifically for patients with LBP; the LBP assessment tool.

2.7 The LBP assessment tool

In brief, the LBP assessment tool was designed to support a biopsychosocial and patient-centred approach in the assessment of patients with LBP. It was based on ICF categories from the Comprehensive LBP core sets and the Rehabilitation set. The LBP assessment tool is web-based and builds on three features: a PRO instrument (PRO-LBP), a ClinRO instrument (ClinRO-LBP) and a graphical overview (Patient profile LBP) (Figure 2).

Figure 2. Features in the LBP assessment tool



The PRO-LBP includes data from patients regarding functioning and disability as well as contextual factors. The ClinRO-LBP is designed to assist health professionals to standardise the clinical examination. The patient profile LBP integrates data from the PRO-LBP and the ClinRO-LBP by displaying the individual patient's functioning and disability in a structured way in accordance with ICF components. The PRO-LBP is completed by patients at home before the consultation, whereas health professionals complete the ClinRO-LBP during the consultation. The patient profile LBP is used in the preparation of and during the consultation. Further clarifications of the LBP assessment tool and its features are unfolded in this dissertation.

3. Aims

The overall aim of this dissertation was to develop an ICF-based tool, *the LBP assessment tool,* to facilitate a biopsychosocial and patient-centred approach to assessment of patients with LBP. Furthermore, to implement, field-test and evaluate this tool in an out-patient clinic at a specialised spine centre.

This was achieved through four studies with the following specific objectives:

Objective I
To explore the perspectives of patients with LBP, to gain an understanding of how to qualify a patient-centred consultation using PROs. This was done by exploring patients' perspectives regarding the assessment of functioning and disability as a part of the development of a new PRO instrument based on ICF core sets (Study I, [124]).

Objective II
To outline the evidence-based and systematic process used to develop the LBP assessment tool (Study II, [125]).

Objective III
To assess the degree of successful implementation after three months and evaluate feasibility of the features in the LBP assessment tool (Study III, [126])

Objective IV
To evaluate whether consultations facilitated by the LBP assessment tool can enhance use of PROs and shared decision-making (Study IV, [127])

4. Methods

This chapter describes the methods used in the four studies in this dissertation. Table 2 presents an overview of the methods, participants, outcomes and analysis.

Table 2. Overview of the four studies in this dissertation

Study	Methods	Participants	Outcomes	Analysis
I	Focus groups interviews	7 patients	Explore patients' perspectives on how to qualify a patient-centred consultation using PROs	Interpretive description
II	Development study	18 patients 10 health professionals	Develop an evidence-based tool based on ICF core sets	Descriptive statistics
III	Implementation study	152 patients 7 health professionals	Primary outcome: • Successful implementation Secondary outcome: • Feasibility	Categorical data: chi-squared test / Fisher's exact test Continuous data: T-test / Mann-Whitney's U test Time-trend analysis
IV	Non-randomised controlled study	531 patients	Primary outcome: • Use of PROs Secondary outcomes: • Use of patient profiles • Shared decision-making (SDM-Q-9)	Categorical data: Chi-square test Continuous data: Wilcoxon rank-sum test. Non-responder analysis

ICF: International Classification of Functioning, Disability and Health

PROs: Patient-reported outcomes

The four studies are presented in chronological order. Please note, the development of the LBP assessment tool was conducted in an iterative process which does not support chronology; initial steps of study II were e.g. conducted before Study I.

4.1 Study setting

All four studies were conducted at an out-patient clinic at the Medical Department of the Spine Centre of Southern Denmark, a secondary-care hospital seeing just above 12,000 patients with back pain annually [128]. The referral criterion is that patients' do not experience a satisfactory improvement after first-line treatment in primary care settings such as general practitioners, physiotherapists or chiropractors. All patients attending the out-patient clinic at the Spine Centre receive a specialised multidisciplinary assessment before referred to further treatment e.g. surgery or rehabilitation in a municipality-led healthcare centre.

As part of standard practice, the referral team contacts all newly referred patients by e-mail using an individual secure platform for digital communication, notifying them of their initial appointment. The e-mail also contains a link to an electronic LBP-specific questionnaire, entitled the SpineData PRO [129]. Patients are asked to complete the SpineData PRO before their scheduled appointment. The SpineData PRO comprises a combination of established PRO instruments, among others the 23-item RMDQ [119] and the EuroQol (EQ-5D) [130]. The items in the SpineData PRO comprise a broad range of biopsychosocial factors within the health domains: pain, activity limitation, participation, mental functions, physical impairment and contextual factors [129]. Data from the SpineData PRO are incorporated into the clinical registry SpineData, which also includes ClinRO data [129]. Summary reports are generated for health professionals, and before seeing a patient at the index consultation, they can access summary reports from the individual patient's SpineData profile. Since 2011, SpineData has been used in routine daily patient care at the Medical Department of the Spine Centre [129].

4.2 Study population

The LBP assessment tool was developed for patients with LBP referred to a specialised multidisciplinary assessment at the Spine Centre. Inclusion criteria in the four studies were: all patients referred to the Spine Centre with a primary diagnosis of LBP with or without leg pain symptoms (sciatica), aged 18-60 years and capable of reading and speaking Danish. Exclusion criteria were patients with neck pain and pain in the upper back.

4.3 Study I – focus group interviews

Study I was an essential step in the development of the LBP assessment tool, because it explored the patients' perspectives aiming at incorporating these in the development of the PRO-LBP and the LBP assessment tool as a whole [124].

4.3.1 Methodology and participants

Data were generated through semi-structured focus group interviews to spur discussions and share patients' experiences [131].

To comply with standards for reporting of qualitative research we used the Consolidated Criteria for Reporting Qualitative Research [132] (Appendix 5). To enhance the quality and transparency of PPI used in Study I, we applied the Guidance for Reporting Involvement of Patients and the Public Short Form checklist [133] (Appendix 6).

During October 2016, eligible patients were identified in the outpatient clinic at the Spine Centre, where the PhD student contacted patients in the waiting room. The inclusion criteria followed the overall inclusion criteria described in chapter 4.2.The intended sample size was a minimum of seven patients, as recommended by COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) when conducting qualitative studies regarding development of PRO instruments [134].

Eleven patients (five women and six men), aged 20–55 years accepted to participate. They were divided into two focus groups in accordance with patients' preferences for time of the interview.

4.3.2 Data collection

The focus group interviews were conducted in November 2016. A semi-structured interview guide was constructed in accordance with the aim of the study and refined based on three individual pilot interviews. Examples of key questions in the interview guide included:

- *How would you describe your current functioning?*
- *In what way do your current symptoms affect your everyday life?*
- *What information about you and your symptoms is important for the health professional to have before the consultation?*
- *What are your immediate thoughts about the new PRO?*
- *What would you emphasise as important with regard to focusing a patient-centred consultation with the use of PRO information?*

Immediately before the focus group interviews, patients completed an initial on-line proposal of the PRO-LBP (briefly described in chapter 4.3.3) at the Spine Centre. This was done to have a common basis for discussing patients' perspectives and preferences, and identifying pros and cons. All patients were familiar with the SpineData PRO.

The PhD student conducted the interviews under the guidance of an experienced qualitative researcher (last author of Study I), who also functioned as an observer. A research assistant took field notes. The interviews took place at the Spine Centre, and each interview lasted two hours. Before beginning the focus group interview, the PhD student informed patients about the purpose of the interview and the overall project.

4.3.3 The initial proposal of the PRO-LBP

The initial proposal of the PRO-LBP used in the focus group interviews was developed by a project group comprising the PhD student, the main supervisor TM and the co-supervisor BSC. The items in the PRO-LBP were based on ICF categories from the Comprehensive LBP core set [33] and the Rehabilitation set [34] (Appendix 7).

The wording of items was based on the definition of the ICF category [5,135], lay language and terminology from the Patient-Reported Outcomes Measurement Information System (PROMIS®) [26,27]. The initial proposal comprised items from the ICF components 'body functions', 'activities' and 'participation'. At this stage of the development process, items regarding 'environmental factors' were not incorporated because these were considered to be a part of the health professionals' assessment, thus incorporated into the ClinRO-LBP. Further description of the initial proposal is found in chapter 4.4 (Study II).

4.3.4 Analysis

Data were analysed in an iterative constant comparative manner by means of the Interpretive description methodology [136,137]. Interpretive description is an inductive research methodology to inform practice-oriented research while maintaining sufficient precision to ensure academic credibility [136]. Interpretive description is recommended in small scale qualitative investigations of a clinical phenomenon with the purpose of capturing themes and patterns within subjective perceptions [138] . Aiming at improving health practice, Interpretive description is inspired by the interpretive hermeneutic tradition and seeks to discover associations and patterns within the phenomenon investigated [136,137]. The methodology seeks a coherent conceptual description that represents associations, relationships and patterns within the phenomenon researched. The overall intention with Interpretive description is to inform clinical practice about complex clinical questions [136].

The focus group interviews were recorded, transcribed and uploaded into NVivo™. Analysis of data comprised a thorough reading of the transcribed data followed by discussions and agreement upon themes. Then manual coding according to the themes were performed followed by condensation of themes and finally critical interpretation and synthesis [139]. Coding and analysis were performed by the PhD student and the last author of Study I collaborating in an iterative process.

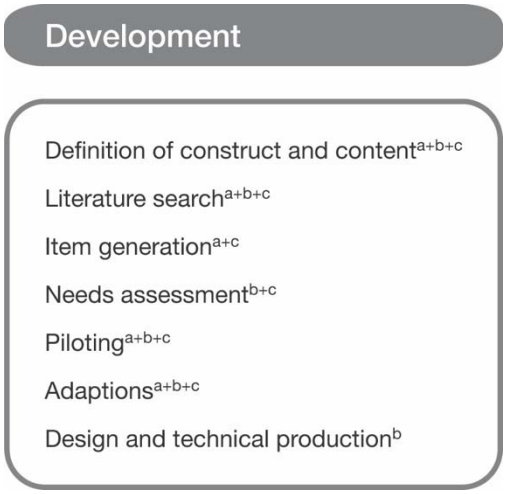
4.4 Study II – the development study

The aim of Study II was to outline the evidence-based and systematic process used to develop the LBP assessment tool [125].

4.4.1 Methods

Evidence regarding development of web-based decision-support interventions [140], measurement instruments [141] and PRO instruments [88] prompted seven elements to be addressed in the development of the LBP assessment tool (Figure 3).

Figure 3. The seven elements addressed in the development process [125]



Element derived from [a] de Vet et al 2011 [141]; [b] Elwyn et al 2011 [140]; [c] Rothrock 2011[88]

The element 'Adaptations' was integrated continuously through the whole process, and is thus not presented as an independent element in chapter 4.4.2. The project group comprising the PhD student, the main supervisor TM and the co-supervisor BSC was responsible for the initial proposal of the LBP assessment tool and final decisions.

4.4.2 Elements to be addressed in the development process

Definition of construct and content

The LBP assessment tool was developed to capture 'functioning and disability' using ICF as the framework [5]. The construct of the LBP assessment tool was based on the Comprehensive LBP core set [33] and the Rehabilitation set [34] (Appendix 7). Detailed descriptions of ICF and the two core sets are provided in chapters 2.2.1 and 2.2.2. In total, the two core sets contain 81 unique ICF categories. The project group allocated ICF categories to the PRO-LBP and the ClinRO-LBP. The allocation was guided by relevance for patients and health professionals, respectively. Continuous feedback from patients or health professionals prompted inclusion and exclusion of ICF categories.

Literature search

To assist and guide the development of the LBP assessment tool, a literature search was conducted regarding 1) the two ICF core sets [33,34], 2) measurement properties of established LBP-specific PRO instruments and 3) content classification of established LBP-specific PRO instruments according to ICF. Literature was searched in the databases SCOPUS and MEDLINE in September 2016. The PhD student conducted the searches. Specific methods for the individual searches are presented in Appendix 8.

Item generation

Item wording of ICF categories allocated to the PRO-LBP was based on the definition of the ICF category [5,135], lay language and terminology from PROMIS® [26,27]. Relevant response options from the PROMIS Physical Function item bank were applied [29]. Item wording of ICF categories allocated to the ClinRO-LBP were based on the definition of the ICF category [5,135] and medical terms familiar to health professionals and commonly used in clinical practice.

The project group developed the initial proposal of the PRO-LBP and the ClinRO-LBP (also described in chapter 4.3.3 (Study I). Three patients were invited to a pre-testing of the initial proposal of the PRO-LBP. One at a time patients answered the initial proposal of the PRO-LBP while the PhD student interviewed him/her using questions about comprehension, wording, degree of difficulty, severe flaws and deficiencies [142]. Three health professionals were invited to a pre-testing of the initial proposal of the ClinRO-LBP, using the same methods as for the PRO-LBP [142]. Notes from the questions were collected and used to adjust the initial proposal of the PRO-LBP and ClinRO-LBP. Furthermore, feedback from the patients was used to qualify the interview guide for the focus group interviews (Study I) [124].

Needs assessment

Involvement of patients and health professionals was essential during the development. Focus group interviews with patients were conducted (Study I) followed by focus group interviews with health professionals (Study II). Focus groups were chosen to facilitate patients' possibilities to elaborate on their perspectives, create discussions and share their experiences. In total, 11 patients and eight health professionals accepted to participate. The two-hour interviews were recorded, transcribed verbatim, and analysed in a four-step analysis guided by the Interpretive description methodology [136]. A thorough description of methods used in focus group interviews with patients is presented in chapter 4.3 [124]. Focus group interviews with health professionals followed methods used for the patients. The PRO-LBP and the ClinRO-LBP were adapted according to results from the focus group interviews.

Piloting

To test the face validity of the PRO-LBP and the ClinRO-LBP, a piloting was conducted [134]. Thirteen patients were invited to pilot test the PRO-LBP. They received a link to the on-line proposal of the PRO-LBP, and subsequently a semi-structured telephone interview was performed to explore their perspectives on understanding, relevance and comprehensiveness. Five health professionals were invited to complete the ClinRO-LBP based on a patient case followed by a questionnaire on understanding, relevance and comprehensiveness. Responses from patients and health professionals were used to guide the further development of the PRO-LBP and the ClinRO-LBP.

Design and technical production

On-line versions of the PRO-LBP and the ClinRO-LBP were designed in a collaboration between an advisory group (four health professionals and the PhD student) and a data manager with analytical and technical expertise. Simultaneously, the patient profile LBP was developed. It was designed to be user-friendly and easy to interpret using graphs, colours and figures rather than numbers and sum scores.

Issues concerning technical considerations such as platforms, site structure, navigation, graphic illustrations and data security were discussed in the project group. The PRO-LBP and the ClinRO-LBP were designed in SurveyXact®. The patient profile LBP was developed in the statistical analysis program R using Shiny Server as the web-based platform, retrieving data from SurveyXact®.

4.5 Study III – the implementation study

The aim of Study III was to assess the degree of successful implementation after three months, and evaluate feasibility of the features in the LBP assessment tool [126].

In Study III the concept *implementation* refers to "methods to promote the systematic uptake of evidence-based practices into routine practice" [143]. The integrated Promoting Action on Research Implementation in Health Services (i-PARISH) framework [144] was used to assist the implementation of the LBP assessment tool. This framework includes the elements *context, innovation, recipients* and *facilitation*. According to i-PARISH, these elements need attention before and during an implementation process to ensure successful implementation [144].

In the following, the elements specified by the i-PARISH framework will be presented followed by a presentation of the steps to facilitate the implementation of the LBP assessment tool.

4.5.1 The i-PARISH elements in relation to the LBP assessment tool

The context in which the LBP assessment tool was to be implemented is described in chapter 4.1 and the *innovation* and the evidence behind the LBP assessment tool is described in chapters 4.4 and 5.2.

