Person-centred prehabilitation program to improve functioning

In patients with severe low back pain planned for lumbar fusion surgery

HANNA LOTZKE

Department of Ortopaedics, Institute of Clinical Sciences,
Sahlgrenska Academy, University of Gothenburg,
Gothenburg, Sweden, 2019

UNIVERSITY OF GOTHENBURG

Gothenburg 2019

Cover illustration by Nina Barne
Layout design by Gudni Olafsson/GO Grafik
Person-centred prehabilitation program to improve functioning

hanna.lotzke@gu.se

ISBN 978-91-7833-267-0 (PRINT)
978-91-7833-268-7 (PDF)
http://hdl.handle.net/2077/56913

Correspondence: hanna.lotzke@gu.se

Printed by BrandFactory, Gothenburg

There are things we know that we know. There are known unknowns. That is to say there are things that we now know we don't know. But there are also unknown unknowns. There are things we do not know we don't know.

DONALD RUMSFELDT, BORN 1932

Person-centred prehabilitation program to improve functioning

In patients with severe low back pain planned for lumbar fusion surgery

HANNA LOTZKE

Department of Ortopaedics, Institute of Clinical Sciences,
Sahlgrenska Academy, University of Gothenburg,
Gothenburg, Sweden, 2019

ABSTRACT

INTRODUCTION: Low back pain is a frequently reported symptom and has turned into a global problem. For people with severe chronic low back pain, spinal fusion surgery can be a treatment option. The outcome of fusion surgery is not always successful and some patients report having a low quality of life after surgery. The overall purpose of this thesis was to develop and evaluate a prehabilitation programme for patients scheduled for lumbar fusion surgery. In addition, the aim was to investigate the pre-surgical level of physical activity in this group.

MATERIAL AND METHODS: In Study I, a person-centred prehabilitation programme was developed in several steps and tested in a single case study design. In Study II, the theoretical framework and the treatment manual for the active intervention were described in detail in the format of a study protocol. In Study III the physical activity level of 118 patients planned for surgery due to degenerative disc disease was investigated objectively in a cross-sectional study. An association between factors in the fear-avoidance model and physical activity were investigated. In Study IV the effect of the prehabilitation programme was evaluated in a randomised controlled trial comparing the active intervention to conventional care. A linear mixed model was used to evaluate the outcome measures at six months after lumbar fusion surgery.

RESULTS: The theoretical framework and the treatment manual of the prehabilitation programme were adjusted after the single case study (Study I). The revised study design was published in a study protocol (Study II). Only 17% of the study group fulfilled the WHO recommendations of physical activity for health benefits. The variable “steps per day” was found to be associated with both fear of movement

and disability (Study III). No statistically significant differences between groups were seen in the primary outcome disability from baseline to six months (Study IV). Among secondary outcome measures, a statistically-significant interaction effect was seen for EQ-5D index with the largest between-group difference seen one week prior to surgery in favour of the active intervention. Both groups reached the minimal important change for the primary outcome, and many of the secondary outcomes already at 8 weeks follow-up.

CONCLUSION: These findings, indicate that patients planned for lumbar fusion surgery have low physical activity level and are thereby at greater risk of poor health. A prehabilitation programme leads to minimal important changes for the primary outcome, and many of the secondary outcomes already at 8 weeks follow-up.

KEYWORDS: chronic low back pain, cognitive behavioural approach, lumbar fusion surgery, physical activity, person-centred care, prehabilitation.

ISBN: 978-91-7833-267-0 (PRINT) 978-91-7833-268-7 (PDF)

http://hdl.handle.net/2077/56913

PERSON-CENTRED PREHABILITATION PROGRAM TO IMPROVE FUNCTIONING

SAMMANFATTNING PÅ SVENSKA

Ländryggssmärta är en av de vanligaste orsakerna till funktionsnedsättning. Även om en endast en liten andel av alla med ländryggsmärta genomgår kirurgi, så har antalet ryggkirurgiska ingrepp ökat, och en del av patienterna är tveksamma eller missnöjda med utfallet av kirurgin. Studier inom andra kirurgiska områden har visat att genom att förbereda patienten inför kirurgi, med så kallad prehabilitering, kan möjligheten till snabbare återhämtning och bättre resultat påverkas.

Syftet med avhandlingen var att utveckla ett prehabiliteringsprogram för personer med svår ländryggssmärta som skall genomgå instrumenterad steloperation av ländryggen och att utvärdera denna intervention i en randomiserad kontrollerad studie. Vidare var syftet att undersöka den fysiska aktivitetsnivån hos denna patientgrupp innan och efter ländryggskirurgi med hjälp av en aktivitetsmätare.

I avhandlingen ingick fyra delstudier. Delstudie I och II handlade om att utveckla ett vetenskapligt väl förankrat prehabiliteringsprogram. Delstudie III undersökte hur fysiskt aktiva patienter med kronisk ländryggssmärta är innan de genomgår planerad steloperation av ländryggen. Vidare undersöktes om psykologiska faktorer som rörelserädsla, katastroftankar och tilltro till sin förmåga att bedriva fysisk träning hade något samband med nivå av fysisk aktivitet. Delstudie IV utvärderade effekten av det utvecklade prehabiliteringsprogrammet gentemot konventionellt preoperativt omhändertagande i en randomiserad kontrollerad studie innefattande 118 patienter som skulle genomgå steloperation av ländryggen. Utvärderingen gjordes med hjälp av patientrapporterade frågeformulär med avseende på smärta, funktion, psykologiska faktorer och hälsorelaterad livskvalitet, samt funktionella tester och mätning av fysisk aktivitet med aktivitetsmätare både före och efter operationen.

I studie I rapporterades hur prehabiliteringsprogrammet utvecklades i flera steg och testades i en pilot-studie. Interventionen justerades därefter utifrån både teoretiska modeller och de praktiska lärdomarna. Detta arbete ledde fram till ett studie-protokoll av den aktiva interventionen, Studie II, som sedan användes i Studie IV.

I den randomiserade studien, Studie IV, påvisades ingen statistisk signifikant skillnad mellan grupperna– med avseende på den primära utfallsvariabeln funktionsnedsättning 6 månader efter operationen. Däremot påvisades en statistisk signifikant skillnad mellan grupperna gällande hälsorelaterad livskvalitet mätt under

perioden från att studien startade till 6 månader efter operationen. Den största skillnaden mellan grupperna gällande hälsorelaterad livskvalitet sågs en vecka före operationen till fördel för den aktiva interventionsgruppen. I båda grupperna sågs signifikanta förbättringar avseende smärta, funktion, och hälsorelaterad livskvalitet relativt tidigt efter operationen. I Studie III konstaterades det att personer med svår ländryggssmärta som skall genomgå steloperationen i ländryggen har en låg fysisk aktivitetsnivå jämfört med WHO:s hälsorekommendationer för fysisk aktivitet. Vidare påvisades det att graden av fysisk aktivitetsnivå inför kirurgin hade ett samband både med rörelserädsla och grad av funktionsnedsättning. Sex månader efter steloperationen uppnådde gruppen som hade genomgått den aktiva interventionen större förbättring avseende fysisk aktivitetsnivå i jämförelsevis med kontrollgruppen som fick sedvanlig behandling.

En stor andel av patienterna (78%) deltog i den aktiva interventionen och prehabiliteringsprogrammet tolererades väl. Om en fysioterapeutisk intervention före kirurgi kommer att visa någon effekt på längre sikt behöver studeras vidare, samt om patienter med högre risk för sämre utfall av kirurgi upplever en större effekt av interventionen.

PERSON-CENTRED PREHABILITATION PROGRAM TO IMPROVE FUNCTIONING

LIST OF PAPERS

This thesis is based on the following studies, which are referred to in the text by their Roman numerals.