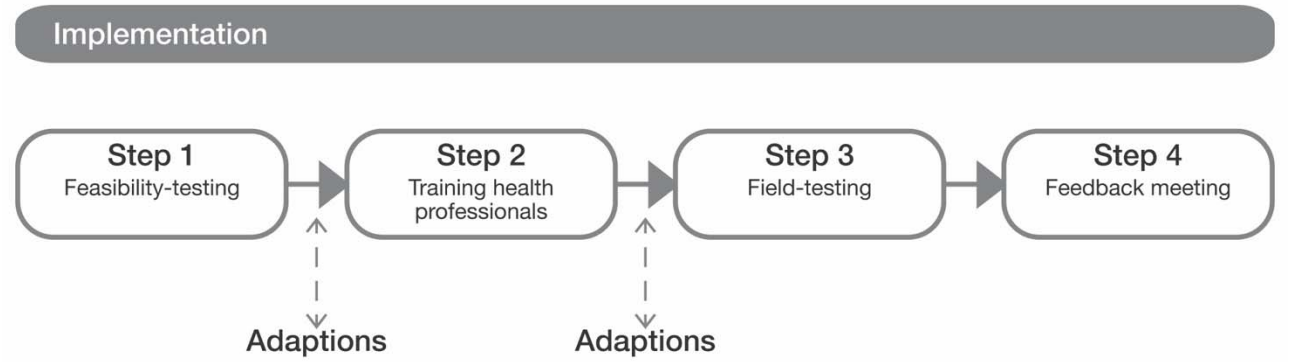
Recipients impacted by the LBP assessment tool were 1) patients referred to the Spine Centre with a primary diagnosis of LBP and 2) health professionals assessing the patients. Patients are described in chapter 4.2. Health professionals assessing the patients included medical doctors, physiotherapists, chiropractors and nurses. Standard procedure was that the primary clinical examination was performed by a medical doctor or a chiropractor. If they needed supplementary assessment to form a rehabilitation plan, an extended LBP assessment was performed by a physiotherapist. All patients consulted a nurse regarding medicine and everyday life issues. The multidisciplinary team used the patient profile LBP (data from the PRO-LBP) to prepare for the consultation, they completed the ClinRO-LBP during the clinical examination, and they used information from the LBP assessment tool for decision-making.

The *facilitator* role was assigned to the co-supervisor BSC, an experienced rheumatologist and head of research at the Spine Centre. BSC is skilled in working with patients with LBP, has knowledge of ICF in clinical practice and insight into the LBP assessment tool. BSC has exhaustive knowledge of the health professionals working at the Spine Centre as well as insight into organisational development. She was involved in the idea behind the LBP assessment tool, which gave her ownership and the status of a local clinical champion [145]. BSC's skills and attributes were essential to achieve the change required for successful implementation [144].

4.5.2 Steps to facilitate the implementation of the LBP assessment tool

Evidence prompted four key steps to facilitate the implementation: feasibility-testing [88,140], training of health professionals [78,146], field-testing [88,140,141] and feedback meetings [22,146]. These steps are presented in Figure 4. Minor adaptions were made after steps 1 and 2.

Figure 4. The four key steps to facilitate the implementation of the LBP assessment tool [126]



Step 1: Feasibility-testing

Feasibility-testing was conducted in collaboration with a physiotherapist to test practical and technical issues. Five patients were asked to complete the PRO-LBP prior to their consultation at the Spine Centre. The physiotherapist used the patient profile LBP to prepare for the consultation and during the consultation. After assessing the patient, the physiotherapist completed the ClinRO-LBP. The PhD student observed the feasibility-test and took field notes. The physiotherapist gave verbal feedback after each consultation regarding the use of the LBP assessment tool. The field notes and the feedback were documented and used for improvements.

Step 2: Training health professionals

Seven health professionals were invited to participate in a training programme encompassing three components (Figure 5).

Figure 5. Components in the training programme [126]

Instructions were given by the PhD student and the main supervisor TM. It was centred on expanding the health professionals' knowledge about 1) ICF used as a framework in rehabilitation, 2) evidence behind the LBP assessment tool and 3) patient-centred care including use of PROs during the consultation. The instruction was tailored to the context and learning goals were created to describe the knowledge and skills to be achieved after the instruction (Table 3).

Table 3. Content areas in the instruction component, including form and learning goals [126]

Content areas	**Form**	**Learning goals** After the instruction, the participants were to be able to…..
Biopsychosocial approach, ICF and rehabilitation	Interactive lecture / group discussion	..understand and discuss the concept of rehabilitation, including ICF as a conceptual framework
Patient-centred care, PRO – why (evidence)	Interactive short lecture	..understand the evidence behind and value of using PROs in routine clinical practice
PRO-LBP – content and how to use	Interactive lecture / partner work / group discussion	..discuss how PROs are utilised today, barriers for implementing PROs and how to use the PRO-LBP in routine clinical practice
ClinRO-LBP – content and how to use	Group discussion	..complete the ClinRO-LBP in clinical practice and summarise the information for use in clinical practice
Patient profile LBP – content and how to use	Group discussion	..apply the patient profile LBP in clinical practice and summarise the information for use in the decision on which rehabilitation to choose, and subsequent planning of the rehabilitation
Reflections of the day and the future process	Short lecture / group discussion	..outline the future implementation (know what to come)

After the instruction component the tryout component allowed health professionals to test the LBP assessment tool before field-testing [147]. They tried out the LBP assessment tool to test procedures and gain confidence in using the tool. The consultations were observed using an observation form (Appendix 9).

The follow-up meeting with health professionals was conducted to discuss observations and experiences from the tryout component. Field notes were taken by the PhD student and used for improvements of the LBP assessment tool before the field-testing.

Step 3: Field-testing

We established a project clinic situated in the Spine Centre for the field-testing. The project clinic was open twice a week. The overall field-testing lasted for five months. The first months was considered an internal pilot phase where outcome data generated contributed to the final analyses [148,149] reported in Study IV [127]. The aim of the internal pilot phase was to assess the short-term implementation of the LBP assessment tool.

We aimed to reach a sample size of ≥100 patients in agreement with COSMIN recommendations [116]. Patients referred to the Spine Centre were consecutively enrolled and assessed by the multidisciplinary team completing the training programme; field-testing followed the same procedure as feasibility-testing. The primary outcome of the field-testing was successful implementation after three months, operationalised as shown in Table 4. The threshold level of 85 % and 70 % respectively, were nominated in accordance with previous findings reporting that

health professionals and patients were satisfied at this level and hence considered feasible and acceptable [150,151].

Table 4. Operationalisation of successful implementation and corresponding threshold level [126]

Outcomes	Operationalisation of outcomes	Threshold level
Percentage of patients where PRO responses were used during the consultation	*Item no. 1*: To which degree was your responses from the PRO used in your dialogue with the health professional?	85 %
Percentage of patients where the patient profile LBP was used during the consultation	*Item no. 2*: Did you see this report during the consultation? [Screenshot was presented to the patient]	70 %

PRO: Patient-reported outcome; LBP: Low back pain

The secondary outcome was feasibility of the PRO-LBP and the ClinRO-LBP from the perspective of patients and health professionals, respectively (Table 5). In addition, comprehensiveness of the PRO-LBP was assessed by reviewing text boxes incorporated into the PRO-LBP to identify potential self-identified concerns not covered by the PRO-LBP.

Table 5. Assessment of feasibility of the PRO-LBP and the ClinRO-LBP

Feasibility	Item	Response options
Ease		
PRO-LBP	How easy was it to fill in the PRO-LBP?*	1 = very easy – 5 = very hard
ClinRO-LBP	How easy was it to fill in the ClinRO-LBP?**	
Comprehensiveness		
PRO-LBP	To which degree do you find the PRO-LBP comprehensive?*	1 = to a great degree – 5 = not at all
ClinRO-LBP	To which degree do you find the ClinRO-LBP comprehensive?**	
Convenience of administration		Completion time, minutes

*Item incorporated into the PRO-LBP; **items incorporated into the health professional survey

Primary outcome data were collected from a successful implementation questionnaire (SI-questionnaire) sent to the patients immediately after their consultation. Data regarding feasibility of the PRO-LBP were collected in connection with the PRO-LBP. A health professional survey ten months post implementation provided data on feasibility of the ClinRO, use of PRO-LBP and the patient profile LBP during the consultations (Appendix 10). Completion time of the PRO-LBP and the ClinRO was obtained from SurveyXact®.

Step 4: Feedback meeting

A feedback meeting with the health professionals was held after three months to promote shared learning and implementation [147]. Before the meeting, health professionals were asked to reflect on which modifications the LBP assessment tool had prompted regarding assessment procedures and multidisciplinary collaboration. Additionally, they should consider technical barriers when using the LBP assessment tool and if they found essential information to be missing. The feedback meeting was recorded. The PhD student and the main supervisor TM listened to the recording twice, and extracted data to identify topics followed by a consensus meeting.

4.5.3 Analysis

A complete-case analysis was used, thus only patients with full completion of the SI-questionnaire were included. Descriptive statistics were used to describe patient characteristics, successful implementation, feasibility and reporting time of the SI-questionnaire; defined as: days from the consultation day until the questionnaire was answered. The chi-squared test or Fisher's exact test were used for categorical data, while t-test or Mann-Whitney's U test were used for continuous data. A non-responder analysis was conducted. To analyse data extracted from the text boxes, ICF linking rules were applied [49]. The ICF linking was carried out by the PhD student and a research assistant trained in ICF. A time-trend analysis was performed to identify potential change in time (months) regarding the use of PRO-LBP and the patient profile LBP.

4.6 Study IV – the non-randomised controlled study

The aim of Study IV was to evaluate whether consultations facilitated by the LBP assessment tool can enhance use of PROs and shared decision-making [127].

4.6.1 Design

A prospective, non-randomised controlled study was conducted. Patients attending a consultation facilitated by the LBP assessment tool (intervention group) were compared with patients attending a conventional consultation (control group).

4.6.2 Participants and allocation

The referral team assigned eligible patients to the intervention group, whereas patients for the control group were identified through the clinical registry SpineData [129]. The method was based on a non-randomised allocation based on time period and patient residence. Specifically, patients attending the Spine Centre from November 2017 to April 2018 and living in selected areas of the Region of Southern Denmark were allocated to the intervention group. Patients attending the Spine Centre in August 2018 and living in the remaining areas of the Region of Southern Denmark were allocated to the control group. Thus, the two groups were observed in the same setting but at different periods of time.

4.6.3 Procedure

Prior to the consultation, patients in both groups were asked to complete a PRO instrument at home. If the patients were not able to complete the PRO at home, it was possible to complete it at the Spine Centre using an in-house iPad. During the consultation health professionals completed a ClinRO instrument documenting the clinical examination. A graphical report displaying data from the PRO and the ClinRO was available to the health professionals on the computer screen prior to and during the consultation. Thus, data were collected and displayed differently in the two groups (Table 6).

Table 6. Collection and presentation of data in the two groups [127]

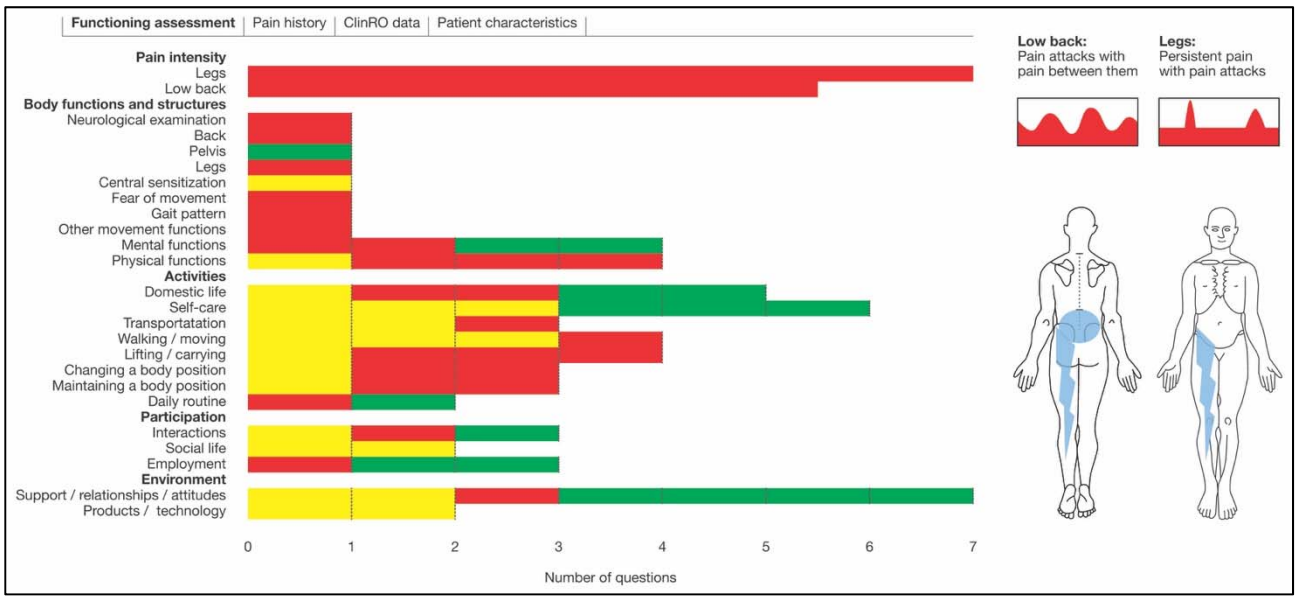
	Intervention group	**Control group**
PRO data collection	PRO-LBP	SpineData PRO
ClinRO data collection	ClinRO-LBP	SpineData ClinRO
Graphical report	Patient profile LBP	SpineData profile

4.6.4 The intervention group

The LBP assessment tool [124,125] was central in the intervention. In addition, the intervention was facilitated by training of health professionals and during the consultation health professionals worked as a team. Training of health professionals is described in chapter 4.5 [126]. Use of PRO

data during the consultation was facilitated by data from the PRO-LBP. Data from the PRO-LBP were available to health professionals and designed to be used in the preparation of and during the consultation. The ClinRO-LBP assisted health professionals to standardise the clinical examination. The patient profile LBP integrated data from the PRO-LBP and the ClinRO-LBP by displaying the patient's functioning and disability in a graphical report, structured in accordance with the ICF components (Figure 6).

Figure 6. Screenshot of the patient profile LBP [127]



The health professionals delivering the intervention comprised a selected group of health professionals from the Spine Centre (n=7) with extensive experience in managing patients with LBP. Characteristics of the health professionals can be found in Table 14.

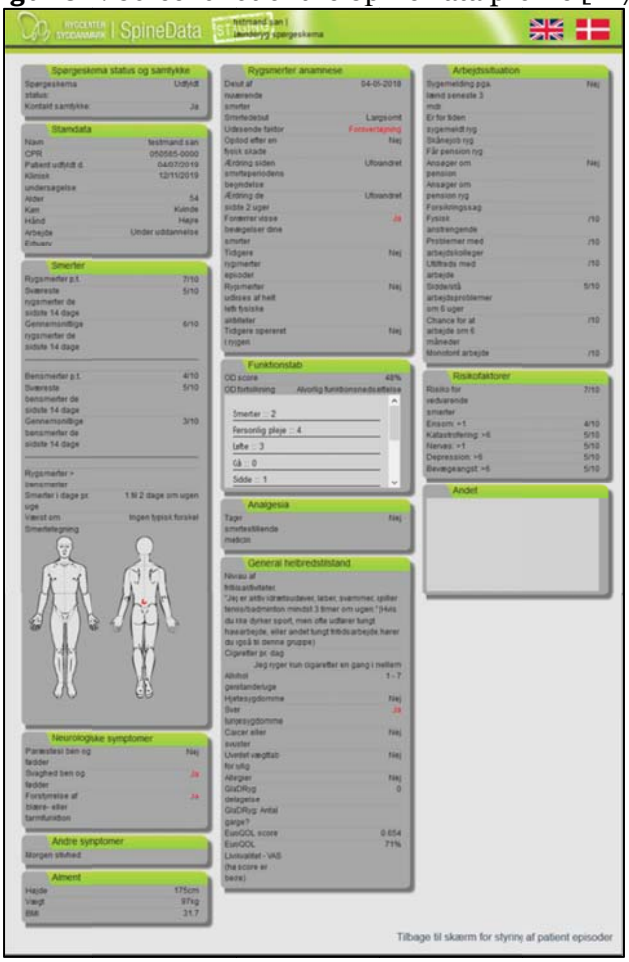
Patients in the intervention group received information about the project, an informed consent form and an electronic link to the PRO-LBP. Patients followed the standard procedure for the LBP assessment tool as described in chapter 4.5 under *Recipients*. Furthermore, the health professionals worked together when assessing, planning, and evaluating the patient. Each day the health professionals had a team meeting to share expertise, knowledge, and discuss the patients.

4.6.5 The control group

Patients in the control group followed usual practice at the Spine Centre using data from the clinical registry SpineData (see chapter 4.1) [129]. In brief, patients in the control group received an electronic link to the SpineData PRO [22] before the consultation. They underwent a conventional LBP clinical examination performed by a multidisciplinary team with extensive experience in managing patients with LBP. Before the consultation, health professionals could

access summary reports from the individual patient's SpineData profile (Figure 7). Health professionals were continuously trained in applying SpineData.

Figure 7. Screenshot of the SpineData profile [127]



4.6.6 Outcome measures

The primary outcome was use of PROs during the consultation measured by self-constructed items. Secondary outcomes were:

- Use of the graphical report of the patient's profile (Figures 5 & 6) measured by self-constructed items.
- Shared decision-making measured by the 9-item Shared Decision-Making Questionnaire (SDM-Q-9), a brief questionnaire designed to measure the extent to which patients are involved in shared decision-making [152]. The SDM-Q-9 has shown good psychometric properties [153]. Responses were scored on a 6-point Likert scale ranging from 0 "completely disagree" to 5 "completely agree", with a total sum score between 0 and 45 points. A high score indicates a high patient experience of shared decision-making.

A patient evaluation questionnaire was constructed to measure the primary and secondary outcomes (Appendix 11).

4.6.7 Data collection

Patients received a link to the patient evaluation questionnaire immediately after their consultation. Data were obtained through SurveyXact®. Non-responders received up to three written reminders and one phone call. Characteristics of patients in the intervention group were collected by the PRO-LBP; for patients in the control group, the SpineData PRO was used. Consequently, pain intensity and disability were measured with two different instruments in the two groups. A visual analogue scale (VAS 0-100) and the ODI were included in the PRO-LBP (intervention consultation), because surgeons at the Spine Centre preferred to use VAS and ODI. The new PRO-LBP aimed at standardising use of instruments across specialities at the Spine Centre. In the SpineData PRO, a numeric rating scale (NRS 0-10) and the 23-item RMDQ were used as they were standard instruments in the SpineData registry at the time of the study.

4.6.8 Analysis

Descriptive statistics were used to describe the patients. To compare pain intensity and disability between patients, NRS data (0-10) were converted into a VAS (0-100), and the RMDQ sum scores were divided into subgroups of disability [154].

A complete-case analysis was used, thus only patients with full completion of the patients evaluation questionnaire were included. The reporting time of the patient evaluation questionnaire was analysed using descriptive statistics. Outcome data generated during the internal pilot phase (Study II) contributed to the analyses. Data regarding "use of PROs" were dichotomised (0=no; 1=yes) by collapsing the response options 1 and 2 into 0, which correspond to "no", and the response options 3, 4 and 5 into 1, which correspond to "yes". Categorical variables were analysed by a Chi-square test. The total sum score of the SDM-Q-9 was transformed into a scale from 0-100 by multiplying the sum score with 20 and dividing it by 9 [152]. The Wilcoxon rank-sum test was used for analysis.

A non-responder analysis was performed on age and gender. An explorative analysis was performed to investigate whether observed differences in patient characteristics were associated with the use of PROs and shared decision-making. Age and gender were added to the explorative analysis. The level of statistical significance was set at a p-value < 0.05 and STATA version 16 was used for all analyses.

4.7 Ethics approval

All studies were approved by the Danish Data Protection Agency [file no. 1-16-02-477-16]. Studies of this type do not need ethical approval according to the Central Denmark Region Committees on Health Research Ethics [file.no. 150/2016]. Additionally, Study IV was approved by the Danish Patient Safety Authority (file no. 3-3013-2513-1). All participating patients and health professionals received oral and written information about the project and were guaranteed anonymity. Written consent was obtained from all participants before entering the studies.

4.8 Patient and public involvement

When using the term PPI in this dissertation it covers involvement of patients and health professionals in the process of developing the LBP assessment tool [125,126]. The aim of involving patients and health professionals was to increase the acceptability, relevance and qualification of the tool, as well as identify elements of importance when applying the tool in routine clinical practice. Thus, PPI was a part of various aspects of this dissertation. A detailed description of PPI is provided in the chapters regarding methods and results of the four studies.

5. Results

Main results from the four studies are presented separately. Detailed presentation of the results is offered in appendices 1-4.

5.1 Results Study I – focus group interviews

A total of seven patients participated in the focus group interviews (Table 7). One group consisted of five patients; one opted out on the day of the interview because of pain. The other group consisted of six patients; three of these opted out without giving an explanation.

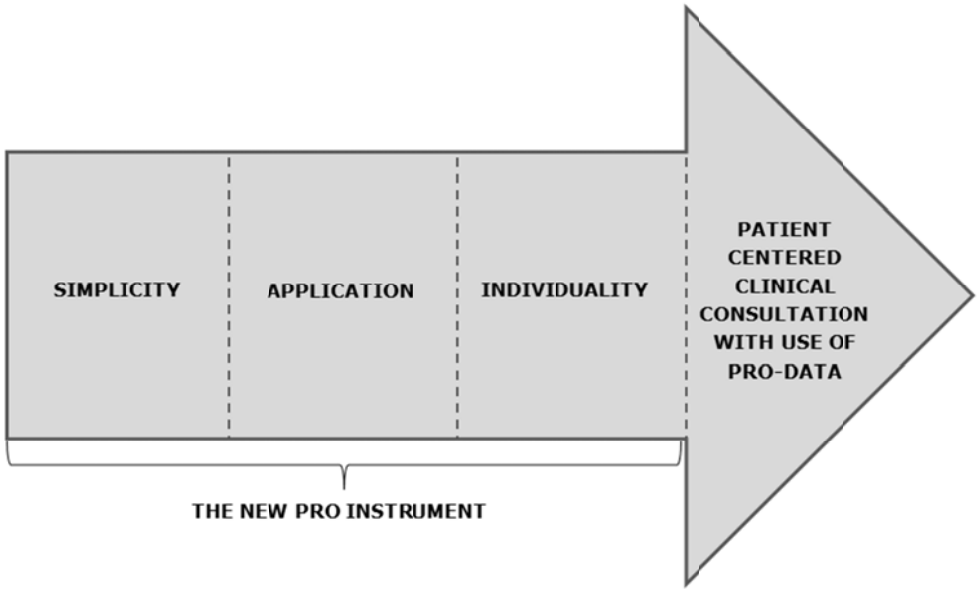
Table 7. Patients in the focus group interviews, study I [124]

ID	Gender	Age group	Diagnosis	Employment status
1	F	40–49	Lumbar herniated disc	Flexi-job
2	M	40–49	Spondylosis with radiculopathy	Full-time employed
3	M	50–59	Lumbar herniated disc	Full-time employed
4	F	20–29	Low back pain, unspecified	Full-time student
5	F	30–39	Lumbar herniated disc	Unemployed
6	M	40–49	Lumbar herniated disc	On sick leave
7	F	40–49	Low back pain, unspecified	On social security benefits

F: female; M: male.

Analysis from the focus group interviews revealed three core themes*: simplicity, application and individuality* [124]. These themes were closely linked in a chain of elements of importance to qualify a patient-centred clinical consultation with the use of PRO data (Figure 8).

Figure 8. Patients' perspectives on the development and application of the PRO-LBP [124]



Below examples of citations consolidating these findings are presented. Further elaboration is offered in Appendix 1.

Simplicity signified that patients found it important that the PRO-LBP comprised a suitable and relevant number of items with no item overlaps. Patients also expressed that too many irrelevant items was a source of annoyance especially when they were in pain and not feeling well.

> *ID 1: It's not just two or three questions you know…it is a lot of questions. That's the feeling I got from having to fill in the old questionnaire, and at the same time my back was killing me. I had great difficulties sitting at my computer, filling out the old questionnaire, and the questions went on for ever and ever. So, my point is: Boil it down and make it manageable. That's what I'm thinking* [124]

Although patients wanted "*to keep it simple*", they were also aware of the importance of getting comprehensive information.

> *ID. 2: Make it as simple as you can, but at the same time get the information you need. However, it does not help if you make it so simple that we have to go through it all with the health professional anyway* [124]

Application indicated that patients found it very important that their PRO data would be used directly during the consultation. They assumed that health professionals used their PRO data in preparation of the consultation and in the dialogue during the consultation. However, patients experienced that health professionals did not use their PRO data, referring to the SpineData PRO.

> *ID. 1: I really did not get the impression that the health professional used the questionnaire [SpineData PRO]. He spent most of the time looking at the referral sheet and the information that it contained. I do not think that he referred to the questionnaire I had completed in any way, and then you start thinking if it matters* [124]

Individuality implied the need for individualised answers. Patients expressed that it was insufficient to tick a box. Instead they suggested that the PRO-LBP should include a text box to allow for self-identified concerns.

> *ID 5: I'm just wondering about the question on being "able to be in a relationship". Well, what exactly is meant by that? You know…if you're not able to have sexual intercourse due to pain then it does affect your relationship, but we're still "in" the relationship. Pain affects*

> *the relationship, and we snap at each other because my back hurts. I think it is a difficult question* [124]

Furthermore, all patients explained how disability affected their everyday lives, and it was of utmost importance to them to be able to describe this to the health professionals before the consultation. Everyday life was mentioned constantly as being the core element when assessing their functioning.

> *ID 4: Yes, everyday life is very important…especially if everyday life doesn't work…then you won't work yourself. That was my biggest concern coming to the hospital with my back pain. All the issues related to "What will my future look like?", "How will my everyday life be?", "How can you help me?" I went in to talk to…. afterwards in relation to education and stuff like that. "Which path should I choose?", "Should I choose something totally different from what I know?" Yes, that's what I'm talking about, and everyday stuff. Posing questions on those kinds of issues is super positive, because that's where your specific individual problems occur in the everyday life…right?* [124]

As part of the content specification for the PRO-LBP, patients expressed how they found the content of the PRO-LBP better than the SpineData PRO. They favoured the PRO-LBP because the items were relevant, straightforward, and sufficiently described the various ways in which their everyday lives were affected by their symptoms. In addition, patients had some specific changes to items in the PRO-LBP. The item about "eating" was rephrased, the item about "moving around using equipment" was omitted, and as patients missed items regarding medication and health care services, we decided to incorporate items from 'environmental factors' into the PRO-LBP. The patients decided that a 7-day recall period was appropriate for the PRO-LBP.

To comply with the patients' request on *simplicity, application* and *individuality,* the PRO-LBP avoided overlapping items and a text box to allow for self-identified concerns were incorporated at the end of the PRO-LBP. To support application of PRO data during consultation, the patient profile LBP was designed.

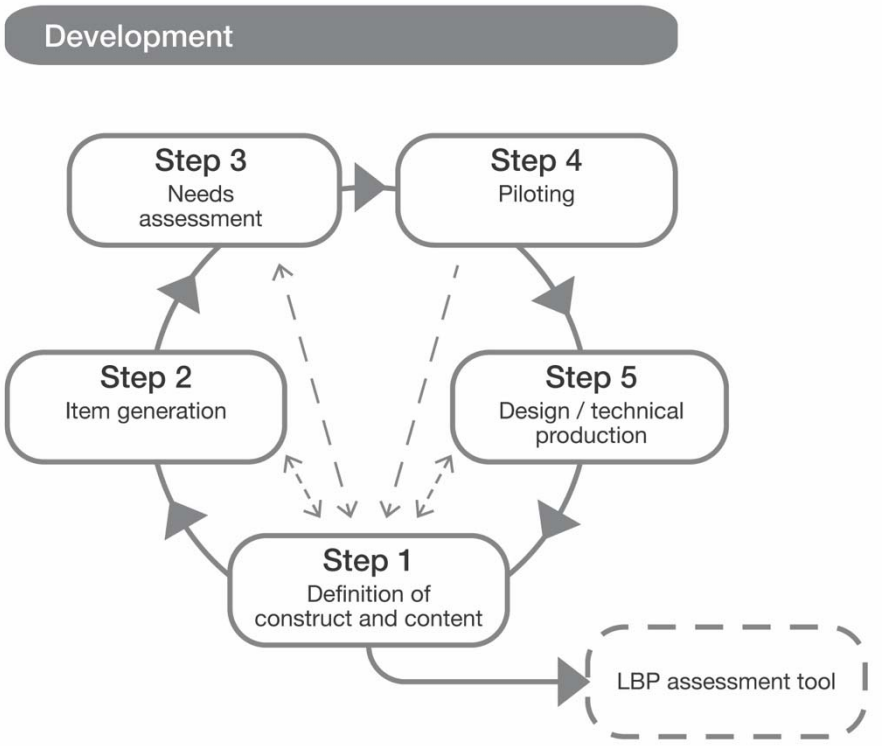
5.2 Results Study II – the development study

The development of the LBP assessment tool was an iterative and comprehensive process with several steps [125]. First, results regarding the steps and then a summary of the features in the LBP assessment tool will be presented below.

5.2.1 Steps in the development process

The development process lasted from August 2016 until July 2017, 11 months in total. The seven elements (Figure 2, chapter 4.4.) derived from evidence [88,140,141] were collapsed into five steps with adaptions between the steps, symbolised by the grey dotted lines (Figure 9).

Figure 9. Steps in the development of the LBP assessment tool [125]



In total, 18 patients were involved in steps 2, 3 and 4, and their contribution was mainly to the development of the PRO-LBP, but they also gave input to graphical displays of PRO data during the consultation. Three patients contributed to item generation (step 2), seven to needs assessment (step 3), and eight pilot tested the PRO-LBP (step 4). Detailed descriptions of contributions from patients are presented in relation to findings from Study I (chapter 4.1) and in the following chapters.

In total, 12 different health professionals were involved in steps 2, 3, 4 and 5, of which seven were involved in at least two steps. The health professionals contributed to the development of the PRO-LBP, the ClinRO-LBP and the patient profile LBP. Five health professionals participated in item

generation (step 2), eight in needs assessment (step 3), three in piloting and four in design and technical production (step 5). Between steps 3 and 4 the advisory group was established comprising four health professionals and the PhD student. Detailed descriptions of the health professionals' contributions are unfolded below.

Step 1: Definition of construct and content

The literature search was incorporated into step 1, because the evidence was fundamental to defining the construct and content. Key results from the three literature searches are presented in Table 8. Detailed descriptions of the included studies are presented in Appendix 12.