I. Lotzke H, Gutke A, den Hollander M, Smeets R, Lundberg M. Developing an evidence-based prehabilitation programme designed to improve functional outcomes after lumbar fusion surgery – A feasibility study using the Medical Research Council framework. *European Journal of Physiotherapy.* Accepted

II. Lotzke H, Jakobsson M, Brisby H, Gutke A, Hägg O, Smeets R, den Hollander M, Olsson L-E, Lundberg, M. Use of the PREPARE (PREhabilitation, Physical Activity and exeRcisE) program to improve outcomes after lumbar fusion surgery for severe low back pain: a study protocol of a person-centred randomised controlled trial. *BMC Musculoskelet Disord.* 2016;17(1):349

III. Lotzke H, Jakobsson M, Gutke A, Hagströmer M, Brisby H, Hägg O, Smeets R, Lundberg M. Patients with severe low back pain exhibit a low level of physical activity before lumbar fusion surgery: a cross-sectional study. *BMC Musculoskelet Disord.* 2018; 19(1):365

IV. Lotzke H, Brisby H, Gutke A, Hägg O, Jakobsson M, Smeets R, Lundberg M. A Person-Centered Prehabilitation Program Based on Cognitive-Behavioral Physical Therapy for Patients Scheduled for Lumbar Fusion Surgery – A Randomized Controlled Trial. Submitted

CONTENTS

ABBREVIATIONS

BMI	Body mass index
LBP	Low back pain
CI	Confidence interval
CBT	Cognitive behavioural therapy
DDD	Degenerative disc disease
ES	Effect size
EQ-5D	EuroQol 5 Dimensions questionnaire
HADS	Hospital Anxiety and Depression Scale
ITT	Intention to treat
MIC	Minimal important change
MRI	Magnetic resonance imaging
ODI	Oswestry Disability Index 2.0
PCC	Person-centred care
PCS	Pain Catastrophising Scale
PSFS	Patient-Specific Functional Scale
PHODA	Photograph Series of Daily Activities
PROMs	Patient-reported outcome measures
RCT	Randomised Controlled Trial
SEES	Self-Efficacy for Exercise Scale
SD	Standard deviation
SSRD	Single Subject Research Design
TSK	Tampa Scale for Kinesiophobia
VAS	Visual Analogue Scale
WHO	The World Health Organisation

DEFINITIONS IN BRIEF

CHRONIC LOW BACK PAIN	Low back pain that lasts longer than 12 weeks (Araksinen et al., 2006).
DEGENERATIVE DISC DISEASE	Disc degeneration and/or accompanying facet arthrosis are considered to be the cause of chronic low back pain (Fritzell et al., 2001).
KINESIOPHOBIA	An excessive, irrational and debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or reinjury (Kori et al., 1990).
SELF-EFFICACY	A person's confidence in his/her ability to perform a specific activity (Bandura 1977).
PERSON-CENTRED CARE	The importance of knowing the person behind the patient–as a human being with reason, will, feelings, and needs – in order to engage the person as an active partner in his/her care and treatment (Ekman et al., 2011).
PHYSICAL ACTIVITY	Any bodily movement produced by skeletal muscles that results in energy expenditure (Caspersen et al., 1985).
PREHABILITATION	The phase before surgery (Carli et al., 2005).
TREATMENT FIDELITY	Refers to the process of monitoring and improving the reliability and validity of the intervention and includes the phase's treatment integrity, treatment differentiation, treatment receipt, and treatment enactment (Bellg et al., 2004).

TREATMENT INTEGRITY	Refers to whether the treatment was provided according to the treatment manual (Bellg et al., 2004).
TREATMENT DIFFERENTIATION	Refers to whether the treatments differ from each other as expected (Bellg et al., 2004).
TREATMENT RECEIPT	Refers to how well the participant understands and shows knowledge of how to use the new treatment skills (Bellg et al., 2004).
TREATMENT ENACTMENT	Refers to how well the participants apply the skills learned (Bellg et al., 2004).

THESIS AT A GLANCE

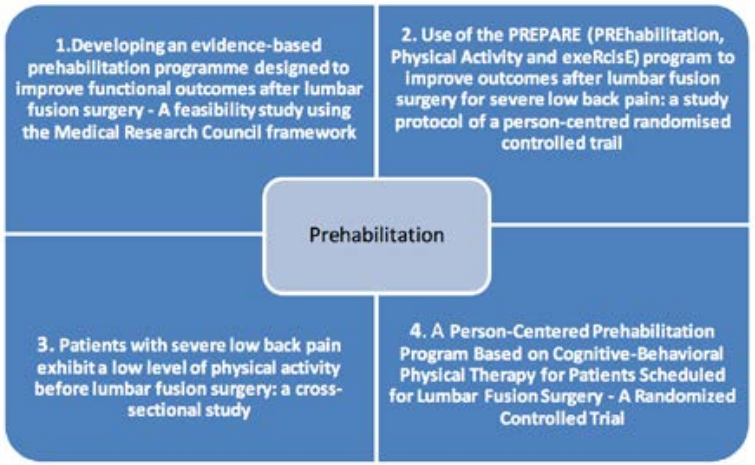

FIGURE 1. Overview of the articles included in this thesis.

Lumbar degenerative disorders are the most commonly reported reasons for receiving elective lumbar spinal surgery. People with chronic low back pain due to degenerative disc disease have usually tried different non-pharmacological interventions to reduce their level of pain and to achieve a higher level of function. If these interventions have failed, lumbar spinal fusion surgery may be an option. The outcome of lumbar spinal fusion surgery is not optimal, and some people may continue to experience low back pain, disability, and a low quality of life. We therefore wanted to develop a new prehabilitation intervention to prepare these people before surgery, with a view to optimising the outcome after surgery.

1

INTRODUCTION

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

1. INTRODUCTION

Low back pain (LBP) is a frequently reported symptom, and 80% of the population experience pain in the lower back at some time during their life (Hoy et al., 2012). For some people, it turns into a chronic condition with disability and reduced quality of life. Most people with severe chronic LBP have tried a plethora of treatment options to reduce the degree of pain and to achieve a higher level of function. In recent years, LBP has turned into a global problem and lumbar fusion surgery may be an option if non-pharmacological interventions have failed. The rate of lumbar fusion surgery for LBP has increased rapidly over the past 20 years (Kepler et al., 2014; Rajaee et al., 2012).

Lumbar degenerative disorders are the most common reasons for performing lumbar spinal surgery. This group of disorders includes disc herniation, spinal stenosis, spondylolisthesis, and degenerative disc diseases. The outcome of surgery is not always successful and some people may still experience continuous LBP, an increased level of disability, and a low quality of life after surgery. The largest group of patients to undergo lumbar spinal surgery, as recorded in the Swedish Spine Register (Swespine) (www.4s.nu), is diagnosed with central and lateral spinal stenosis. However, the patients who underwent lumbar fusion surgery due to severe chronic LBP, as reported in Swespine until 2016, belonged to the group with the highest intensity of back pain. This group also reported having a high level of disability and a markedly reduced quality of life before surgery. The patients in this subgroup of degenerative lumbar disorders are rather young, with a mean age of 46 years, and they ought to continue to take part in the labour force and live an active life for a number of years to come. Twenty three per cent of the patients who underwent fusion surgery for LBP reported that they were uncertain or dissatisfied with the outcome 5 years after surgery (Fritzell et al., 2016). There are no international or national guidelines that could guide clinicians as to how to prepare people with lumbar degenerative disorders who will undergo surgery for an optimal outcome of lumbar spinal surgery (Gilmore et al., 2015; Rushton et al., 2012). However, it has been suggested that for people with chronic disabling LBP, treatments including physical activity in combination with cognitive behavioural techniques have proven to be effective (Kamper et al., 2014; Koes et al., 2010).

The studies in this thesis were initiated to develop an active prehabilitation intervention in conjunction with lumbar fusion surgery, to objectively assess the level

of physical activity, to determine psychological risk factors before spinal fusion surgery, and to evaluate the prehabilitation intervention that was developed, using a randomised controlled trial.

1.1 LOW BACK PAIN

One widely accepted definition of LBP is pain restricted to the back below the mark of the twelfth rib and above the inferior gluteal folds; it is often associated with referred leg pain down one or both legs (Anderson, 1986). Generally, LBP is seen as an activity-limiting pain with or without pain down the legs (Hoy et al., 2012). LBP may include pain from several different anatomical structures such as the lumbar vertebrae, intervertebral discs, facet joints, ligaments, muscles, and neural structures (Deyo et al., 2001).

Acute LBP is usually defined as a period of pain lasting less than 6 weeks, and sub-acute LBP is defined as pain with a duration of between 6 and 12 weeks (van Tulder et al., 2006). More than 70–80 % of all people will have one or more episodes of LBP during their lifetime (Hoy et al., 2010; van Tulder et al., 2006). LBP usually improves considerably within 6 weeks and the pain decreases over time, but recurrence of pain within 12 months has been reported to occur in 57–71% of patients (Itz et al., 2013). It has also been shown that a previous history of LBP is the most dominant predictor of recurrent LBP (Taylor et al., 2014).

In a systematic review, the mean prevalence of LBP was found to be 31%, the mean point prevalence to be 18.0% and the lifetime prevalence to be 39.0%. (Hoy et al., 2012; Hoy et al., 2014). The number of years lived with disability caused by LBP has increased globally by 54% since 1990, and today LBP is the leading cause of years lost to disability in high-, and middle-, and low-income countries (Hoy et al., 2014). LBP is most prevalent in women and in people between 40 and 80 years of age (Hoy et al., 2010). LBP is also the most common cause of work-related disability in people under the age of 45, which are usually the most productive years in a person's life (Andersson, 1999; Hoy et al., 2012). The global burden of LBP affects the economy of both the individual and that of society as a whole (GBD 2016 Collaborators, 2017; Hoy et al., 2014; Rapoport et al., 2004).