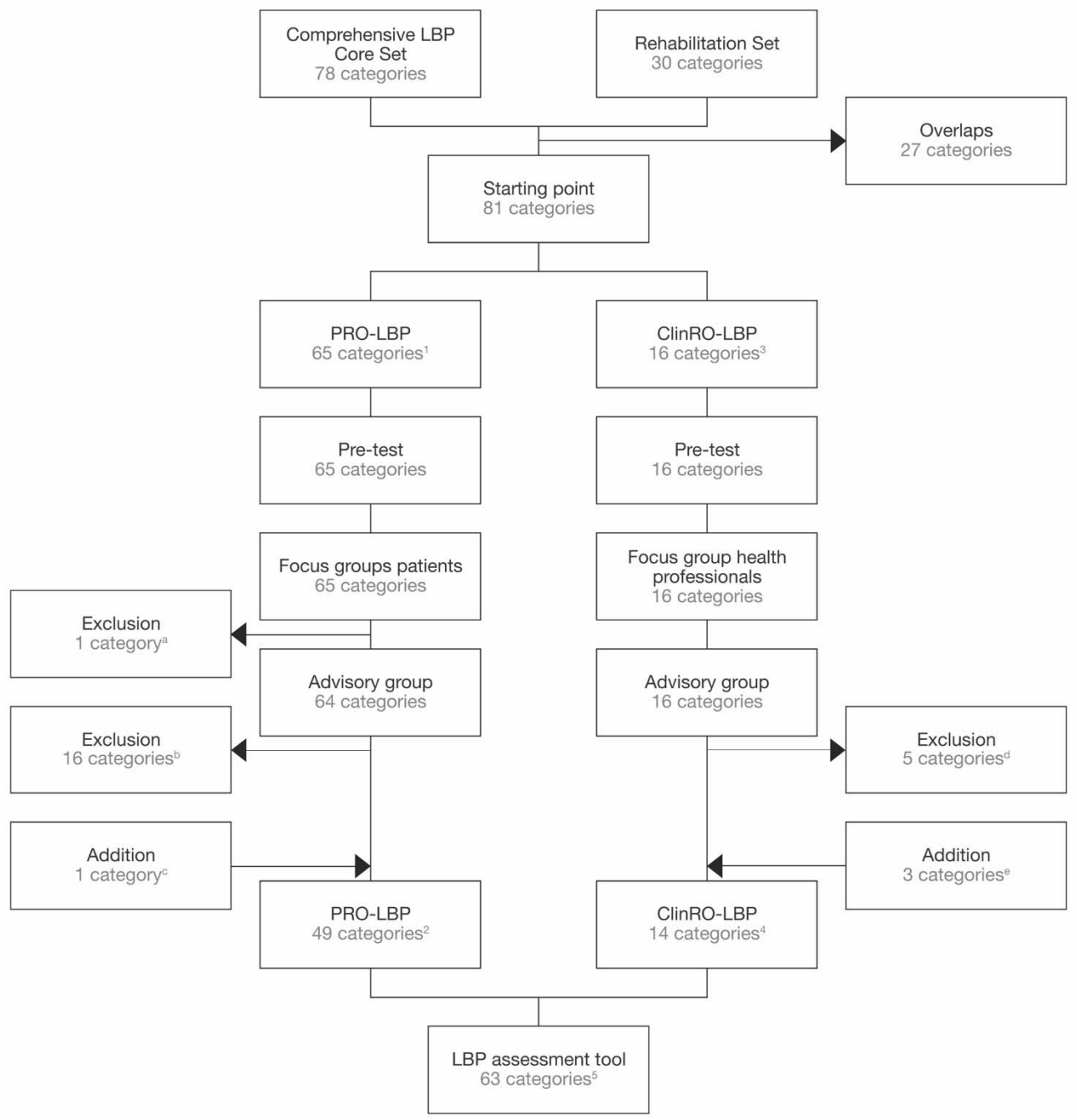
Table 8. Key results from the literature search

Search	**Number of studies**	**Key results**
The two ICF core sets		
LBP core set	n= 22	1) Applicable in clinical practice 2) Captures the problems of patients with LBP 3) Broadens the perspective of participation and environmental factors
Rehabilitation set	n=0	-
Measurement properties on established LBP-specific PRO instruments (reviews)	n=21	1) The ODI and the RMDQ were the most frequently evaluated PRO instruments 2) Their structural validity is problematic and content validity is understudied
Content classification of established LBP-specific PRO instruments according to ICF	n=7	1) Few instruments addressed environmental and personal factors 2) Use of the LBP core set as a starting point is supported 3) Due to reduced coverage of ICF in established LBP-specific PRO instruments, it was endorsed not to use them.

ODI: Oswestry Disability Index; RMDQ: Roland Morris Disability Questionnaire

The content of the LBP assessment tool was based on a starting point of 81 unique ICF categories [33,34], of which 65 were allocated to the PRO-LBP and 16 to the ClinRO-LBP (Figure 10).

Figure 10. Flowchart exclusion and addition of ICF categories [125]



[a] PRO-LBP exclusion: d465; [b] e120; e150; e225; e255; e325; e330; e360; e425; e455; e460; e465; e540; e550; e575; e585; e590;
[c] PRO-LBP addition: b525;
[d] ClinRO-LBP exclusion: b260; b715; b720; b735; s770;
[e] ClinRO-LBP addition: b265; b280; b789;
[1] Initial proposal PRO-LBP: 8 categories from 'body functions' (BF); 32 from 'activities and participation' (AP); 25 from 'environmental factors' (EF);
[2] PRO-LBP: 9 categories from BF; 31 from AP; 9 from EF;
[3] Initial proposals ClinRO-LBP: 11 categories from BF; 5 from BS;
[4] ClinRO-LBP: 10 categories from BF; 4 from BS;
[5] LBP assessment tool: 18 categories from BF, 4 from BS, 32 from AP; 9 from EF

During development of the PRO-LBP, 17 ICF categories were excluded and 1 added (Figure 10). Findings from the focus groups with patients (Study I) resulted in exclusion of the ICF category *d465 Moving around using equipment* while recommendations from the advisory group resulted in a reduction of ICF categories from the 'environmental factors' component from 25 to 9. Thus we used the environmental factors categories from the Brief LBP core set except *e550 Legal services, systems and policies*. Furthermore, the ICF category d525 *Defecation functions* were added by request from the advisory group.

During development of the ClinRO-LBP discussions in the advisory group lead to alterations of ICF categories included (Figure 10). Five ICF categories were excluded due to "not relevant in a hospital setting". Three ICF categories; *b265 Touch function*, *b280 Sensation of pain* and b789 *Movement functions, other specified and unspecified,* were added because health professionals found them important as part of the clinical examination.

Step 2: Item generation

For the majority of items in the PRO-LBP standard-wordings from PROMIS and corresponding five-point response options were used (Appendix 13). Two males and one female (mean age of 49 years) participated in the pre-testing. Three main findings emerged: 1) items were comprehensible, 2) no items were irrelevant and 3) an introduction was needed to explain the aim of the PRO-LBP.

Wording of items in the ClinRO-LBP was kept short and simple with language familiar to health professionals. Two different response options were applied (Appendix 14). One medical doctor, one physiotherapist and one chiropractor participated in the pre-testing. Main findings led to adaptions regarding wording of items in the ClinRO-LBP.

Step 3: Needs assessment

Main focus in step 3 was to explore the perspectives of patients and health professionals. Findings from focus group interviews with patients are presented in Study I see chapter 4.2 [124].

Eight health professionals participated in the focus group interview. They represented the multidisciplinary team at the Spine Centre comprising; two chiropractors, two medical doctors, two physiotherapists and two nurses. The analyses revealed three main themes: 1) diversity in clinical practice; 2) comprehensive assessment of functioning and 3) reduced use of PROs in the consultation.

- *Diversity in clinical practice* was related to diverse viewpoints primarily due to different professional backgrounds.
- *Comprehensive assessment of functioning* signified that health professionals found assessment of functioning challenging and complex. Therefore, they found it beneficial to make an

assessment in collaboration with other health professionals with different professional backgrounds.

- *Reduced use of PRO data in the consultation* implied that health professionals found data from the SpineData PRO hard to interpret and they were sceptical about the clinical relevance and meaning. Thus, use of data from the SpineData PRO during the consultation varied considerably among the health professionals.

As a result of the focus group interview, the advisory group was established to have more time to discuss the content of the PRO-LBP and the ClinRO-LBP as well as to consider how to facilitate the use of PROs and the LBP assessment tool in routine clinical practice. The advisory group met four times for two hours between January and April 2017. The advisory group ensured that important items from the health professionals' perspective were addressed in the PRO-LBP. Consequently, items regarding "pain location" (Figure 11) and "pain course pattern" (Figure 12) [155] were included in the PRO-LBP. The advisory group concurred with the patients and found a 7-day recall period appropriate for the PRO-LBP.

Figure 11. Entry question about pain location [125]

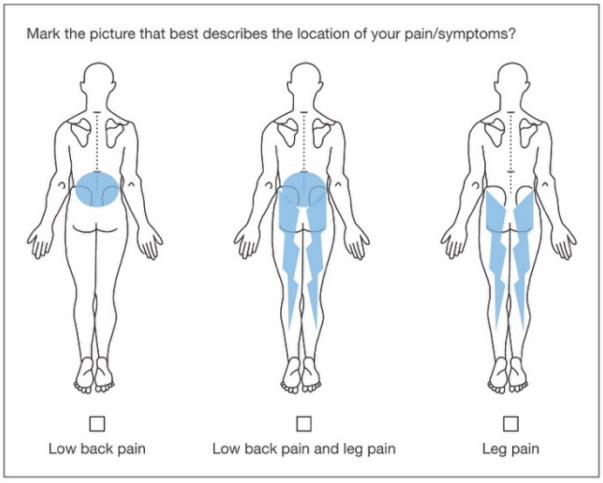
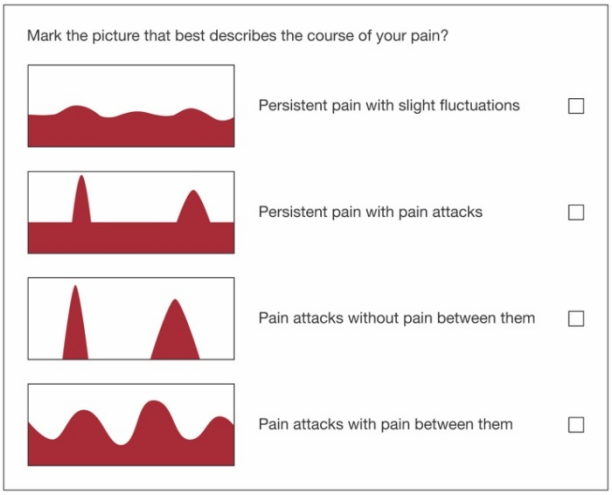


Figure 12. Question about pain course pattern [125,155]



The work in the advisory group resulted in three adaptions to the ClinRO-LBP. As mentioned in chapter 4.2.1, they excluded five ICF categories and generated new items for three added ICF categories (Figure 10). Finally, the advisory group recommended reducing the health professionals' registration burden, thus "no problem" was marked by default (calculated variable) in the ClinRO-LBP.

Step 4: Piloting

Of the thirteen patients invited to the piloting of the PRO-LBP, four males and four females completed the PRO-LBP followed by a telephone interview. Mean age of the participants was 55 years, and the mean completion time of the PRO-LBP was 27 minutes (range: 15 to 40 minutes). Generally, patients were pleased with the PRO-LBP because it was easy to complete and included relevant and meaningful items. Patients were especially happy with the text box allowing to express self-identified concerns. The piloting of the PRO-LBP led to clarifications of items.

Two physiotherapists, two medical doctors and one chiropractor were invited and accepted to participate in the piloting of the ClinRO-LBP. Their feedback resulted in three adaptions; 1) reorganisation of items to make them more applicable to routine workflow, 2) clarifications regarding wordings and 3) inclusion of a summarising section to make an overall assessment of the findings from the clinical examination.

Step 5: Design and technical production

This step revealed that developing a web-based tool built on three features is a complex and time-consuming process requiring several iterative steps. Furthermore, the PRO-LBP and the ClinRO-LBP were designed iteratively with the patient profile LBP, as an adaption in one would lead to changes in the other. Finally, in-depth knowledge about encryption, authentication and logging was essential in the development process. Step 5 resulted in a prototype of the LBP assessment tool.

5.2.2 Summary of the features in the LBP assessment tool

In total, the LBP assessment tool ended up comprising ICF categories from all ICF components. A total of 63 ICF categories were included; 19 from 'body functions'; 4 from 'body structures'; 31 from 'activities and participation' and 9 from 'environmental factors'. The hitherto undeveloped ICF component 'personal factors' was addressed by items regarding age, gender, other health conditions and lifestyle.

The PRO-LBP

The PRO-LBP ended up covering 49 ICF categories, 9 ICF categories from 'body functions', 31 from 'activities and participation' and 9 from 'environmental factors'. The corresponding items were organised in 15 sections, reflecting 16 ICF domains and 'personal factors' (Table 9).

Table 9. Sections in the PRO-LBP, corresponding ICF domain and number of items [125]

Sections	**ICF domain**	**No of items**		
		LBP	LBP and leg	Leg pain
1. Patient information	Personal factors (not classified)	6	6	6
2. Pain	b2 Sensation of pain	12	27	17
	e1 Products and technology	2	2	2
3. Mobility	d4 Mobility	17	17	17
4. Self-care	d5 Self-care	6	6	6
5. Domestic life	d6 Domestic life	5	5	5
6. Work and employment	d8 Major life areas	4	4	4
7. Community, social and civic life	d9 Community, social and civic life	2	2	2
8. Interpersonal interactions and relations	d7 Interpersonal interactions and relations	3	3	3
9. General tasks and demands	d2 General tasks and demands	2	2	2
10. Physical functions	b4 Functions of the cardiovascular, haematological, immunological and respiratory systems b5 Functions of the digestive, metabolic and endocrine systems b6 Genitourinary and reproductive functions	4	4	4
11. Mental functions	b1 Mental functions	4	4	4
12. Products and technology	e1 Products and technology	2	2	2
13. Support and relations	e3 Support and relations e4 Attitudes	5	5	5
14. Services, systems and policies	e5 Services, systems and policies	2	2	2
15. Patient's self-identified concerns	-	1	1	1
Total number of items		77	92	82

LBP: low back pain

The ClinRO-LBP

The ClinRO-LBP ended up covering 14 ICF categories, 10 ICF categories from 'body functions' and 4 from 'body structures'. The corresponding items were organised in six sections, reflecting five ICF domains (Table 10).

Table 10. Sections in the ClinRO-LBP, corresponding ICF domain and number of items [125]

Sections	ICF domain	No of items
1. Neurological examination	s1 Structures of the nervous system b2 Pain b7 Neuromusculoskeletal and movement-related functions	17
2 Assessment of the spine	b2 Pain b7 Neuromusculoskeletal and movement-related functions s7 Structures related to movement	15
3. Assessment of the pelvic region	b2 Pain s7 Structures related to movement	3
4. Assessment of the lower limp	b7 Neuromusculoskeletal and movement-related functions s1 Structures of the nervous system s7 Structures related to movement	7
5. Summarising section		4
6. Clinical assessment	b1 Mental functions b7 Neuromusculoskeletal and movement-related functions	4
Total number of items		50

The patient profile LBP

The patient profile LBP was designed in a simple graphical format easy to interpret and aiming at being user-friendly for both patients and health professionals. In Figure 13, a full-page screenshot of the patient profile LBP is presented (also presented in the methods section regarding Study IV, Figure 6).

On the top of the screenshot, four headers are presented (Figure 13). The header *'Functioning assessment'* displays data from the PRO-LBP and the ClinRO-LBP. To the left ICF components with the corresponding ICF domains are listed together with color-coded bars of the results from the PRO-LBP and the ClinRO-LBP (Table 11). Pain intensity (VAS 0-100) is displayed at the top. The advisory group decided to present pain intensity in the following sub scores: Green=0-30, Yellow=31-70 and Red=71-100.