1.1.1 Chronic low back pain

LBP is usually defined as being chronic when the pain lasts longer than 12 weeks (Airaksinen et al., 2006; van Tulder et al., 2006) or when the pain "extends beyond the expected period of healing" (Loeser et al., 2008; Merskey et al., 1994a). The exact time point is difficult to establish, but for LBP three to six months is mostly considered to be the time when the transition from acute LBP to chronic LBP occurs (Airaksinen et al., 2006; van Tulder et al., 2006). Chronic LBP is seen as a long-lasting condition with a different course and progression in different people (Airaksinen et al., 2006). Different factors have been associated with the development from acute to chronic LBP, for example symptom-related factors (Chou et al., 2010), lifestyle factors (Chou et al., 2010; Hendrick et al., 2011), psychological factors (Chou et al., 2010; Pinheiro et al., 2016; Wertli et al., 2014; Wertli et al., 2013), and social factors (Chou et al., 2010).

Chronic LBP and other pain conditions can be categorised according to symptomatic severity differences such as mild, moderate, or severe pain (Boonstra et al., 2014; Jensen et al., 2011). A person with severe chronic LBP may have an altered pain-modulating system, e.g. central sensitisation (Melzack, 2001; Meyer et al., 1994; Nijs et al., 2011), that has however not been investigated in this study.
The prevalence of chronic LBP is difficult to establish, but it has been suggested to exceed 20% in the European population. Approximately 11–12% of this population are disabled due to their LBP condition (Airaksinen et al., 2006).

1.1.2 Consequences of chronic low back pain

Disability and functional limitations have been identified as the major consequences of chronic LBP (Costa Lda et al., 2012). In another study, at least one out of five individuals with chronic LBP reported having limitations in activity (Von Korff et al., 1996). For most people with chronic LBP, the pain is constant and causes difficulties in many daily activities such as dressing, standing, lifting, and walking. Symptoms such as disturbed sleep, worries, and loss of some of the enjoyments in life have been reported (Hoy et al., 2014). Chronic LBP has an impact on the overall well-being of a person, since it affects both physical and psychological health, and also social responsibilities such as work and family life (Manchikanti et al., 2009, 2014).

1.2 DEGENERATIVE LUMBAR SPINE DISORDERS

Degenerative lumbar spine disorders include some well-defined diagnoses such as disc herniation, central or lateral spinal stenosis, spondylolisthesis, and also less well-defined diagnoses such as degenerative disc disease (DDD) (Fritzell et al., 2016). In 2015, 8 049 patients in total had been included in the Swespine, and the distribution of the diagnoses was disc herniation 27%, central and lateral stenosis 57%, spondylolisthesis 4%, and DDD 8% (Fritzell et al., 2016).

Lumbar disc herniation is defined as rupture of the annulus fibrosus, with disc material localized beyond the limits of the intervertebral disc space (Fardon et al., 2014), which means that the disc material has been displaced from its normal location. This material may be a combination of the nucleus pulposus, cartilage from the endplate(s), and annular tissue (Fardon et al., 2014). The displaced disc material may affect nervous tissue and cause pain in one or both legs, and also neurological symptoms involving weakness and/or reduced sensitivity in the lower extremities.

In spinal stenosis, the thickness of the structure ligamentum flavum plays a major role. This structure can reduce the diameter of the spinal canal, or its lateral recesses, by narrowing–often in combination with disc bulging and/or facet joint hypertrophy (Deyo et al., 2001; Yoshiiwa et al., 2016). People with spinal stenosis sometimes report having LBP, and more often radiating leg pain. The back and leg pains get worse while standing up and the pain is reduced while sitting, or when bending the back forward. Furthermore, these patients often have a wide gait and reduced walking capacity (Allen et al., 2009; de Schepper et al., 2013).

Spinal stenosis is the most common condition affecting the lumbar spine, and is also the major reason for spine surgery in older adults. The number of patients diagnosed increases with age (Kalichman et al., 2009a) and the diagnosis is set from the typical patient history and typical findings on radiological investigation (preferably magnetic resonance imaging (MRI)), together with clinical findings (Kalichman et al., 2009a).

A diagnosis of spondylolisthesis refers to the anterior displacement of a vertebra in relation to the vertebra below. This can occur from a stress fracture or a congenital defect in the pars interarticularis of the vertebra (isthmic spondylolisthesis) (Kalichman et al., 2009b) or from degeneration of the facet joints and the disc in

a motion segment (degenerative spondylolisthesis) (Deyo et al., 2001). Spondylolisthesis may contribute to narrowing of the spinal canal, as in spinal stenosis. The degenerative processes of the spine increase with age and the highest prevalence of degenerative spondylolisthesis has been observed in individuals aged 60–69 years (Kalichman et al., 2009b). People diagnosed with degenerative spondylolisthesis may report having severe LBP and radiating leg pain in one or both legs (Deyo et al., 2001). However, the association between LBP and degenerative spondylolisthesis is somewhat controversial (Kalichman et al., 2009b).

1.2.1 Degenerative disc disease

For the purpose of this thesis, I have chosen to study patients with chronic LBP who are classified as having degenerative disc disease.

Disc degeneration is characterized by loss of disc signal intensity and nucleus pulposus dehydration, and/or reduced disc height on MRI. Position-induced aggravation is typical anamnestic information in these patients, indicating a mechanical origin (Adams et al., 2006; Cloward, 1963), but signs of instability between the vertebrae are usually not obvious (Axelsson et al., 2004). Several factors together can contribute to chronic LBP, but in a meta-analysis it was found that MRI findings of disc bulge, disc degeneration, disc extrusion, disc protrusion, Modic 1 changes, and spondylolysis are more prevalent in younger people with LBP that in pain-free people (Brinjikji et al., 2015). A number of studies have shown that different factors can accelerate disc degeneration: genetic factors, female gender, age, and lifestyle factors such as morbid obesity and cigarette smoking (Battie et al., 1995, 2004; Kujala et al., 1996). The same factors have also been shown to be associated with LBP (Borenstein, 2001; Ferreira et al., 2013; Livshits et al., 2011; Shiri et al., 2010a, 2010b; Zhang et al., 2016, 2018).

However, degenerative changes in the lumbar spine and in the disc can also be found in asymptomatic people, and are regarded as an inevitable process in most humans (Boden et al., 1990; Jensen et al., 1994; Kalichman et al., 2010; Powell et al., 1986). Thus, the term lumbar degenerative disc disease (DDD) is used for patients with chronic LBP when disc degeneration and/or accompanying facet arthrosis are considered to be the cause of pain. DDD (Swedish designation "segmental pain") is reserved for the clinical entity, where pain history, physical examination, and radiological investigation (usually MRI) all point to the same source

of pain, restricted to one or a few lumbar segments (Fritzell et al., 2016, 2001).

Fusion surgery for DDD with or without referred pain is controversial, but for certain patients with severe chronic LBP it is considered a treatment option (Phillips et al., 2013). Data from Swespine show that patients with DDD have functional limitations, with a mean score using the Oswetry Disability Index (ODI) of 45 points (severe disability); 50% reported having a walking capacity of less than one kilometer, with a mean back pain intensity of 67 mm (VAS), and a mean leg pain intensity of 44 mm (VAS), and 70% had had LBP for more than two years. One year after spinal fusion surgery, the mean score on ODI had decreased to 24 points, 71% reported having a walking capacity of > 1 kilometer, mean back intensity (VAS) had decreased to 32 mm, and leg pain intensity had decreased to 20 mm (VAS). Moreover, 72% of the patients were satisfied with the outcome of surgery (Fritzell et al., 2016).

1.2.2 Lumbar spinal fusion surgery

In total, about 110,000 patients have been recorded in the Swespine register over the last 20 years; approximately 10% of these patients had a primary diagnosis of DDD or isthmic spondylolisthesis and underwent lumbar fusion surgery (Fritzell et al., 2016). In 2008, the most frequent diagnosis in the United States in patients undergoing spinal fusion surgery was reported to be degenerative disc disease of a lumbar disc segment, representing 14% of the spinal fusions performed (Rajaee et al., 2012).

The rate of lumbar fusion surgery is increasing worldwide (Harris et al., 2009; Rajaee et al., 2012) and the highest rate has been found in the USA (Deyo et al., 2005, 2010). From 1998 to 2008, lumbar fusion surgery increased by approximately 140% in the United States. In 1998, lumbar fusion surgery was performed in 64 of 100,000 adults and 2008 the figures had risen to 136 of 100,000 adults (Rajaee et al., 2012). In the USA in 1992, lumbar fusion surgery represented 14% of the total spending for back surgery, which increased to 47% in 2003 (Weinstein et al., 2006). The number of complex fusion interventions (360° fusion, a combination of anterior and either transverse process or posterior fusion techniques, or fusion at more than two levels) had increased by almost 15% during the years from 2002–2007 in patients over 60 years of age (Deyo et al., 2010). The same pattern has been described in different countries; for example, in Australia the fusion rate increased

by 175% from 1997 to 2006 (Harris et al., 2009) and in the United Kingdom it increased 14% from 2008 to 2010 (Rushton et al., 2015; The Health and Social Care Information Centre, 2011).

1.2.3 Fusion surgery for degenerative disc disease

Results from a relatively recent systematic review suggested that lumbar fusion surgery can be a treatment option for patients with a verified diagnosis of DDD, both to reduce pain and improve function (Phillips et al., 2013). Most spine specialists agree that fusion surgery may be considered in selected patients with longstanding severe chronic LBP and high a disability level, preferably after an intensive and active rehabilitation period of up to two years (Airaksinen et al., 2006; Livshits et al., 2011; Phillips et al., 2013).

Several different surgical techniques are used in spinal fusion surgery, such as posterolateral fusion, with or without instrumentation, transforaminal or posterior lumbar interbody fusion, and anterior lumbar interbody fusion. In later years, other approches such as lateral approches and minimally invasive fusion have been added as alternatives (Noorian et al., 2018; Wang et al., 2014). In a systematic review, Wang et al., concluded that it is difficult to make any recommendations regarding the superiority of any technique, partly due to methodological differences in the studies included (Wang et al., 2014). Lately, motion preserving techniques, such as a disc prosthesis, have also become an on option in selected patients with chronic LBP (Skold et al., 2013).

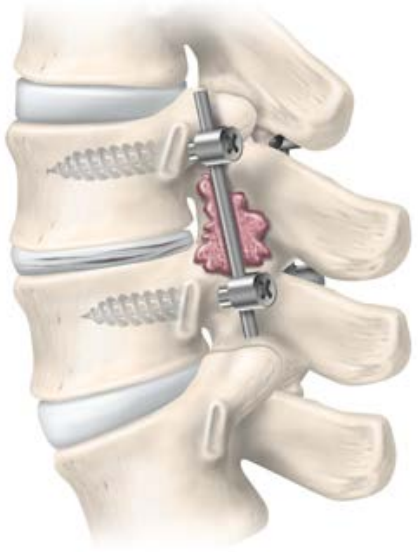

FIGURE 2. Fusion surgery for chronic LBP due to degenerative disc disease.

1.2.4 Non-surgical factors that influence the outcome of lumbar spine surgery

Several non-surgical factors that have an influence on lumbar surgical outcome have been identified in different studies. Factors such as those that are patient-specific factors, e.g. smoking, age, and comorbidities (Adogwa et al., 2014; Bekelis et al., 2014; McGirt et al., 2017, 2015); baseline functional status, e.g. higher baseline disability score, higher LBP, and leg pain (Chotai et al., 2017; McGirt et al., 2017); and occupation-related factors, e.g. unemployment and workers' compensation (Carreon et al., 2010; Gum et al., 2013; McGirt et al., 2017), have been reported to influence the outcome after lumbar spinal surgery.

1.2.5 Psychological factors that influence the outcome of lumbar spine surgery

Several studies have shown that the preoperative level of psychological disturbance might predispose for poorer outcome after lumbar spine surgery (Abbott et al., 2010, 2011; Adogwa et al., 2013; Celestin et al., 2009; Havakeshian et al., 2013; McGirt et al., 2017). Factors that have been shown to be of interest are anxiety, depression, fear-avoidance beliefs, coping strategies, pain catastrophising, mental health, and expectations of surgical outcome (Abbott et al., 2010; Abtahi et al., 2015; Archer et al., 2014; Celestin et al., 2009; Mannion et al., 2007; Trief et al., 2006).

Depressive symptoms have been found to be a predictor of poor surgical outcome, measured as continuous pain and disability, in patients who undergo lumbar fusion surgery (Adogwa et al., 2014; DeBerard et al., 2001; LaCaille et al., 2005; Wahlman et al., 2014). Even though depressive symtoms are a strong predictor of poor outcome after lumbar surgery, patients with depressive symptoms could benefit from lumbar fusion surgery under certain conditions, and this type of problems is not considered a contraindication for fusion surgery (Havakeshian et al., 2013; Hägg et al., 2003; Wahlman et al., 2014). It has, however, been suggested that alternative interventions should strongly be advised for these people–both before and after surgery–for improvement of outcome (Wahlman et al., 2014).

Fear-avoidance beliefs, have been found to be significant predictors of postoperative pain and functional outcomes for up to two years after surgery (Mannion et al., 2007). Furthermore, Havakeshian et al. found that fear-avoidance beliefs about physical activity were the only baseline psychological factors that predicted

outcome using a disability score (Roland-Morris disability score) after lumbar spinal surgery (Havakeshian et al., 2013).

For patients who underwent lumbar fusion surgery, Abbott et al., found that pre-psychological variables (pain catastrophising, control over pain, and self-efficacy) were significantly associated with both lower functional outcomes using disability scores (ODI) and intensity of higher back pain at 2-year follow-up (Abbott et al., 2011).

1.3 PHYSICAL ACTIVITY

Physical activity has a well-documented positive effect on health, and should be recommended to everyone regardless of whether or not a person suffers from any particular health condition (GBD 2016 Collaborators, 2017; Lee et al., 2012; May et al., 2015; WHO, 2009; Wilmot et al., 2012). People who are physically active have a lower rate of "premature" mortality and chronic diseases (Lee et al., 2012; WHO, 2009; Wilmot et al., 2012). However, one quarter of the European population does not fulfil the WHO recommendations for physical activity (Gerovasili et al., 2015). There are various reasons in a general population for having a low level of physical activity, and the factors that correlate most strongly are age, gender, poor health status, low self-efficacy, and low motivation (Bauman et al., 2012; Trost et al., 2002).

LBP has been suggested to be a barrier to physical activity (Ryan et al., 2009; Spenkelink et al., 2002). A stronger focus on health in relation to the huge LBP problem worldwide has been promoted in a recent publication (Buchbinder et al., 2018). There are known risk factors associated with LBP–such as high body mass index (BMI), high blood pressure, and a low level of physical activity (Hoy et al., 2010; Shiri et al., 2010a; Steffens et al., 2016). Lifestyle factors such as smoking (Shiri et al., 2010b) and obesity (Shiri et al., 2010a; Zhang et al., 2016, 2018) are associated with the occurrence of LBP episodes, and physical activity may reduce the risk of developing chronic LBP (Shiri et al., 2017).

Furthermore, psychological factors included in the fear-avoidance model (e.g. pain catastrophising, fear of movement, and poor self-efficacy) can also be barriers to, or influence physical activity (Lundberg et al., 2011; Woby et al., 2007).

A meta-analysis has shown that those with chronic LBP and a high level of disability are most likely to have a low level of physical activity (Lin et al., 2011). Most guidelines promote physical exercise as a central recommendation for people with LBP and chronic LBP (O'Connell et al., 2016). It has, however, been suggested that patients with chronic LBP may need extra support and tailor-made recommendations to overcome barriers to physical activity in order to increase the level of physical activity (Schaller et al., 2017).

Some studies have investigated physical activity levels in the lumbar spine surgical population (Lindback et al., 2017; Mancuso et al., 2017; Mobbs et al., 2016; Rolving et al., 2013; Smuck et al., 2018), but only a few studies have investigated the preoperative level of physical activity (Lindback et al., 2017; Mobbs et al., 2016; Norden et al., 2017; Rolving et al., 2013). Moreover, in most studies the reported physical activity level has been collected using questionnaires, which is considered to be less valid than using data that has been collected objectively with a movement device such as an accelerometer (Slootmaker et al., 2009). None of the aforementioned studies have assessed physical activity objectively in patients with degenerative disc disease who undergo lumbar fusion surgery.

From a public health point of view, it is important to investigate how physically active the group of patients who are offered surgical interventions for their severe LBP are, in relation to guidelines on health-enhancing physical activity (WHO, 2009, 2010). Moreover, from a clinical perspective, such knowledge is important to guide clinicians and also the patient in his/her prehabilitation phase.

1.3.1 Physical activity recommendations for adults aged 18–64 years

The WHO recommendation for adults aged 18–64 is that health-enhancing physical activity should be 150 minutes of at least moderate-intensity aerobic physical activity (e.g. brisk walking) per week, or at least 75 minutes of vigorous-intensity aerobic physical activity (e.g. running) throughout the week, or an equivalent combination of moderate- and vigorous-intensity activity (WHO, 2009, 2010). Aerobic activity (brisk walk, running) should be performed in bouts of at least 10-minutes. Performance of muscle-strengthening activities involving major muscle groups is recommended, on two or more days every week (WHO, 2009). Recommendations of health-enhancing physical activity are based on a dose relationship between physical activity and health. The more active one is, the better the effect, but the highest

health benefits are probably to be gained by an individual who goes from being very inactive to being moderately physically active (WHO, 2010).