Table 11. Definition of colour-coded bars in the patient profile LBP

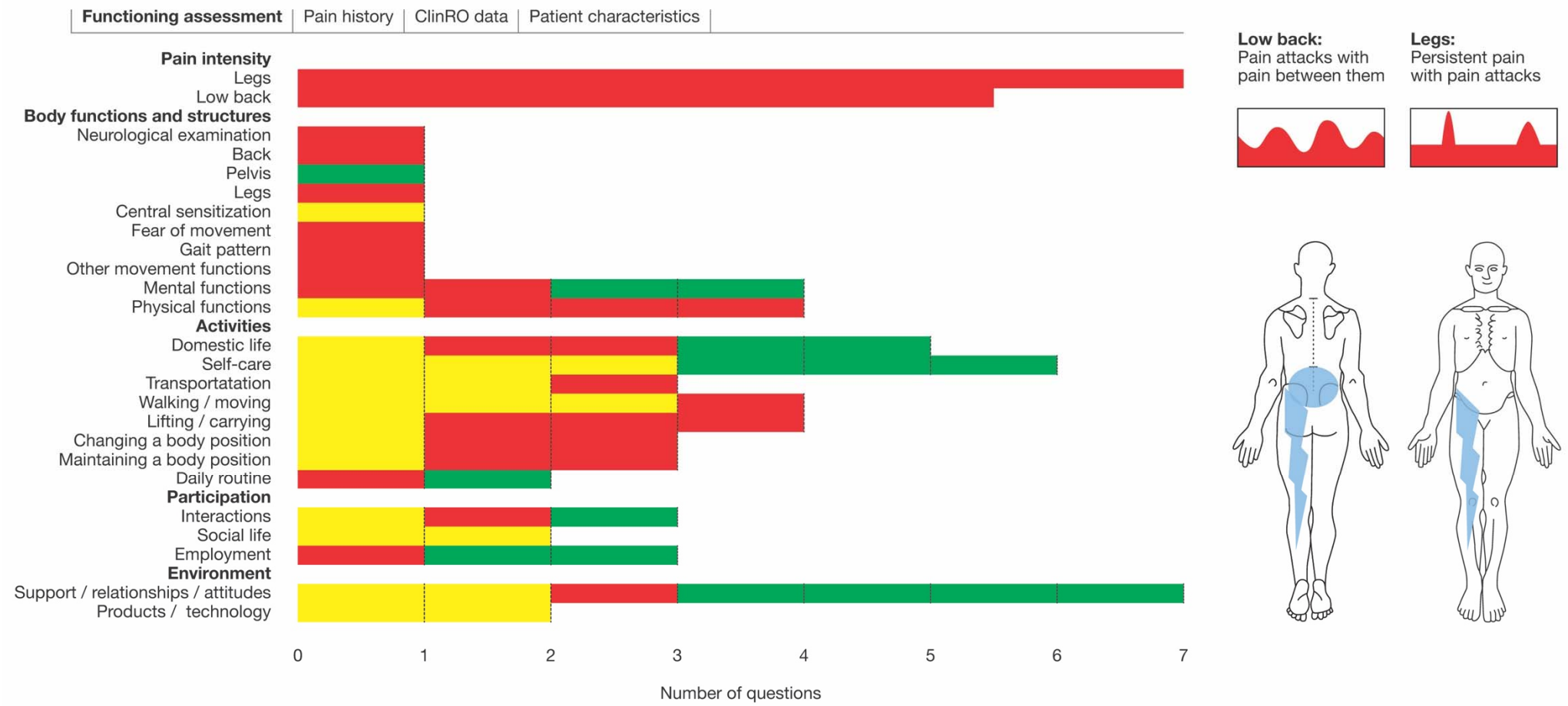
Colour-coded bars	Response options	Interpretation
PRO-LBP		
Green	1	No disability
Yellow	2 and 3	Mild disability
Red	4 and 5	Severe disability
ClinRO-LBP (data from summarising section and clinical assessment)		
Green	1	No positive findings
Yellow	2	Positive findings with moderate impact on functioning
Red	3	Positive findings with significant impact on functioning

The colour-coded bars are interactive; when tapping the bar, the underlying items and responses are shown on the screen. The horizontal line at the bottom defines the number of items within each ICF domain, ranging from one to seven items. The ICF domain 'Support/relationship/ attitude' e.g. comprises seven underlying items. To the right, the patient's pain pattern [155] and pain location are displayed. In the bottom left corner patient's self-identified concerns are displayed (information from the text box in the PRO-LBP).

The header *'Pain history'* was designed by request from the nurses. It covers information about the patient's pain including onset, character, location, duration, soothing factors, +/- leg pain symptoms and use of pain relieving drugs. The nurses wanted to use this information during their dialogue with patients about pain relieving drugs and pain management.

The header *'ClinRO data'* presents all items and responses from the ClinRO-LBP, while the header *'Patient characteristics*' covers patient characteristics such as height, weight, body mass index, smoking habits, alcohol consumption, former back surgery, comorbidity, ODI score [117] and the European Quality of life score [156].

Figure 13. Full-page screenshot of the patient profile LBP [125]



The patient's self-identified concerns:

5.3 Results Study III – the implementation study

The implementation process lasted from August 2017 to January 2018 and comprised four steps; feasibility-testing, training of health professionals, field-testing and a follow-up meeting with health professionals [126].

5.3.1 Step 1: Feasibility-testing

The feasibility-testing progressed without complications. As a result of the feasibility-testing, minor adaptions were made regarding logon and the visual presentation of data.

5.3.2 Step 2: Training health professionals

Seven health professionals participated in the training programme. Health professional characteristics can be found in Table 14.

The instruction component was conducted as planned; the content and the learning goals were delivered. The immediate evaluation by the health professionals was positive, and no further instruction seemed necessary before the tryout period.

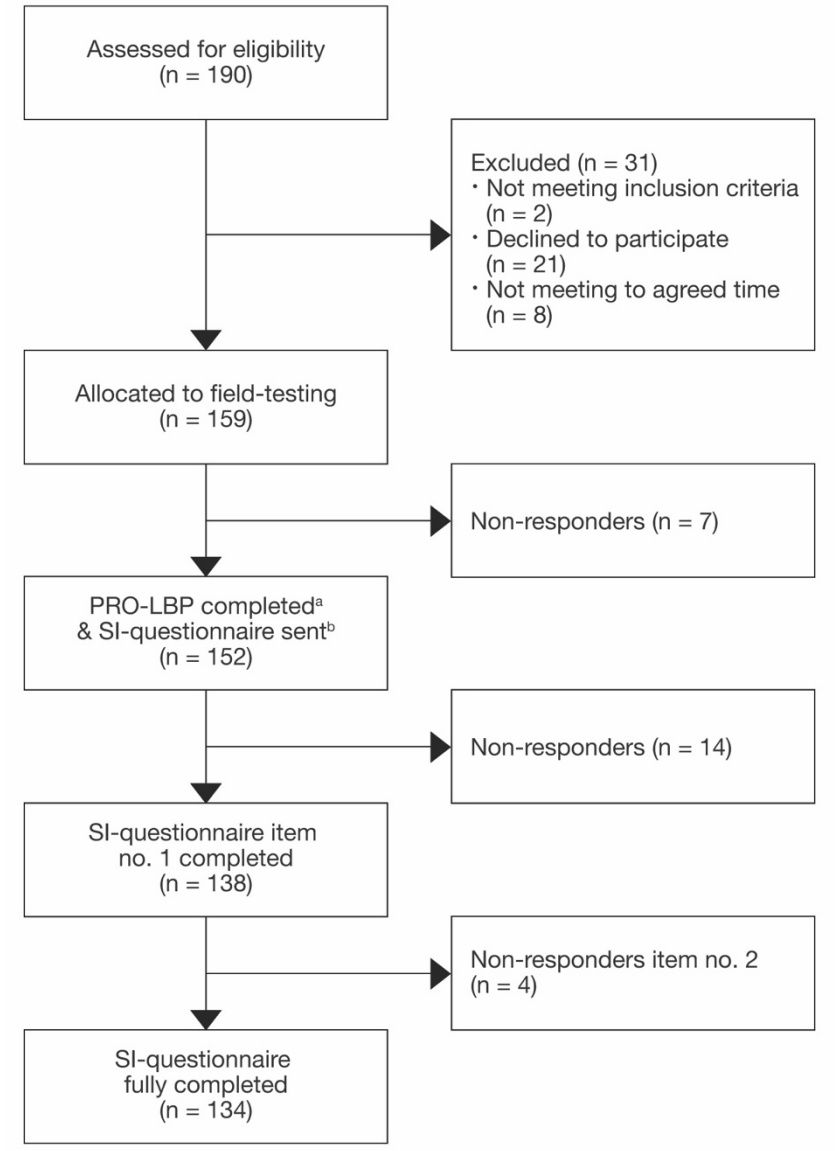
Observations from the tryout period showed that the LBP assessment tool was usable. Still, use of the PRO-LBP varied considerably among the health professionals.

At the follow-up meeting with health professionals the following issues emerged: 1) the ClinRO-LBP was easy and quick to fill in, 2) information regarding body mass index, catastrophising and fear of movement was missing and 3) the PRO-LBP facilitated patient involvement; however, more training was requested. As a result, items about height and weight were added to the PRO-LBP, while information on pain catastrophising [38] and fear of movement [39] was added to the ClinRO-LBP. Generally, the health professionals accepted the LBP assessment tool and found it ready for field-testing.

5.3.3 Step 3: Field-testing

In total, 159 patients participated in the first 3 months of the field-testing. Of the 159 patients, 152 completed the PRO-LBP (96 % response rate), and 134 completed the SI-questionnaire (88 % response rate) (Figure 14). The reporting time displayed a median of 3 days (p25-p75: 1-9) after the consultation.

Figure 14. Flowchart of participants, Study III [126]



SI-questionnaire: Successful implementation questionnaire

The non-responder analysis (n=25) showed significant differences between responders and non-responders with regard to duration of pain, employment status and ODI score[2]. Among responders a higher proportion had leg pain that persisted for more than 3 months and more were employed compared to non-responders. In comparison, non-responders had a lower ODI score compared to responders. Demographics and clinical variables for patients completing the PRO-LBP (n=152) are presented in Table 12.

[2] During the writing of this dissertation an error was found in the non-responders analysis in study III [147]. The error has been corrected in this dissertation, and will be corrected in study III during the revision process [147].

Table 12. Patient demographics and clinical variables, Study III [126]

Variable	n (%)[a] *(n=152)*
Gender, women	76 (50)
Age in years, median (p25-p75)	48 (37;54)
Pain location	
Back pain	28 (18)
Back pain and leg pain	115 (76)
Leg pain	9 (6)
Duration of pain, > 3 months	
Back pain*	127 (89)
Leg pain**	95 (77)
Worst pain within 7 days, 0-100, median (p25-p75)	
Back pain*	75 (61;81)
Leg pain**	69 (52;81)
Pain-relieving drugs (yes)	131 (86)
Employment status	
Employed (full time, part-time or flexi-job[b])	107 (70)
Unemployed	13 (9)
Enrolled in education	5 (3)
Retired (disability pension or age-related pension)	10 (7)
Vocational training or interdisciplinary rehabilitation programme	10 (7)
Stay-at-home husband/wife	7 (5)
Sick leave (full time or part-time)***	49 (34)
Previous back surgery (yes)	14 (9)
Current smoker	38 (25)
Comorbidity in addition to back pain	61 (40)
Disability, ODI 0-100%, mean (SD)****	36 (16)
General health, EQ VAS, 0-100, mean (SD)****	51 (22)

aData are presented as frequency count n (%), unless stated otherwise; bFlexi-job is defined as a job offered to individuals with reduced work ability*n=143; **n=124;***n=142;****n=151

ODI: Oswestry Disability Index; SD: Standard deviation; EQ VAS: EuroQol visual analogue scale

Successful implementation of the LBP assessment tool

Main results regarding successful implementation showed that 79 % of the patients reported that their responses from the PRO-LBP were used during the consultation, and 69 % of patients were presented with the patient profile LBP during the consultation (Table 13).

Table 13. Successful implementation in total and variation over time [126]

	Proportion (95 % Confidence Intervals)			
	Total	**Variation over time**		
SI-questionnaire	*(n=138)*	November *(n=64)*	December *(n=46)*	January *(n=29)*
Use of PRO-LBP	79% (71;85)	81% (70;89)	80% (66;89)	69% (49;83)
Use of patient profile LBP	69% (60;76)*	68% (54;79)**	75% (60;86)***	62% (43;78)

*n=134;**n=61;***n=45; SI-questionnaire: Successful implementation questionnaire

Results from the health professionals' survey (n=7) showed that they used responses from the PRO-LBP to some extent; all health professionals reported that they presented the patient profile LBP to the patients during the consultation.

Feasibility of the PRO-LBP

Overall, patients found the PRO-LBP feasible: 59 % (95% CI: 50;66) found it "very easy" or "easy" to complete, while 95 % (95% CI: 90;98) found it comprehensive. The average completion time was 28 minutes. In total, 35 % of the patients reported self-identified concerns in the text box; however, the information did not result in new items as 95 % of the mentioned concerns were already covered by the PRO-LBP. Notably, 60 % of the patients who wrote in the text box elaborated on their pain even though it was already included in the PRO-LBP.

Feasibility of the ClinRO-LBP

Of the seven health professionals participating in the field-testing, five conducted the clinical examination of the patients using the ClinRO-LBP (Table 14). All together they completed 151 ClinRO-LBPs, of which the chiropractor completed 42 %.

Table 14. Health professional characteristics [126]

Id	Sex	Age	Background	Years working with LBP	Years working at the Spine Centre	Number of ClinRO-LBPs completed
1	M	51	Chiropractor	25	8	63
2	F	63	Medical doctor	9	7	43
3	F	45	Nurse	8	8	0
4	F	50	Nurse	6	6	0
5	F	57	Medical doctor	20	4	39
6	F	38	Physiotherapist	12	7	2
7	F	41	Physiotherapist	15	8	3

The five health professionals completing the ClinRO-LBP provided data for feasibility. Four found the ClinRO-LBP "very easy" or "easy" to complete. They all agreed that the ClinRO-LBP was comprehensive.

However, the health professionals suggested to omit two items regarding muscle endurance functions (b740) of the paraspinal musculature and the lower limp, because they were not relevant for the clinical examination (Appendix 14). The average completion time of the ClinRO-LBP was two minutes.

5.3.4 Step 4: Feedback meeting

All seven health professionals participated in the feedback meeting (Table 14). Most health professionals were satisfied with the LBP assessment tool and found it useful for routine clinical practice. The nurses were most satisfied with the LBP assessment tool. One nurse expressed:

> *ID 3:"the information is perfectly presented to me"* [126]

The physiotherapists were less satisfied. One physiotherapist *said:*

> *ID 7: "I do not like the tool. It doesn't give me the concrete information that I need as a physiotherapist. I believe it is quicker to ask the patient"* [126]

Three main themes emerged from the feedback meeting. The LBP assessment tool: 1) facilitated a positive consultation based on the patient's perspective 2) allowed for a more biopsychosocial approach and 3) gave a quick overview [126].

A positive consultation based on the patient's perspective signified a smooth and positive consultation because all patients were able to fill in the PRO-LBP and their answers were useful. One health professional said:

> *ID 2:"It was a pleasure to see how patients were able to fill in the PRO-LBP, their answers were useful, and the LBP assessment tool helped address what matters to the patients"* [126]

Allowing for a more biopsychosocial approach to functioning and disability meant that health professionals included the interaction between functioning and environmental factors such as support or barriers from relatives, the general practitioner, the workplace and social services. A health professional stated:

> *ID 1:"The LBP assessment tool broadens my approach to functioning and leads me away from only somatic and body function"* [126]

Still, the health professionals expressed concerns regarding their competencies to manage the psychosocial issues. Finally, the health professionals stated that the LBP assessment tool *gave a quick overview* pinpointing the patient's disability.

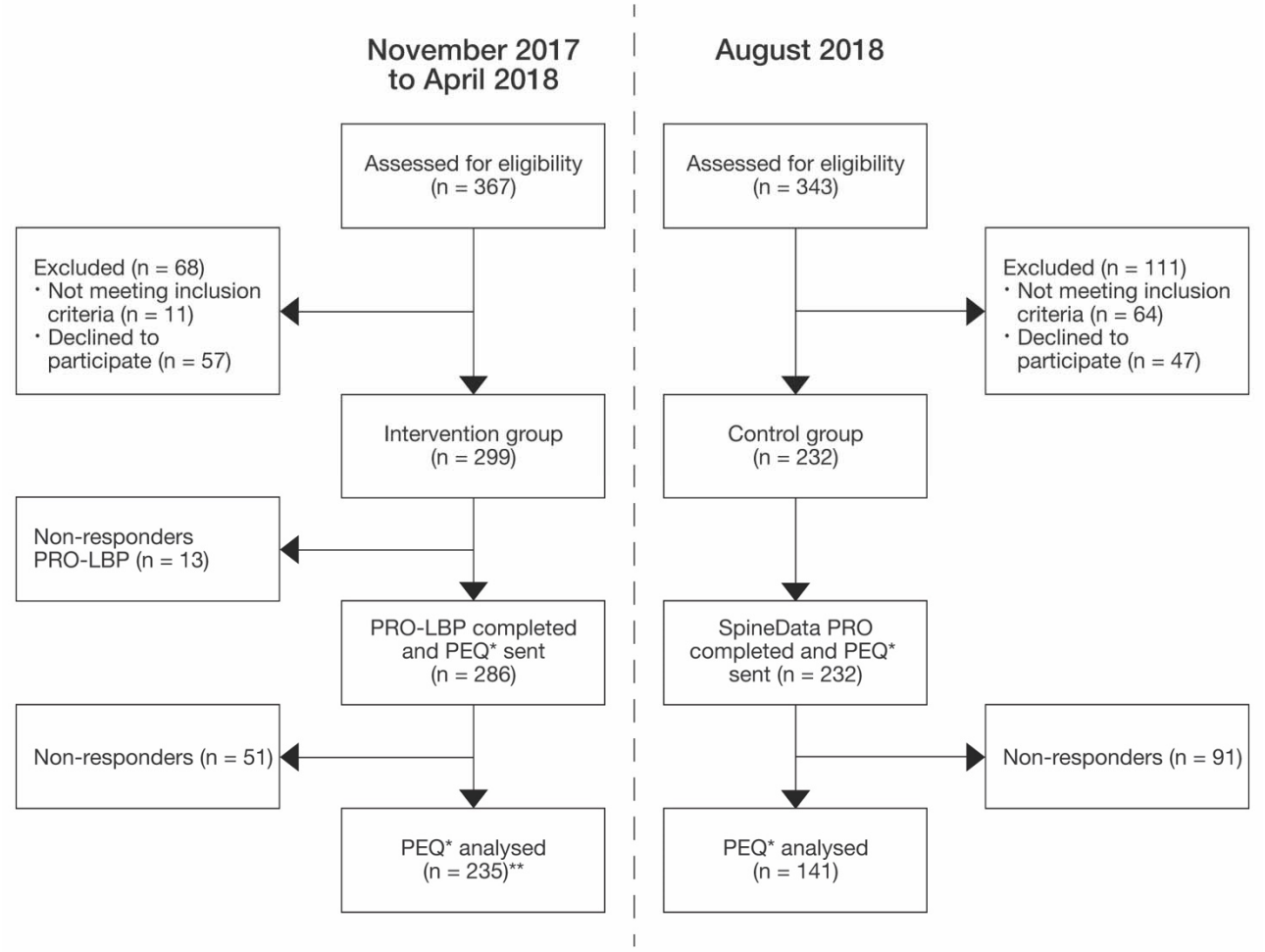
> *ID 3: "It [The LBP assessment tool] gives a quick overview and facilitates a sound use of our time with the patient"* [126]

Discussion about the usefulness of the ClinRO-LBP revealed that the health professionals liked it as a checklist for the assessment, but they still had to look for the conclusion in the patient's health record e.g. to complete a referral for rehabilitation. The health professionals had some suggestions for improvement; to include a text box at the end of the ClinRO-LBP to be able to add information, improve the design and technical production of the LBP assessment tool and to incorporate the data into the patient's health record. Their suggestions were discussed after the field-testing.

5.4 Results Study IV – the non-randomised controlled study

A total of 299 patients from the project clinic were allocated to the intervention group and 232 patients from SpineData were allocated to the control group (Figure 15) [127].

Figure 15. Flowchart of participants, Study IV [127]



*PEQ: Patient evaluation questionnaire

**Data regarding the item "use of patient profile LBP in the consultation" were missed in 4 patients due to technical issues, thus this analysis was based on 231 patients (Table 16)

In the intervention group, 235 patients completed the patient evaluation questionnaire (response rate 82 %); this applied to 141 patients in the control group (response rate 61 %). The reporting time for the intervention group showed a median of 2 days (p25-p75: 1-9) after the consultation and a median of 20 days (p25-p75: 12-33) for the control group. Demographics and clinical characteristics of patients are presented in Table 15.

Table 15. Patient demographics and clinical variables, Study IV [127]

	Intervention group	**Control group**
Patient characteristics	*n=235*	*n=141*
Gender, women, n (%)	113 (48)	84 (60)
Age, years, mean (SD)	45 (11)	46 (11)
Disability, mean (SD)		
Oswestry Disability Index (0-100 %)	34 (16)	-
Roland Morris Disability Questionnaire (0-23)	-	14 (6)[a]
Pain duration > 3 months, n (%)		
Back pain	197 (90%)[b]	110 (81%)[c]
Leg pain	142 (75%)[d]	98 (80%)[e]
Pain intensity, mean (SD) (0-100)		
Back pain	70 (21)[b]	80 (20)[f]
Leg pain	67 (23)[d]	70 (30)[c]
On sick leave (full- or part-time), n (%)	71 (32)[g]	54 (48)[h]
Current smoker, n (%)	53 (23)	39 (29)[i]
Previous back surgery, n (%)	26 (11)	26 (19)[c]
Comorbidity in addition to back pain, n (%)	99 (42)	52 (38)[c]
General health, EQ VAS, mean (SD)	53 (23)	47 (25)[i]

[a]n=133; [b] n=220; [c]n=136; [d]n=188, [e]n=123; [f]n= 138; [g]n=225; [h]n=112; [i]n=135;

SD: Standard deviation; EQ VAS: EuroQol visual analogue scale

All patients reported moderate disability, corresponding to an ODI mean score of 34 % in the intervention group and an RMDQ mean sum score of 14 in the control group (Table 15). Statistically significantly differences in patient characteristics between the two groups were found. Patients in the intervention group reported having a longer back pain duration (p=0.02) and a better general health (p=0.01) than the control group. The control group had a significantly higher proportion of sick leave (p<0.00) and previous surgery (p=0.03) compared to the intervention group.

The non-responder analysis, performed in 51 patients from the intervention group and 91 patients from the control group, found no significant differences with regard to gender, but non-responders were significantly older that responders in both groups. Non-responders in the intervention group were 3.7 (95 % CI: 0.5; 7.02) years older (p=0.03) and in the control group they were 6.7 (95 % CI: 3.9; 9.6) years older.

Outcomes

When comparing use of PRO data during the consultation, 78 % (95 % CI: 72;82) of patients in the intervention group reported that their PRO data were used compared to 58 % (95 % CI: 49;65) in the control group (p < 0.00). When comparing use of the patient's profile and shared decision-making, a significantly higher use was reported in the intervention group compared to the control group (Table 16).

Table 16. Comparison of use of PROs, the patient's profile and shared decision-making [127]

	Intervention group *(n=235)*	**Control group** *(n=141)*	
Primary outcome	Value	Value	p-value
Use of PROs*	78 % (72;82)	58 % (49;65)	p<0.00
Secondary Outcomes			
Use of the patient's profile*	68 % (61;73)#	43 % (35;52)	p<0.00
Shared decision-making†	71 (68;73)	66 (62;69)	p=0.01

*Data are presented as percentages with 95 % confidence intervals (CI); †Data are presented as sum scores 0-100 with 95% confidence intervals; #n=231

The explorative analysis regarding differences in patient characteristics showed that the higher proportion of patients on sick leave in the control group was the only parameter associated with the use of PROs. Patients on sick leave more frequently reported that their PRO data were not used during the consultation (p=0.02). Two additional analyses performed among all participants showed no association between sick leave and use of PROs (p=0.06), and no association between sick leave and shared decision-making (p=0.85).

6. Discussion

In the following chapter, the four studies included in this dissertation will be discussed. First, the main findings will be presented and compared with existing literature. Second, reflections on ICF will be presented. Finally, methodological strengths and limitations will be addressed followed by a discussion of the external validity of the findings.

6.1 Summary of main findings

Each of the four studies contributed with valuable knowledge to the development, implementation, field-testing and evaluation of the LBP assessment tool.

Study I informed the understanding of the patient perspective in LBP [124]. Tree main themes reflected the patients' experiences regarding facilitation of a patient-centred consultation with the use of PRO data. *Simplicity* emphasised patients' wish to keep items to a minimum and avoid item overlaps; *individuality* referred to patients' need to address individual challenges, and *application* signified patients' expectations of active use of the PRO data during the consultation. Patients' perspectives were incorporated into the continued development of the LBP assessment tool.

Study II contributed with an exhaustive description of the process used to develop the LBP assessment tool [125]. The tool was developed to capture 'functioning and disability' using ICF as a framework. The construct of the LBP assessment tool was based on the Comprehensive LBP core set [33] and the Rehabilitation set [34]. The development process included five steps: 1) Definition of construct and content, 2) Item generation, 3) Needs assessment, 4) Piloting and 5) Design and technical production (Figure 8). In total, 18 patients and 12 health professionals were involved in several steps of the development process. The LBP assessment tool included ICF categories from all ICF components covering 63 categories of which 49 were allocated to the PRO-LBP and 14 to the ClinRO-LBP. The tool also comprised items regarding the undeveloped ICF component 'personal factors'.

Study III contributed with findings from the implementation process (Figure 3) [126] assisted by the i-PARISH framework [134]. Feasibility testing showed that patients and health professionals found the PRO-LBP and the ClinRO-LBP feasible for routine clinical practice. Training of health professionals including a tryout period revealed that they accepted the LBP assessment tool and found it ready to be field-tested in a larger population. Main findings from the field-testing showed the LBP assessment tool was feasible to patients and health professionals; however, successful implementation was not reached after three months. The feedback meeting held with health professionals revealed three main findings. The LBP assessment tool 1) facilitated a positive

consultation based on the patient's perspective 2) allowed for a more biopsychosocial approach and 3) gave a quick overview of the patient's functioning and disability.

Study IV contributed to the evaluation of the LBP assessment tool [127]. We found that patients attending consultations facilitated by the LBP assessment tool reported a significantly higher use of their PRO data and their patient profile during the consultation compared to patients attending usual care. Moreover, patients in the intervention group experienced being more involved in decision-making.

6.2 Comparison with existing literature

6.2.1 Study I - focus group interviews

The literature is sparse on perspectives of patients with LBP regarding PRO development and use of PRO data as a part of routine clinical practice. Thus, Study I add important information to this knowledge gap [124].

Patients' aspirations to keep items to a minimum and avoid item overlaps were probably caused by their experiences when filling in the SpineData PRO [129]. The SpineData PRO merges several established and validated PRO instruments into one questionnaire [129]. Thus, several items may address the same domain, which in a patient perspective can be perceived as a repetition of items. Concerns have been raised about burdening patients with too many questions [157], because it may affect the validity of the responses and lead to low response rates [158]. The results from this dissertation showed that patient involvement in the preparation of the PRO-LBP produced a PRO instrument reflecting the patient perspective. Despite the comprehensiveness of the PRO-LBP, patients found it feasible and the response rate was not negatively affected. This support the importance of involving patients at an early stage of PRO development and implementation [91].

Active use of the patients' own PRO data during the consultation was essential, which is in accordance with existing literature regarding patient involvement and shared decision-making [71,77,78]. A recently published study examined patients' viewpoints on use of PRO data as a part of routine clinical practice in patients with inflammatory arthritis [80]. Similar to our findings, they found that patients expect active use of their PRO data during the consultation [80]. Furthermore, they found that PRO instruments should be able to address the individual's challenges [80]. This is also consistent with our finding of individuality [124].

6.2.2. Study II - the development study

Study II contributed with important knowledge to the existing body of evidence regrading application of ICF core set in clinical practice and involving patients and health professionals in the

development of tools [125]. Thus in this chapter focus is on the Comprehensive LBP core set [33] and the Rehabilitation set [34], followed by a discussion of involving patients and health professionals in the development of the LBP assessment tool.

Functioning and disability are typically assessed by health professionals [159]. Health professionals' ratings of ICF categories from the LBP core set have been reported [160-162], but the literature regarding patients' ratings is limited [159]. Two studies reported on the LBP Core Set Self-Report Checklist [47,48]. Just like the PRO-LBP, the LBP Core Set Self-Report Checklist was developed to operationalise ICF categories from the LBP core set with a self-reported instrument and with the aim to overcome limitations of established LBP-specific PRO instruments [116,118]. The LBP Core Set Self-Report Checklist was limited to consider only the 'activities' and 'participation' components. It has thus been recommended to examine self-reports of other ICF components such as 'environmental factors' in further research [47]. With the PRO-LBP we have contributed to this knowledge gap, as the PRO-LBP adds items regarding 'environmental factors' [125]. Although 'personal factors' is not classified [5], we decided to develop items corresponding to personal characteristics such as gender, age, comorbidity and lifestyle [125]. A strong argument for doing so was that personal factors have some effects on the individual's disability, thus they are important in explaining functioning to obtain a biopsychosocial perspective [163].

The Rehabilitation set was developed to standardise reporting of functioning in rehabilitation practice and to enable comparison of health and health-related data within and across health systems [34]. Even though ICF core sets assist *what to measure*, they are not clinical tools phrased in familiar language to health professionals [55]. In addition, many ICF categories are not intuitive and their broad nature prevents health professionals from using them on a daily basis in routine clinical practice [55]. To enhance the use of the Rehabilitation set in routine clinical and rehabilitation practice, it was embedded as part of international efforts towards system-wide implementation of ICF [52,54,55]. In Japan [54], Italy [52] and China [55] 'simple, intuitive descriptions' of ICF categories contained in the Rehabilitation set were developed. These simple, intuitive descriptions were developed in a multi-stage, national consensus process and present the original ICF category definition in a user-friendly language [54]. Together these initiatives have laid the first stepping stones towards a system-wide application of an ICF-based clinical data collection tool in routine clinical and rehabilitation practice [52,54,55]. Experiences from the Italian study suggest that these simple intuitive descriptions of the Rehabilitation set have the potential to be used not only in Italy, but also in the rest of Europe [52].

As presented above, existing literature regarding the LBP core set and the Rehabilitation set offers several proposals of clinical tools to enhance the use in routine clinical practice. However, to the best of our knowledge, the LBP assessment tool is the first clinical tool to integrate ratings from

patients and health professionals based on categories from the Comprehensive LBP core set [33] and the Rehabilitation set [34].

Involving patients and health professionals was essential during the development of the LBP assessment tool [124,125]. Their perspectives qualified the content of the tool and contributed with input on how data from the LBP assessment tool should be displayed [125].To ensure that the collected PRO data were relevant and meaningful for patients and health professionals, both target groups were involved in the development of the PRO-LBP. Involving both patients and health professionals is an important prerequisite in PRO development and implementation [77]. While patients are the ones to self-report the outcomes, health professionals use the data to guide clinical decisions [97]. We found it challenging to balance patients and health professionals' preferences regarding selection of items especially because their views varied. In accordance with previous findings, we found that patients preferred to report on how LBP affected their everyday lives, while health professionals preferred to assess physical issues they knew how to treat and manage [97,98].

6.2.3 Study III - the implementation study

Study III illuminated implementation of the LBP assessment tool [126] and supported that implementation of innovations into routine clinical practice is a complex process [164,165]. Therefore, research recommends that implementation of innovations and new procedures into clinical practice needs to be accommodated by a framework [143]. We choose to use the i-PARISH framework [144] to assist the implementation of the LBP assessment tool. First, because it includes concepts that need to be considered for successful implementation [166] and second, because it is widely applied, tested and reviewed [144]. We acknowledge that other implementation frameworks could have been used, but overall the i-PARISH framework prompted our understanding of critical elements related to successful implementation of the LBP assessment tool.

Facilitators have a key role in successful implementation [167]. In a systematic review and meta-analysis examining the effect size of practice facilitation found that clinical practice is three times more likely to implement guidelines when a local facilitator is involved [168]. We appointed an internal facilitator (co-supervisor BSC) who worked with the health professionals and provided practical help and support throughout the implementation process. A variety of skills and personal attributes are necessary to be an effective facilitator [167]. Furthermore, strong leadership is essential to support successful implementation [169]. We believe that BSC possessed the necessary skills to fulfil the role as an effective facilitator and we consider the appointment of a facilitator to be essential for our implementation process [126].