Step recommendations

Seven thousand five hundred steps per day are thought to be equivalent to the WHO recommendations for health (Tudor-Locke et al., 2011). These recommendations could be realistic for adults with a disability, but they might need to be adjusted to the individual's personal capacity and level of physical activity (WHO, 2010).

1.4 PREHABILITATION

Prehabilitation is defined as the concept of improving the person's functional and mental capacity to buffer against potential harmful effects of a significant stressor (Carli et al., 2005). In the surgical setting, a prehabilitation phase aims to optimise the patient's health, both physically and psychologically. This prehabilitation may enhance function before surgery, and also prevent a decline in function and well-being after surgery (Carli et al., 2005). This concept has been evaluated in certain patient groups undergoing different types of major surgery (Cabilan et al., 2016; Le Roy et al., 2016; Lemanu et al., 2013), but there have been very few studies to evaluate a prehabilitation period before lumbar spinal surgery.

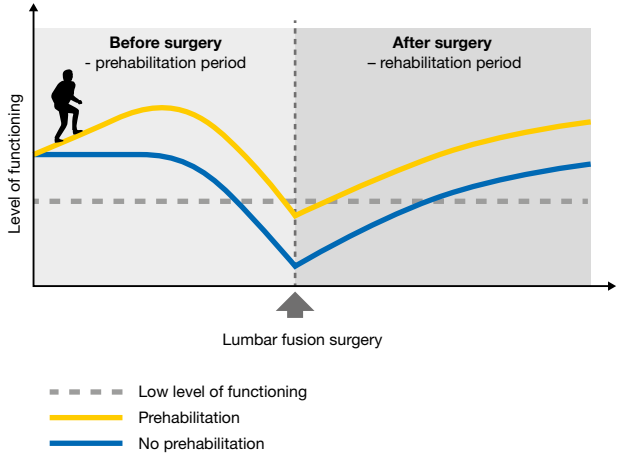

FIGURE 3. Overview of the concept of prehabilitation.

1.4.1 Prehabilitation for patients undergoing lumbar surgery

Gilmore et al. completed a systematic review and concluded that the evidence for preoperative or postoperative rehabilitation for patients undergoing lumbar spinal surgery was questionable, and that there was a need for further research in this area (Gilmore et al., 2015). Furthermore, a recent systematic review concluded that there is a lack of evidence for physiotherapy before lumbar spinal surgery and further research is needed to evaluate the effectiveness of prehabilitation to improve function and pain after surgery (Gometz et al., 2018).

In 2010, Nielsen et al. published a randomised controlled trial (RCT) that investigated a prehabilitation and early rehabilitation intervention for patients with degenerative lumbar disease who were planned for lumbar fusion surgery. The active intervention group underwent an intensive home-based exercise programme including optimisation of analgesic management; this was compared with the control group, which received the clinic's routine care before surgery. The result of this trial showed that the group with an integrated programme of prehabilitation and early rehabilitation improved function and achieved the pre-defined recovery milestones more quickly than the control group (Nielsen et al., 2010).

To date, three randomised trials have been published comparing a period of prehabilitation for patients waiting for lumbar spinal surgery with conventional care (Lindback et al., 2017; Louw et al., 2014; Rolving et al., 2015).

Louw et al., conducted an RCT with one group receiving a preoperative pain education programme and one group receiving the usual care for patients undergoing lumbar surgery for radiculopathy. These workers could not detect any significant difference between the groups regarding pain intensity and function one year after surgery (Louw et al., 2014).

Rolving et al., published an RCT evaluating a prehabilitation programme for patients with degenerative disease, spinal stenosis, or spondylolisthesis. The prehabilitation programme included standard treatment care and additionally, four preoperative and two postoperative group sessions. The content of the intervention was based on the principles of cognitive behavioural therapy (CBT) and was delivered by a multidisciplinary team. The patients underwent spinal fusion surgery and were followed up one year after surgery. No difference was found between the

group participating in the preoperative CBT intervention and the control group regarding outcome, as measured by Oswestry Disability Index (ODI) (Rolving et al., 2015).

A recent RCT by Lindbäck et al., investigated a prehabilitation programme for patients with degenerative lumbar spine disorders who were on the waiting list for decompression, disc herniation, and fusion surgery, with two different intervention arms. The patients were randomised either to the physiotherapy group or to the control group on the waiting list. The interventions were delivered as two sessions per week for nine weeks. The physiotherapy group received individual physiotherapy according to a treatment-based classification and a supervised exercise programme with a behavioural approach to reduce fear avoidance. The control group on the waiting list received one session of standardised information from an orthopaedic surgeon about surgery, information of post-surgery rehabilitation, and advice on keeping active. One year after surgery, no statistically significant difference between the two groups was found regarding disability score (ODI) (Lindback et al., 2017).

To summarise, these three studies evaluated a prehabilitation period for patients with a variety of degenerative lumbar disorders who were on the waiting list for lumbar spinal surgery.

The above prehabilitaton studies differed in their content, in the number of sessions delivered before and after surgery, and in the theoretical models behind the interventions. The results from these studies could not identify the best time point, the optimum number of sessions, or the type of intervention most appropriate for patients undergoing lumbar spinal surgery.

1.5 THE RATIONALE FOR THE CONTENT OF THE PREHABILITATION PROGRAMME USED IN THIS THESIS

I have used the term "active intervention" to describe the person-centred prehabilitation programme that was developed during the work in the studies included in this thesis.

National and international guidelines recommend that people with chronic LBP should stay active (despite their pain), undergo supervised exercise therapy, to be

given cognitive behavioural treatment, and be given multidisciplinary treatment when such a treatment can be offered (Kamper et al., 2014; Koes et al., 2010; van Tulder et al., 2006).

Chronic LBP, a high level of disability, and psychological factors such as fear-avoidance beliefs and self-efficacy may be barriers to physical activity. A recent publication has recommended that all actions related to LBP should be in synergy with the WHO recommendations, such as having people reach the recommended level of physical activity (Buchbinder et al., 2018).

There was a gap in our knowledge of how to prepare people with chronic LBP who are scheduled for lumbar fusion surgery.

We therefore wanted to develop and evaluate a prehabilition programme with the aim of targeting fear-avoidance beliefs and self-efficacy, and to increase or maintain the physical activity level of these people before lumbar fusion surgery with a view to improving the functional outcome after surgery.

The main aim of developing the active intervention was to encourage the participant to stay active regardless of his/her severe LBP problem. The prehabilitation programme was based on the theoretical framework of Vlaeyen et al., (Vlaeyen et al., 1995) and was developed further by Woby et al., (Woby et al., 2007), and it involved different cognitive behavioural techniques (Kåver, 2006).

2

AIMS OF THE THESIS

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

2. AIMS OF THE THESIS

2.1 OVERALL AIM

The over-arching aim of this thesis was to investigate whether a physiotherapeutic person-centred prehabilitation programme based on a cognitive behavioural approach would improve functioning after lumbar fusion surgery in patients with degenerative disc diseases, as compared to conventional care.

2.2 SPECIFIC AIMS/HYPOTHESES

This thesis has two parts. The first part is about developing and designing a physiotherapeutic person-centred prehabilitation programme with a cognitive behavioural approach, using the Medical Research Council framework for developing a complex intervention (Craig et al., 2008), (Studies I and II).

The second part is about evaluation of the effect of the prehabilitation programme developed in the first part (Studies III and IV).

The specific research aims were to:

- describe the developmental process and study design of a physiotherapeutic person-centred prehabilitation programme with a cognitive behavioural approach (Studies I and II)
- evaluate the feasibility of the prehabilitation programme in a pilot study (Study I)
- investigate the preoperative level of objectively measured physical activity (Study III), and to explore associations in the fear-avoidance model at this level (Study III)
- determine whether patients who receive the active intervention experience a greater reduction in disability levels after surgery, compared to conventional care (Study IV)
- determine whether patients who receive the active intervention experience a larger decrease in leg and back pain intensity, less pain catastrophising, less pain-related fear, less depressive symptoms, increased self-efficacy for exercise, better health-related quality of life, better patient-specific functioning, increased physical activity levels, and an increased physical capacity after surgery compared to conventional care.

All between-group differences were hypothesised to be greatest at 6 months after surgery (Study IV).

3

METHODS

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

3. METHODS

3.1 THEORETICAL FRAMEWORK

This thesis is based on a combination of philosophical standpoints, theoretical models, and treatment principles.

3.1.1 Definitions and classifications

Pain is a complex sensory and emotional experience, and it is not just a signal of tissue damage. Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey, 1979; Merskey et al., 1994b). Pain is always individual and subjective, i.e. each one of us learns what pain is through experience from episodes of pain earlier in life. Pain is the experiencing of actual or possible tissue damage in one or several parts of the body, and is most often associated with an unpleasant feeling, so it is connected to a negative emotional experience as well. A person can describe and experience pain without actually having tissue damage or without there being any other pathophysiological cause, but for that person, the pain is real and should be acknowledged as being pain– in accordance with the definition of the International Association for the Study of Pain (Merskey et al., 1994b).

Our active intervention rested on the assumption that pain is a subjective phenomenon, so we decided to use a person-centred approach to care as the over-arching philosophy of the intervention.

3.1.2 Person-centred approach

The person-centred approach to care is a multi-dimensional concept that takes into account and addresses the patient's unique combination of biomedical, behavioural, and emotional problems (Ekman et al., 2011). The focus of the person-centred approach is concentration on the patient's needs, preferences, and values. Knowing the person behind the patient–a human being with reason, willpower, feelings, and needs–is a central principle in the person-centred approach (Ekman et al., 2011).

The person-centred approach to care rests on the bio-psychological-social model that takes into account all aspects of a person's difficulties in the rehabilitation process (Leplege et al., 2007). Every person is unique, different from any other, so even when a person seeks help for the same problem, the intervention delivered should

be unique and individualised (Ekman et al., 2011).

The central question is who the person behind the disease is, and the patient should be involved as an active partner in his/her care and decision process (Ekman et al., 2011). He/she should be treated with respect and dignity, and the view of the person-centred approach is that the person is responsible for his/her own actions and behaviour.

Firstly, the patient's narrative (illness narrative) is used as the base of this approach, with the aim of engaging the patient in the rehabilitation process. The narrative is used to capture the person's suffering in everyday life and the impact that this has on his/her life. The idea is to capture the individual's subjective experience, personal history, and emotions, and all of these considerations should be taken into account in the rehabilitation process. An individual assessment of each patient is needed (Ekman et al., 2011).

Secondly, a partnership with shared decision making should be established, with the aim of learning from each other. The patient should be involved as an active partner in his/her rehabilitation, and the patient's competence and expertise must be acknowledged. The patient is considered to be an expert in his/her disease, and a collaborative atmosphere with mutual decision making and goals that reflect the person's needs and preferences is central to this approach. Treatment options concerning the patient's illness should take his/her lifestyle, preferences, beliefs, values, and health issues into account (Ekman et al., 2011).

Thirdly, documentation of the narrative should be done, and a health plan should be decided upon together with the patient. This health plan should include both short-term and long-term goals, together with the actions needed to achieve each goal (Ekman et al., 2011).

3.1.3 Bio-psychosocial model

The bio-psychosocial model is widely accepted today, and it views pain and disability as being a dynamic and reciprocal interaction between biological, psychological, and sociocultural variables that influence the person's reaction to pain (Engel, 1977; Turk et al., 1999).

This theoretical model highlights the different dimensions of pain and disability. All factors in the model should be considered when treating a patient, since all of them have an impact and influence the response to treatment (Engel, 1977). The biological part of a disease is known to affect psychological factors and the social context in which the person exists (Turk et al., 2002). The model decribes the relationship between the pain problem our patients are seeking help for, their beliefs and reactions about pain, and the nature of the interplay between these different dimensions (Waddell, 2004).

Since pain has a multi-dimensional nature and is considered to be subjective, there is a need to treat the whole person in all of his/her complexity, so it is necessary to use a wide spectrum of treatment approaches to reduce pain and disability in a patient who is seeking help for his/her chronic LBP problem.

FIGURE 4. The bio-psychosocial model (Engel 1977).

3.1.4 The cognitive behavioural approach

The cognitive behavioural approach has been recommended and used frequently in rehabilitation of people with chronic LBP (Turk, 2003).

The cognitive behavioural approach takes into account how thoughts, memories (cognitions), bodily reactions, and feelings (affective factor) all contribute to human behaviour. All of these factors are involved in the experience of pain (Turk, 2003). This approach considers that people are active processors of both internal and external information, and psychological factors such as expectations and feelings of self-efficacy are of importance for the experiencing and maintenance of pain (Turk, 2003).

The overall aim of using a cognitive behavioural approach is to shift focus from pain relief to pain management by assessing thoughts about pain, avoidance behaviour, feelings, bodily reactions, painful experiences, and the consequence of these (Eccleston et al., 2009; Williams et al., 2012). The basis of this approach is to involve the patient in the rehabilitation process despite the pain condition that he/she is seeking help for (Williams et al., 2012). Cognitive behavioural interventions usually involve different cognitive and behavioural techniques, with the aim of reducing and challenging unhelpful thoughts and feelings, and of changing behaviour (Beck, 1995).

3.1.5 Cognitive behavioural intervention in the context of lumbar surgery

Cognitive behavioural interventions addressing psychological factors such as fear of movement and catastrophising thoughts associated with more pain and disability–before lumbar spinal surgery–could have a positive effect on postoperative disability and pain (den Boer et al., 2006; Mannion et al., 2007). Otherwise, even if these psychological risk factors are present before lumbar spinal surgery, one could offer cognitive behavioural interventions–not only pre-operatively but perhaps also postoperatively–to prevent reactivation/occurrence or to reduce these factors further. Such interventions might have a positive effect on the outcome of lumbar spine surgery (Abbott et al., 2010, 2011; Archer et al., 2011; Christensen et al., 2003; Havakeshian et al., 2013). However, cognitive behavioural interventions before surgery are not common in the context of lumbar spine surgery (Rolving et al., 2015) and there is a need for further research in this area.

3.1.6 The cognitive behavioural fear-avoidance model

The cognitive behavioural fear-avoidance model is a theoretical model based on the bio-psychosocial model (Lethem et al., 1983; Norton et al., 2003; Vlaeyen et al., 1995). The fear-avoidance model was first used in the context of pain by Lethem et al., and it explains how fear of pain and avoidance behaviour contribute to the maintenance of pain in the absence of identifiable organic pathology (Lethem et al., 1983). During the last three decades, several adaptations of the fear-avoidance model have been developed and tested in different pain contexts (Fordyce et al., 1984, 1982; Lethem et al., 1983 ; Linton et al., 1984; Philips, 1987; Vlaeyen et al., 1995).

These earlier fear-avoidance models have all contributed with important ideas to the most generally recognized cognitive behavioural fear-avoidance model presented by Vlaeyen et al. (Vlaeyen et al., 1995). The basic principle of Vlaeyens's model is the way in which pain is interpreted by the person who experiences it, and how this interpretation can lead to two different paths, confrontation or avoidance (Vlaeyen et al., 2000, 2012a). One pathway is when the acute pain is perceived as being unpleasant but is not interpreted as a threat or catastrophe. These people will confront their pain and will maintain or take up their daily activities just as soon as healing of the tissue has occurred or as soon as it is possible to take on normal activities. The other pathway is when pain is interpreted as being catastrophic, which will cause pain-related fear (e.g. fear of pain, fear of harm, fear of movement). A vicious circle may be initiated, in which catastrophising thoughts give rise to pain-related fear and avoidance behaviour. This behaviour can be adaptive in the acute pain stage, but worsen the problem in the case of long-lasting pain (Leeuw et al., 2007a; Vlaeyen et al., 2000). The long-term consequences of avoidance behaviour regarding daily activities may lead to disability, negative mood, and experience of further pain, initiating a vicious circle (Vlaeyen et al., 2000). The underlying theory for this model is based on learning theory with classical (Pavlovian) and operant conditioning (Gatzounis et al., 2012; Turk, 2003). The cognitive fear-avoidance model can be used to explain and understand the complexity of chronic pain and the pathway that may lead to disability, a reduced level of activity, and depression (Leeuw et al., 2007a; Vlaeyen, 2012b, Vlaeyen et al., 1995, 2000).

One treatment strategy that has been developed from the fear-avoidance model is called "exposure in vivo", and has been proven to be effective for patients with LBP and fear-avoidance beliefs; it has been evaluated in different pain populations and contexts over the years (de Jong et al., 2008; den Hollander et al., 2016; Leeuw et al., 2008; Linton et al., 2008; Vlaeyen et al., 2001, 2002b; Woods et al., 2008). During the treatment sessions, behavioural experiments are carried out with the aim of challenging the person with activities that they fear or avoid (den Hollander et al., 2010; Leeuw et al., 2008; Linton et al., 2008). If the person learns that his/her expectations about the negative consequences of movements are not quite true, the he/she will re-adjust his/her beliefs, and become less afraid and more physically active. Several studies have shown that if the fear of movement decreases, the disability and even the pain experienced decreases (de Jong et al., 2005; Leeuw et al., 2008; Vlaeyen et al., 2002a).