Adequate training of health professionals have been shown to enhance the integration of a biopsychosocial approach in patients with LBP [20,21]. In Study III, training of health

professionals was used to facilitate the implementation of the LBP assessment tool [126]. We found that the tool allowed health professionals to be more biopsychosocially oriented. Still, the health professionals expressed concerns about their competencies to manage psychosocial issues. This is in line with previous research, indicating that health professionals can identify psychosocial factors and value their importance, but due to lack of confidence in managing psychosocial issues, their use can be limited [170,171]. It seems that we can modify health professionals' beliefs about and attitudes to LBP, but to achieve and sustain changes in clinical practice are more challenging [26,170]. It has been argued that educational programmes for e.g. physiotherapist tend to focus on the biomedical approach to LBP [26]. Consequently, full implementation of the biopsychosocial approach will not succeed before educational programmes focus more on the biopsychosocial approach with the goal to start a new professional culture [26].

Despite feasibility-testing, training of health professionals and nomination of a local facilitator, the LBP assessment tool was not successfully implemented after three months [126]. The reduced success may be attributed to several reasons. First, we acknowledge the complexity of the LBP assessment tool with three new features to be implemented along with the goal to shift health professionals away from a biomedical towards a more biopsychosocial approach. Evidence suggests innovations that are perceived to be *simple* to use are more easily adopted [172,173]. We incorporated instruction and tryout in the training programme because perceived complexity can be reduced by practical experience and demonstration [174]. Previous work has stated that the most successful implementation occurs when the following criteria are met: "(1) the evidence is scientifically robust and matches the needs of health professionals and patients; (2) the context is open to change with sympathetic cultures, strong leadership, and appropriate monitoring and feedback and (3) there is appropriate facilitation of change with input from facilitators" [169]. We believe that our implementation process met these criteria, except for appropriate monitoring. It could be argued that continuous monitoring during the field-testing could have identified unknown factors and thereby increased the likelihood of obtaining successful implementation [175].

The feedback meeting with the health professionals allowed to accommodate their needs, identify concerns and obstacles, thus we believe the feedback meeting was important to facilitate implementation of the LBP assessment tool [126]. Previous research has shown that including feedback meetings within the existing team meeting is necessary to facilitate implementation of PROs [146].

6.2.4 Study IV - the non-randomised controlled study

Study IV demonstrated that patients in the intervention group reported a significantly higher use of PROs during the consultation (78 %) compared with the control group (58 %) [127]. Previous research has shown that patients and health professionals find a level around 80-85 % to be

feasible and acceptable [150,151]. Thus, the 78 % reported by the intervention group is considered acceptable; however, 58 % in the control group was far from an acceptable level. The reduced use of PROs in the control group was disturbing because the SpineData PRO has been used in the Spine Centre since 2011 [22]. On the other hand it is consistent with our findings from Study I, as health professionals at the Spine Centre stated that their use of the SpineData PRO varied considerably [125]. This underlines that PRO implementation in clinical consultations is challenging and needs persistent facilitation [145] and training of health professionals [83,146]. It has been shown that teaching health professionals how to use and act on PROs in clinical practice is a key step in supporting patient involvement and shared decision-making [146]. We believe that the tailored training of health professionals in the intervention group promoted ownership and correct use of PRO data and contributed to the higher use of PRO data [127]. Moreover, the higher use emphasised that acceptance by health professionals is essential to the success of using PRO data as a part of routine clinical practice [176,177].

A number of systematic reviews have found that use of PROs is clinically meaningful, but the impact of PROs was limited [75,178-180]. Results from Study IV showed both clinical meaningfulness and that it was possible to enhance the use of PROs and shared decision-making during the consultation by means of the LBP assessment tool, tailored training of health professionals and appointment of a facilitator [127].

6.3 Reflections on ICF

ICF has gained considerable influence globally, and is now generally accepted as the international standard for describing functioning and disability [5]. The literature on the use of ICF has grown [29,181-183]. Although ICF is widely used, it has been subject to emerging critiques pointing towards the need to revise it [184-191]. Since the LBP assessment tool was based on ICF, some of these points of critic will be discussed in this chapter.

6.3.1 Criticism regarding the ICF model

One of the main points of critic has been directed against the ICF diagram (Figure 1) putting the health condition at the top [187,190]. This may give the impression that the medical perspective is dominant despite the biopsychosocial perspective of ICF [187]. To reduce the dominance of the health condition and to emphasise the biopsychosocial perspective, several alternative ICF diagrams have been suggested [187,188,190]. Heerkens et al suggested to remove 'health condition' from the diagram and include it in the component 'personal factors', whereas Mitra el al suggested to move 'health condition' to the same level as 'body functions', 'activities' and 'participation' [190]. Furthermore, an ICF diagram has been suggested in which 'environmental factors' surrounds the

other components and 'personal factors' is put on top [187]. Finally, it has been suggested to position 'participation' at the center to stress its importance [187].

The authors of these alternative diagrams argue that it is time for a revision of ICF [187,188,190]. However, the current ICF diagram maintain value if no (known) health condition is present [192]. In addition, it can be argued that ICF should not necessarily be read from the top to the bottom and from left to right. As an example, health professionals usually start the history talk by asking patients about personal factors (e.g. name, age, work); continue to environmental factors (e.g. living status, support from family and friends) and then move onto functioning. Furthermore, it could be argued that evidence does not support a revision, as the majority of research is on the components rather than on the relationship between them [29,181,193]. However, we do agree that ICF should be continuously reviewed, which is in accordance with the view of WHO. As they launched ICF they acknowledged that "*any diagram is likely to be incomplete and prone to misinterpretation because of the complexity of interactions in a multidimensional model*" [5]. Furthermore, since 2008 there has been an annual update of ICF [194] and with a new version in 2020 it can be argued that ICF has been open to change [5].

In addition to the diagram the full ICF model has been debated, and the question has been raised: 'how patient-centred is ICF?' [185,190,195]. For instance, it has been argued that the perspectives of patients are not expressed enough in ICF, especially because ICF is not a patient-oriented tool. Thus, assessment does not require the involvement of the person with the disability [195,196]. By introducing the LBP assessment tool we have shown that ICF offers opportunities to assess functioning from both the perspectives of health professionals and patients. Still, patients' ratings of ICF are limited in clinical practice [47,48].

6.3.2 Criticism regarding the ICF classification

Points of criticism regarding the classification have mainly focused on the lack of relevant items regarding factors related to the working environment [197] and that the component 'personal factors' is not classified [198].

To most individuals, employment is important because it covers financial needs, it provides a basis for the individual's social status and social role and it is central to self-confidence and identity [199]. In Europe, LBP is the most common source of work absence [14]. A key component of work disability is vocational rehabilitation, with the goal to enable workers to keep their job or return to work after a health condition [197]. Vocational rehabilitation is a complex and multifaceted process and therefore the need for a framework that is integrative, comprehensive and biopsychosocial similar to ICF was recommended [200]. In 2012 the Work Rehabilitation Questionnaire (WORQ) [200] based on ICF core set for vocational rehabilitation [201] was developed. WORQ is a generic

questionnaire, developed to better understand the extent of problems in functioning that people may have due to their health condition(s) and who are undergoing work or vocational rehabilitation [200]. In the PRO-LBP we included ICF categories from the domain 'Work and employment' (d840-d859) to address work disability. With the benefit of hindsight, we probably could have derived selected items from the WORQ to the PRO-LBP to collect specific information regarding work functioning [200]. Therefore, we recommend exploring this in further studies.

In contrast to the other components of ICF, 'personal factors' is not implemented with a classification system even though the component is a part of the classification [5]. Thus, there is no definition, no inclusion and exclusion criteria as well as no recommendations for how they should be documented [198]. Consequently, there is uncertainty about what is contained in this component and therefore it has been argued that 'personal factors' should not be applied [198]. We chose to include items regarding 'personal factors' in the PRO-LBP such as age, gender, lifestyle and comorbidity [125]. In the literature it has been argued that disregarding 'personal factors' raises ethical concerns as it would mean reducing the person to his or her functioning status [163]. Also, it has been stated that one "unclassifiable' element does not affect the validity of the whole model [163]. The debate about 'personal factors' has led to a need for further research about their purposes, definitions and ethical use [163]. The WHO Family of International Classifications Network has already initiated this work [163]. Overall, we included 'personal factors' in the LBP assessment tool because they were relevant and useful and because we believe they contributed to the comprehensive and in-depth understanding of functioning and disability.

Originally the ICF classification was intended to complement the ICD classification to capture and provide the full picture of health or health-related status of an individual [5,27]. Currently, there is, however, no evidence that this has been realised [202], but to enhance the link between ICF and the ICD, WHO has introduced a supplementary chapter for functioning assessment in the 11th revision of ICD containing 46 codes for specific functioning entities [203].

Despite the debate, ICF has changed the thinking about functioning and disability [204]. In several ways this dissertation contributes with important knowledge to the debate concerning ICF. First, the dissertation showed that it was possible to develop operational items for patients to enhance patients' ratings of ICF in clinical practice [125]. Second, it supported that when using ICF it is possible to describe functioning without necessarily assigning a diagnosis. We found that when patients were asked to describe their own situation, their main focus was on how LBP affected their everyday lives, and less on the diagnosis [124]. Third, the LBP assessment tool had a positive impact on the consultation and showed that when ICF was truly used in routine clinical practice it allowed the health professionals to apply a more biopsychosocial approach [126]. Finally, we

documented that the LBP assessment tool in combination with training and facilitation enhanced a more patient-centred consultation [127].

6.4 Strengths

Overall, this dissertation has some strengths both in terms of the chosen methods and the effort to cover research that, to date, has scarcely been covered in the literature.

First, we succeeded to develop, implement, field-test and evaluate the impact of the LBP assessment tool in a real-world setting in a relatively large sample of patients with LBP.

Second, the methods used to develop and implement the LBP assessment tool were considered robust due to the following elements:

- ICF was used as the scientific basis. ICF provides a standard language and conceptual basis for understanding functioning and disability. Furthermore, ICF provides a classification that makes it possible to develop universally applicable assessment tools such as the LBP assessment tool.
- We used the Comprehensive LBP core set [33] in combination with the Rehabilitation set [34]. This broadened the assessment compared to using solely the LBP core set. Previously it has been stated that condition-specific core sets are limited because of the risk of omitting important information as patients often present with a combination of issues that will not be accounted for when using a diagnosis-specific core set [205].
- PPI was embedded within the development. Thus, patients and health professionals from different disciplines contributed to the content and the design of the LBP assessment tool. We believe that tailoring the LBP assessment tool to the end-users maximised the acceptability and reduced implementation barriers. This was proven to be true as shown in Study III, where the tool was found feasible by patients and health professionals [126].
- The process was guided by evidence from three relevant sources; development of web-based decision support systems [140], measurement instruments [141] and PRO instruments [88]. Each source contributed with various elements of importance resulting in a systematic, solid and comprehensive development process.
- The combination of qualitative and quantitative methods resulted in a more complete understanding of functioning and disability in patients with LBP.
- We applied a widely used, tested and reviewed implementation framework, the i-PARISH to facilitate awareness of the critical elements before implementation of the LBP assessment tool [144].

- We used web-based questionnaires which compared to paper questionnaires have shown to improve the response rate [206]. This may explain the overall sufficient response rate in Study III [126] and Study IV [127] of at least 60 % [207] (further discussed in chapter 6.5.2).

This dissertation provides new and valuable knowledge to the limited literature, especially regarding patient involvement in PRO development [91] and patients' perspectives regarding using PROs to support management of the individual patient [74-76]. In addition, it is underlined that training of health professionals and facilitation are important when aiming to implement new procedures into routine clinical practice. Finally, this dissertation introduces a proposal of a new ICF-based tool that has proven to be feasible in routine clinical practice. Moreover, it facilitates a biopsychosocial and patient-centred approach to patients with LBP.

6.5 Limitations

When assessing the result of the current dissertation, considerations to potential sources of bias that may have affected the result, must be made before an overall conclusion can be drawn. Hence, the internal validity of studies will be discussed in this chapter.

6.5.1 Study I - focus group interviews

We had challenges in the recruitment of patients to the focus group interviews, as several of the invited declined to participate [124]. There is a risk that the patients we included may have been “healthier” and more resourceful compared with patients who declined to participate. Moreover, the four patients opting out on the day of the interviews proved to be the ones who experienced the worst pain, thus being unable to drive to the Spine Centre and to sit down during the two-hour interview. Despite recruitment challenges and patients opting out, we managed to include the intended sample size of a minimum of seven patients. We do not believe the relatively low patient sample compromised the findings, because it is in accordance with COSMIN recommendations for qualitative research in development of PRO instruments [134]. Moreover, the PRO-LBP provided room for individual perspectives, and we thus believe it is applicable to patients who experience more pain than the ones who participated in the interviews.

Interviewer bias must be considered in Study I [124]. Interviewer bias is defined as: "the tendency of the interviewer to obtain answers that support preconceived notions" [208]. To reduce the risk of interviewer bias, the PhD student followed a structured interview guide and a senior researcher and registered nurse (last author of Study I) participated to broaden the perspectives and reduce the risk of preconceived notions by the PhD student, which could have influenced the findings [124,125].

6.5.2 Selection bias

Selection bias may occur when participation or follow-up is not complete in a study or if the participants differ from those not included [209]. The risk of introducing selection bias was found in studies II [125], III [126] and IV [127].

Study II – the development study

In Study II, eight health professionals from different disciplines were appointed to participate in the focus group interview [125]. The appointment was performed by the management at the Spine Centre and according to the principle of voluntariness. It could be argued that the participating health professionals were those most positive towards a biopsychosocial approach and also those who were most open minded to change behaviour.

We acknowledge that inclusion of patients and health professionals in Study II could have been prone to selection bias, thus leading to an overestimation of our findings. Still, we believe that the results are in any way atypical of what would be found with a larger group of patients and health professionals, as both groups varied in age, gender and health professionals also varied concerning years of work experience and professional discipline.

Study III – the implementation study

In Study III, 190 patients were assessed for eligibility out of which 11 % declined to participate (Figure 14) [126]. Data on these patients were not accessible but could have informed us about potential selection bias. Due to missing information about non-participants, we cannot draw any conclusions on that basis.

Selection bias may also occur during follow-up due to non-response (attrition bias). A web-based questionnaire as well as the decision to send three written reminders and make one phone call was used to boost response rates and increase the representativeness of data [206,210]. In Study III, we found a response rate of 84 % [126]. In accordance to survey research, a response rate of at least 60 % is considered sufficient to ensure that non-response bias threatens the validity of the findings [207]. However, we found differences in patient characteristics between responders and non-responders. The direction of these characteristics was mixed. On the one hand, non-responders experienced reduced disability and a shorter duration of leg pain; on the other hand, a higher proportion of responders were employed. Due to the high response rate and the mixed direction of patient characteristics, we expect attrition bias did not overestimate the impact of the LBP assessment tool.

Study IV – the non-randomised controlled study

In Study IV some considerations must be taken into account [127]. The allocation of patients was based on a non-randomised selection, and we may thus have introduced selection bias [127].

First, differences in participation rates between the groups were found; 68 % in the control group and 83 % in the intervention group (Figure 15) [127]. Information on the excluded patients could have given us an understanding of potential selection bias; however, similar to Study III, we are not able to draw any conclusion. Second, patient characteristics differed between groups. The explorative analysis revealed that sick leave in the control group was the only parameter associated with the use of PROs. To determine whether sick leave could have modified the observed effect of the LBP assessment tool, we conducted two additional analyses among all participants. First, we tested the association between sick leave and use of PROs and second, we tested the association between sick leave and shared decision-making. No associations were found which reduced the risk of selection bias and supported the effect of the LBP assessment tool.

Differential attrition was found, as the non-response rate of the patient evaluation questionnaire was lower (18 %) in the intervention group compared to the control group (39 %). A possible explanation for this difference could be the willingness of patients in the intervention group to participate because the subject of the questionnaire felt more relevant to them compared to patients in the control group. We restricted the analysis to participants with full outcome information. Comparing the responders and the non-responders showed a slight discrepancy in age in both groups. This could have led to attrition bias [211]. Patient involvement has been shown to vary according to the patient's age, and younger patients (≤50 years) tend to be more involved than older patients [204]. However, our study participants were rather young (mean age was 44 years), and the minor age differences were probably not of critical importance to the outcome. However, it is known that non-responders often report poorer functioning than responders [42] and that social inequality in study participation in general is an issue that should be considered [206]. As mentioned previously, we were not allowed to collect further patient characteristics on the non-responders due to the general data protection regulations [207]. Collecting this information could have provided us with important knowledge about the non-responders and a further understanding of a potential association between patient characteristics and the use of PRO data and shared decision-making.