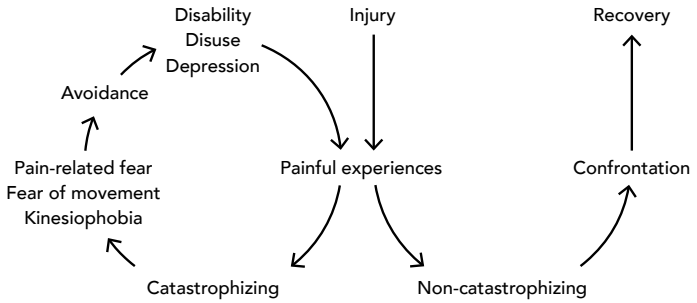

FIGURE 5. The cognitive behavioural fear-avoidance model by Vlaeyen et al. 1995.

Woby et al. investigated the cognitive-fear-avoidance model further and included functional self-efficacy as a cognitive factor influencing disability and pain in this model. He found that of the cognitive factors (pain-related fear, pain catastrophising, functional self-efficacy) functional self-efficacy was most strongly related to disability in a population of chronic patients with LBP who were referred for physiotherapy (Denison et al., 2004; Woby et al., 2007).

Self-efficacy is a concept that explains a person's confidence in his/her ability to perform a specific activity (Bandura, 1977). In patients with LBP, both self-efficacy and fear-avoidance beliefs are possible predictors of disability (Ayre et al., 2001; Woby et al., 2007), and the variables are highly correlated to each other (de Moraes Vieira et al., 2014). Modification of one variable may contribute to change in the other variable (de Moraes Vieira et al., 2014). A higher level of self-efficacy has been shown to be associated with lower levels of pain and disability in different chronic pain populations (Costa Lda et al., 2011; Denison et al., 2004; Dohnke et al., 2005). The degree of importance of the self-efficacy concept for outcome in patients who undergo lumbar fusion surgery is not known (Abbott et al., 2011).

This modified cognitive behavioural fear-avoidance model was used as the theoretical model in our active intervention (see Figure 18).

3.2 DESIGN OF THE ACTIVE INTERVENTION

The active intervention was designed in two phases, each involving several steps.

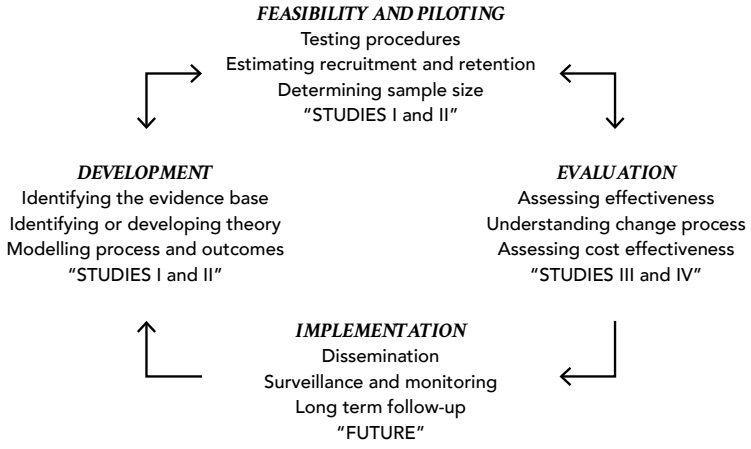

FIGURE 6. Key elements of the development and evaluation process as described by the Medical Research Council framework for developing a complex intervention (Craig 2008).

A complex intervention is usually described as an intervention that includes several interacting components within the experimental and control intervention (Craig et al., 2008). The components in the Medical Research Council (MRC) framework are development, feasibility and piloting, evaluation and implementation. The development of our active intervention was assessed through the different phases of this framework. The different phases in the framework are not expected to be seen as a straight line from one phase to the other. Instead, they should be seen as belonging to a process (Campbell et al., 2000). The procedure of the new intervention and the theoretical framework was first tested in a feasibility study (Study I), and thereafter described in detail in a study protocol (Study II). Finally, the active intervention was evaluated in the form of a randomised controlled trial (Study IV).

DEVELOPMENT OF THE PILOT INTERVENTION, STUDY I

Phase 1, Development

Best evidence practice is defined as the interaction between and combination of clinical expertise, patient values, and best research evidence. All these factors are important in the decision making process when planning and optimising an intervention (Sackett et al., 1996).

Identification of the evidence base and development of theory

The first step was to gain an understanding of the best evidence-based practice. This included review of the literature and collection of information from clinical expertise and practice. By using the theoretical fear-avoidance model, Vlaeyen et al. (Vlaeyen et al., 1995, 2000) and Linton et al. (Linton et al., 2001) developed a cognitive behavioural treatment called "exposure in vivo". This treatment has been evaluated and developed further on the basis of new theoretical knowledge and evidence from several clinical studies (de Jong et al., 2008; Hollander et al., 2010, 2016; Leeuw et al., 2008; Vlaeyen, 2012b). When we started to plan our study in 2012, we made contact with the researchers and clinicians in Maastricht, the Nederlands Their research showed that "exposure in vivo" with a behavioural cognitive approach–the aim of which was to reduce fear of movement and pain catastrophising thoughts–could increase functioning in people with different chronic pain syndromes (de Jong et al., 2008; Leeuw et al., 2008; Vlaeyen et al., 2001, 2002b).

Modelling process and outcomes

The original treatment protocol for "exposure in vivo" was developed and evaluated in Maastricht and involved 14 session; it was provided by a multidisciplinary team at a rehabilitation centre. To learn more about their "exposure in vivo" treatment, our research team made a visit to this rehabilitation centre before starting to develop our new prehabilitation intervention. After the visit, the original treatment protocol from Maastricht was adjusted in several steps in order to be feasible in an orthopaedic surgical setting. The first draft of the pilot intervention was written for patients with chronic LBP due to degenerative disc disease who were scheduled for lumbar fusion surgery (Study I).

Phase 2, Feasibility and piloting

Our pilot intervention was evaluated in two steps. Firstly, the feasibility of our first

draft, Study Protocol 1.0, of the pilot intervention was evaluated after we had tested it on a few patients awaiting lumbar fusion surgery. Secondly, a new protocol of the pilot intervention was written (Study Protocol 2.0) and tested in the form of a Single Subject Research Design (SSRD) study (Lundervold et al., 2000; Zhan et al., 2001).

Testing procedures and training of the therapist: Step 1

Treatment fidelity refers to the process of monitoring and improving the reliability and validity of the intervention and includes the phase's treatment integrity, treatment differentiation, treatment receipt, and treatment enactment (Bellg et al., 2004).

The process of evaluating treatment fidelity in our pilot study is described below (Study I).

Treatment integrity refers to whether the treatment was provided according to the study protocol. Some strategies for evaluation of treatment integrity are writing a study protocol, monitoring of the therapist when delivering the intervention (by an observer or from videotape recording), and testing whether new treatment skills are attained by the therapist (Bellg et al., 2004). In our study, two of the researchers from Maastricht came to Gothenburg and one of them looked on while the therapist delivered the pilot intervention (Study Protocol 1). Information from the therapist delivering the intervention together with the observer's feedback was collected. After discussions among the research group, a new treatment manual was developed (Study Protocol 2.0) and was tested in a SSRD study.

Treatment receipt involves both an assessment part and an optimisation part, and refers to how well the participant understands and shows his/her knowledge of how to use the new treatment skills (Bellg et al., 2004). The first session in our intervention included a behavioural analysis using the Photograph Series of Daily Activities (PHODA) (Leeuw et al., 2007b). They were asked to place each of the 27 photographs of daily activities on a scale from 1 to 100, to form a hierarchy of harmful activities. They were asked to place the photographs answering the question "How harmful do you think this activity would be to your back?", with 1 representing (=) not harmful and 100 = extremely harmful. The therapist noted that it was difficult for some participants to place the photographs on the scale. Most of the participants already thought that their back was injured and that the activities shown on the photographs could not do further harm to their back. Thus,

the opening question was changed to "How afraid are you of doing the activity the person is doing in the picture?".

Testing procedures, outcomes, and evaluation of the pilot intervention: Step 2
Treatment differentiation and treatment enactment. During step 2, the feasibility of the pilot intervention (Study Protocol 2.0) was tested in an SSRD study. The aim of this SSRD study was to evaluate treatment differentiation (whether the treatments differed from each other as indented) and treatment enactment (how well the participants applied the skills they learned) (Bellg et al., 2004). Both of these parts were evaluated after the SSRD study, and the changes that were made were included in a new treatment manual (Study Protocol 3), which is presented in this thesis under the heading Summary of results.