Although the non-randomised design resulted in selection bias we believe that the reason for non-responders to withdraw from Study IV was unrelated to LBP, their treatment, the intervention or the outcome (use of PROs). This in combination with a response rate in both groups above the recommended 60% [199] implies that attrition bias did not alter our result.

6.5.3 Information bias

Information bias occurs during data collection and when key information is either measured, collected, or interpreted inaccurately [209].

The main risk of information bias in studies III [126] and IV [127] would be subject to self-reported data. The primary outcome in both studies was 'use of PROs during the consultation', which was measured by the self-developed patient evaluation questionnaire; thus, we used a non-validated questionnaire. This may have led to misclassification, because there was a risk that patients have completed the questionnaire incorrectly or because they misunderstood the questions. The misclassification is non-differential in Study IV because it is expected to be the same for both groups [127].

To reduce risk of recall bias, the questionnaire was sent to the patients immediately after their consultation at the Spine Centre. In Study III, the patients reporting time was 3 days after the consultation and recall bias did thus not affect the result. In Study IV, the reporting time differed considerably, as the intervention group responded 2 days after the consultation and the control group responded 20 days after. The relatively prolonged reporting time in the control group could have reduced the reported use of PRO data and shared decision-making simply because patients may have had an imprecise memory of the consultation. Another reason could be that the control group found the content of the patient evaluation questionnaire irrelevant compared to patients in the intervention group. Altogether, problems with recall bias in the control group could have led to an overestimation of the effect of the LBP assessment tool.

6.5.4 Confounding

A potential important limitation to studies III [126] and IV [127] is the risk of confounding due to missing information regarding patient characteristics, which may be associated with patient involvement. In general, highly educated patients opt for greater involvement than less educated patients [212-214]. Moreover, highly educated patients tend to have a greater capacity for attaining and understanding basic health information needed to make appropriate health decisions [212]. Unfortunately, we did not collect information on patients' educational level. In Study IV, the patients in the intervention group experienced a higher use of PROs and shared decision-making compared with the control group. If we assume that patients in the intervention group had a higher educational level than patients in the control group, this might have led to an overestimation of the effect of the LBP assessment tool. However, to properly understand if educational level could be a potential confounder, these data need to be collected and analysed in future research.

There are various ways to reduce the risk of confounding, including randomisation in the design of a study and adjustment in data analysis [209]. Conducting a randomised controlled trial (RCT) was

a part of the initial project plan for this dissertation. However, it was not found applicable and feasible due to continuous organisational changes at the Spine Centre. In study IV adjusting for imbalances in patient characteristics between the groups were considered, but because some health professionals could have seen patients in both groups the assumption of independence between data was not meet. Therefore, analysis adjusting for imbalance in patient characteristics was not performed.

6.5.5 Contamination

The risk of inducing contamination must be considered with regard to Study IV [127]. The two groups were observed in two different periods of time, with patients in the intervention group being observed before patients in the control group. As mentioned before there is a risk that health professionals assessing patients in the intervention group may also have assessed patients in the control group. Thus, health professionals could have passed on their skills and experiences from the intervention group into the control group in such a way that their behaviour changed when they assessed patients in the control group. Contamination generally biases the estimated treatment effect towards the null; however, the significantly lower use of PROs in the control group indicated that contamination was not a problem, and thus not affecting our results.

6.5.6 Summary - internal validity

The internal validity of this dissertation was threatened by selection bias and information bias. In summary, selection bias at entry and attrition bias at follow-up should be acknowledged and kept in mind when interpreting the results. Despite the differences between groups in Study IV [127], we do not believe that sick leave modified the results. However, further research is warranted to obtain a better understanding of educational level and other potential factors that may be associated with the use of PROs and shared decision-making. The main potential source of information bias lies in problems arising from self-reported data and in measuring the primary outcome with a non-validated questionnaire. With regard to Study IV, information bias was not considered a problem as it was non-differential misclassification; thus, it was expected to be the same for both groups. In conclusion, we consider the internal validity to be acceptable and thus the findings of this dissertation to be trustworthy.

6.6 External validity

Some threats to the external validity of this dissertation must be acknowledged. First, reflections on results regarding generalisability to patients attending the Spine Centre will be considered, followed by reflections regarding generalisability to similar patients in different settings.

To explore if patients included in this dissertation reflected the general population at the Spine Centre, the PhD student reviewed the 2019 Spine Centre annual report [128]. Our exclusion criteria resulted in exclusion of patients younger that 18 and older than 60 years, patients unable to read and speak Danish as well as patients with pain in the neck and upper back. The annual report showed that in 2019, 12,475 patients attended the Spine Centre, out of which 73 % had a primary diagnosis of LBP [128]. Furthermore, 69 % were between 18-60 years, whereas only 1 % completed the SpineData PRO in a language other than Danish [128]. This supports that the patient samples in studies III [126] and IV [127] are similar to the majority of the LBP population at the Spine Centre, and our results can thus be generalised to patients in the daily clinic at the Spine Centre.

Regarding generalisability of our results to similar patients in different settings, we have to consider results from Study I first [124]. Despite the small patient sample of seven patients we argue that the findings are transferable to the context of other patients with LBP, and even other groups of patients. This is because the sample of patients managed to hold the information power high [215] and because the findings reflected research in the field [80,84,157,216].

Second, the studies were conducted in a single specialised secondary-care hospital. The aspects of specialisation e.g., specialised health professionals training, caseload, and the establishment of multidisciplinary teams reduced the generalisability of our study results to other settings. We found the LBP assessment tool to be feasible in a second-line Spine Centre, but it is unknown whether it is feasible and effective in a first-line setting, for example, in general practice, physiotherapy clinics or chiropractor clinics. However, because we used a systematic development process, based the LBP assessment tool on ICF and involved patients and health professionals, we expect the LBP assessment tool has the potential to be used in other settings.

Third, we acknowledge that we included a selected group of patients with LBP; namely patients where first-line treatment was not successful and referral to second-line treatment was appropriate. On the one hand it could be argued that our results cannot be directly generalised to first-line patients. On the other hand, ICF does not distinguish between first-line and second-line treatment, and it could be argued that our results are generalisable to the LBP population outside the Spine Centre.

In conclusion, we consider the external validity to be good. First because we used broad inclusion criteria resulting in a study population that closely resembles real-life patients at the Spine Centre. Second, because the studies were conducted in a real-world setting making it possible to take interactions of variables in the real-world into account. Finally, because the methods used to develop the LBP assessment tool is considered robust, the LBP assessment tool is expected to be usable in other settings such as primary care, which is the first step in the management of LBP.

7. Conclusions

The overall aim of this dissertation was to develop an ICF-based tool, *the LBP assessment tool,* to facilitate a biopsychosocial and patient-centred approach to assessment of patients with LBP. Furthermore, to implement, field-test and evaluate this tool in an out-patient clinic at a specialised Spine Centre. The four studies in this dissertation contributed with important knowledge within the research field to be able to respond to the overall aim.

Patients' perspectives provided essential knowledge about elements of importance to patients with LBP when aiming for a patient-centred consultation using PROs. This led to qualification of the PRO-LBP, and supported the importance of involving patients in development of PRO instruments.

The development of the LBP assessment tool introduced the first tangible evidence-based tool based on all ICF components integrating biopsychosocial perspectives provided by patients and health professionals to be used in routine clinical practice. The LBP assessment tool facilitated the implementation of ICF core sets in clinical practice.

Implementation of the LBP assessment tool supported the health professionals towards a biopsychosocial approach based on patient perspectives. Patients and health professionals found the tool feasible in routine clinical practice. Successful implementation was not reached after three months, thus more attention to facilitation, training and longer implementation time was needed.

Evaluation of the tool in a real-world setting documented that consultations facilitated by the LBP assessment tool enhanced the use of PROs and patients' experiences of being involved in decision-making compared with usual care. It was emphasised that PROs and shared decision-making can promote a patient-centred consultation. The positive results support that successful implementation of PROs in routine clinical practice needs to be accompanied by continuous facilitation and training of health professionals.

In conclusion, the LBP assessment tool succeeded to facilitate a smooth and positive consultation based on the patient perspective. Moreover, it supported health professionals to apply a biopsychosocial and patient-centred approach to assessment of patients with LBP.

8. Perspectives

"Stop seeing low back pain solely through a medical lens"

Professor Nadine Foster, Nordic Back Pain Seminar 2018

This quotation supported by recent evidence regarding the importance of using a biopsychosocial and patient-centred approach to patients with LBP [1,6,21,22] obviously reflects the idea for this dissertation. With the development, implementation, field-testing and evaluation of the LBP assessment tool, this dissertation can be considered pioneering work in the field. It contributes with important steps on the pathway towards understanding what is needed to truly implement a biopsychosocial and patient-centred approach in routine clinical practice among patients with LBP.

In 2018, the Lancet series of papers on LBP illuminated international, multidisciplinary consensus on management of LBP [1,20,21]. Two of the key recommendations were to *1) include a biopsychosocial framework to guide assessment and management of LBP and 2) comply with recommendations in clinical guidelines because doing more of the same will not reduce back-related disability or its long-term consequences* [1,20,21]. By introducing the LBP assessment tool, we have included a biopsychosocial framework to guide assessment and management of LBP, and provided health professionals with a tangible tool that has been shown to support them towards a biopsychosocial and patient-centred approach in routine clinical practice. The remaining key question is whether the LBP assessment tool also has the potential to support health professionals to comply with recommendations in clinical guidelines; in other words, reduce use of medication, imaging and surgery [21].

The findings of this dissertation are reckoned to have implications for practice as well as for research. Still, there are several unanswered questions, which need to be examined. This chapter will close by outlining recommendations for future research.

8.1 Implications for clinical practice

The LBP assessment tool should be considered a strong candidate for a user-friendly tool with the potential to support health professionals in a shift towards a more biopsychosocial approach to patients with LBP. The LBP assessment tool is based on operational items from ICF core sets with the potential to facilitate the utility of ICF in routine clinical practice. China [54], Italy [52] and recently Japan [55], have taken the lead in developing 'simple intuitive descriptions' of ICF categories to inform a system-wide implementation of ICF in routine clinical practice. With the development of the LBP assessment tool, we have laid a solid foundation and starting point for a process in Denmark towards generating 'simple intuitive descriptions' of ICF categories contained

in the LBP core set and the Rehabilitation set. This may be the first small step towards a system-wide implementation of ICF in Denmark among patients with LBP.

The LBP assessment tool integrates perspectives provided by patients and health professionals into one tool. Thus, it collects a wide spectrum of biopsychosocial perspectives taking into account all the aspects that impact on and burden a patient's life. Moreover, the LBP assessment tool has the potential to support medical doctors, physiotherapists and chiropractors to perform a biopsychosocial, systematic and comprehensive assessment of functioning and disability. Hence, patients with LBP can receive a consistent assessment regardless of whether they consult a medical doctor, physiotherapist or chiropractor.

The LBP assessment tool can enhance active use of PROs and shared decision-making during the consultation, resulting in a more patient-centred approach. Still, training of health professionals and continuous facilitation is a prerequisite for successful implementation of PROs into routine clinical practice.

8.2 Implications for research

This dissertation emphasised that patients must be involved in the PRO development [124]. In other words, researchers and health professionals involved in PRO development should change from the traditional "top down" to "bottom up" methodologies, which include involving patients in as many steps as possible [73,145]. In our research patients were involved from the beginning, and their perspectives were taken seriously by incorporating them into the LBP assessment tool. Moreover, their perspectives guided the continuous development of the tool. We believe that involving patients in the development of the PRO-LBP improved the content validity, ensured that language and terminology were appropriate for patients with LBP, and the items within the PRO-LBP fully assessed the impact of LBP on the patients' everyday lives. Based on the known differences between what mattes to patients and what matters to health professionals [114], involving health professionals in the development process was just as essential as involving patients. Overall, this dissertation underlines that involving the end-users in the development of tools is essential in ensuring that the content matches their perspectives.

Study II contributed with valuable knowledge to research by providing a detailed description of the process used to develop a user-friendly tool for ICF core sets [125]. This enables other researchers to replicate or to get inspired to develop similar tools. In addition, Study II showed that ICF core sets can be used as a starting point, and operational items including specific items and response options for core sets can be developed [125]. By proposing the PRO-LBP based on ICF, we contributed to research regarding LBP-specific PRO instruments. It has previously been suggested

to develop a new LBP-specific PRO instrument based on ICF, but it has not been accomplished until now [217]. Heterogeneity in the choice of measurement instruments in clinical trials hinders comparisons between studies, also within LBP [218]. With the LBP assessment tool, we have provided an instrument that enables the collection and provision of internationally comparable data on functioning and disability among patients with LBP.

8.3 Recommendations for future research

Due to the positive findings in this dissertation one could argue that a natural extension would be to test the LBP assessment tool in an RCT - the gold standard for highly valid research. As mentioned in chapter 6.5.4, the initial project plan for this dissertation included an RCT. The RCT was planned to compare consultations facilitated by the LBP assessment tool with usual practice, in terms of reducing the surgery rate within three months. During the planning of the RCT, the Spine Centre implemented several organisational changes resulting in changed daily workflow and health professionals were assigned to other tasks. As a consequence, we changed plans and designed the non-randomised study (study IV) [127]. Seen in the clear light of hindsight this was a good decision, because even more organisational changes were implemented during the study period. With the experience I have gained working with this dissertation, I would not recommend testing the LBP assessment tool in an RCT due to its complexity, methodological challenges regarding randomisation and implementation barriers. Furthermore, a tightly controlled trial may be hard to generalise to real-world practice.

On the contrary, I recommend the following future research directions for the LBP assessment tool:

1. A validation study examining the content validity of the LBP assessment tool. The tool was used at the Spine Centre for almost a year, included approximately 600 patients, and has the potential to be used in a validation study.
2. A cross sectional study comparing rehabilitation plans devised via the LBP assessment tool with rehabilitation plans devised via usual practice. The aim will be to examine whether the LBP assessment tool can qualify the rehabilitation plans by bringing focus to biopsychosocial perspectives. Ultimately, qualification of rehabilitation plans may improve patients' health-related quality of life and reduce health care costs. This study is planned.
3. A feasibility study to test the LBP assessment tool in primary care. On a short-term basis, the tool has the potential to support general practitioners, physiotherapists and chiropractors to conduct a biopsychosocial, systematic and comprehensive assessment to be used in rehabilitation planning. On a long-term basis, research to determine if the LBP assessment tool is appropriate for large-scale implementation in primary care is suggested.

9. References

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9. Appendices

Appendix 1 Study I – focus group interviews

Appendix 2 Study II – the development study

Appendix 3 Study III - the implementation study

Appendix 4 Study IV – the non-randomised controlled study

Appendix 5 Consolidated Criteria for Reporting Qualitative Research

Study I, Appendix 1

Appendix 6 Guidance for Reporting Involvement of Patients and the Public Short Form checklist

Study I, Appendix 2

Appendix 7 The Comprehensive LBP core set and the Rehabilitation set

Study I, Appendix 3

Study II, Supplementary table S1

Appendix 8 Methods for the three literature searches

Study II, Supplementary table S2

Appendix 9 Observation form used in the tryout component

Study III, Supplementary table S1

Appendix 10 Health professionals questionnaire 10 months post implementation

Study III, Supplementary table S2

Appendix 11 Patient evaluation questionnaire (PEQ)

Study IV, Supplementary table S2

Appendix 12 Studies included in the three literature searches

Study II, Supplementary table S3, S4, S5

Appendix 13 Items in the PRO-LBP

Study II, Supplementary table S6

Study III, Supplementary table S4

Appendix 14 Items in the ClinRO-LBP

Study II, Supplementary table S7