Phase 3, Evaluation

The "Evaluation" phase was the second part of the work for this thesis, with the aim of determining whether participants who received the active intervention (Study Protocol 3) would have a better outcome after lumbar fusion surgery (Study IV). One of the most important considerations when evaluating a new intervention is to determine whether the intervention would be effective in everyday practice, and how the intervention varies from participant to participant and at different study sites (Craig et al., 2008).

Phase 4, Implementation

The phase "Implementation" will be part of my future research.

3.3 STUDY POPULATION

TABLE 1. Overview of the design, number of participants, time of inclusion and analysis of the studies included in the thesis

Studies	**Study I**	**Study III**	**Study IV**
Study Design	Single Subject Research Design Study	Cross-sectional study	Randomised Controlled Trial
Participants	Patients with Chronic LBP due to Degenerative Disc Disease		
Number of participants	N=11	N=118	
Time for inclusion	January 2013 to November 2013	April 2014 to June 2017	
Analysis	Data visually inspected in level, trend and variability	Multiple linear regression model	Linear mixed model

All the participants included in this thesis were patients with severe chronic LBP due to degenerative disc diseases, who were scheduled for lumbar fusion surgery. In Study I, the participants were recruited from one spine surgery clinic in Gothenburg, Sweden. The participants in Studies III and IV were recruited from two spine surgery clinics and one university hospital, all in Gothenburg, Sweden. All the participants had met a spinal surgeon who, after clinical examination and MRI, made a medical diagnosis of degenerative disc disease and–after obtaining patient consent–placed them on the waiting list for lumbar fusion surgery. The coordinators from each spine clinic regularly had contact with the physiotherapist responsible for the inclusion procedure in the study, who asked the patients questions concerning the inclusion and exclusion criteria (see below) and their willingness to participate. The patients who were eligible for the study got an appointment with a physiotherapist (independent observer) for baseline evaluation, 8 to 12 weeks before surgery. After the baseline assessment, the participants were randomised either to the active intervention or to conventional care. All participants gave their written informed consent before taking part in the study.

Inclusion criteria, Studies I, III, and IV

- 18 to 70 years of age
- Severe LBP with degenerative changes of 1 to 3 segments of the lumbar spine
- Additional minor radiating symptoms in one leg
- Lumbar fusion surgery with or without a surgical procedure for disc herniation, foraminal decompression, or isthmic spondylolisthesis.

Exclusion criteria, Studies I, III, and IV

- Previous decompression surgery for spinal stenosis
- Spinal malignancy
- Dominating radiculopathy
- A confirmed neurological disorder or rheumatic disorder
- Severe deformities in the thoracolumbar spine (e.g. idiopathic scoliosis)
- Poor knowledge of Swedish.

3.3.1 Ethical approval

All participants gave written consent after being given oral and written information, and the studies were approved by the Regional Ethical Review Board in Gothenburg (Dnr 586-11 with an amendment, Dnr 527-15). The study protocol was registered in Current Controlled Trials (ISRCTN17115599) on 18 May 2015.

3.4 PROCEDURE STUDIES I, II, III AND IV

3.4.1 Procedure, Study I

TABLE 2. Baseline characteristics of participants included in Study I

Patient	Gender W=Woman M=Man	Age (years)	Back Pain, Duration (years)	Leg Pain, Duration (years)	BMI (kg/m2)	Sick- leave
1	W	37	> 2 years	> 2 years	27.8	100%
2	W	49	> 2 years	No pain	23.2	0%
3	W	40	> 2 years	> 2 years	27.3	100%
4	M	46	> 2 years	> 2 years	24.0	0%
5	W	43	> 2 years	> 2 years	21.1	0%
6	M	42	> 2 years	No pain	36.0	0%
7	W	48	> 2 years	> 2 years	25.1	50%
8	W	36	1-2 years	1-2 years	22.2	25%
9	M	45	1-2 years	No pain	24.4	100%
10	M	49	1-2 years	No pain	24.7	75%
11	W	34	> 2 years	No pain	21.6	0 %

Body Mass Index BMI, kg/m^2; Sick leave range 0-100%

The participants were recruited from January to November 2013. The sample size of the pilot study was based on the recommendations in the literature for a pilot study (Vet et al., 2011).

The pilot study was set up as an SSRD study with an A-B-C design. The study used a baseline phase (A), an intervention phase (B), and a follow-up point (C). Before the SSRD study started, demographic data were collected (gender, age, BMI, pain duration, and sick-leave) (Table 2) using the Swespine register baseline questionnaire (www.4s.nu). The dependent outcome measures used were Tampa Scale of Kinesiophobia (TSK) (Lundberg et al., 2004), Pain-Catastrophising Scale (PCS) (Sullivan et al., 1995), back and leg pain intensity (using VAS) (Price et al., 1983),

and disability (using ODI) (Fairbank et al., 2000). These outcome measures were finished both before the study started (before phase A) and after phase B was completed, at study point C.

During phase A and phase B, all 11 participants received a questionnaire covering four items (1, 12, 13, and 16) from the TSK and four items (2, 6, 12, and 13) from the PCS. The items from the questionnaires of the TSK and PCS were selected based on the literature (de Jong et al., 2008; Vlaeyen et al., 2002b) and after discussions among the research team. Furthermore, daily measures of patient-specific functioning were used, (the Patient-Specific Functional Scale (PSFS)). The questionnaire including these items was sent to the participants by e-mail every morning. In addition, all participants were given an accelerometer to measure their daily physical activity. They were told to wear the accelerometer during the time that they were awake and to remove the accelerometer before any activities that involved water. The participants started to wear the accelerometer on the day after the baseline assessment (phase A) and during the whole of phase B.

The intervention phase (phase B) contained the pilot intervention (B1, 4 sessions) and the conventional care intervention (B2, 1 session). The baseline phase (phase A) was between eight and 14 days, and the intervention phase (B1 and B2) was between 5 to 21 days, due to the different numbers of sessions and the participants' individual time schedules. All the participants received both interventions but in a different order. Six participants received the pilot intervention first, and five participants received conventional care first. The daily changes are presented in graphs with delineation of the phases (see example Figure 16, result section). One physiotherapist (HL) delivered the pilot intervention, and two other physiotherapists–all working at the same spinal surgical clinic–delivered the conventional care intervention. A description of the pilot intervention (Study Protocol 2) is given in Figure 7. The conventional care intervention included one session of preoperative information on the core exercise programme, and details of the postoperative rehabilitation routine. Also, the participants were encouraged to keep active and to start the exercise programme before surgery.

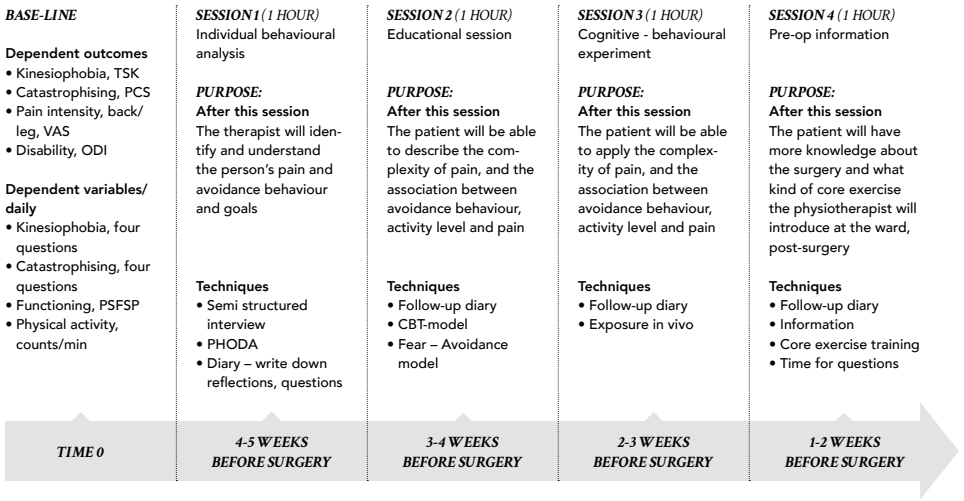

FIGURE 7. Study Protocol 2.0, tested using a single-subject research design.

3.4.2 Procedure, Study II

The theoretical framework (see Figure 18), and the treatment manual (Study Protocol 3) for the active intervention is described in detail in Study II.

3.4.3 Procedure, Studies III and IV

TABLE 3. Baseline characteristics of participants included in Studies III and IV

	Study III N=118	Study IV – active intervention N=59	Study IV – conventional intervention N=59
	Cross-sectional	Randomised Controlled Trial	
Age, mean (SD)	45.7 (8.3)	44.8 (8.2)	46.7 (8.5)
Gender (Men/women)	55/63	26/33	29/30
Body Mass Index, mean (SD)	26.3 (3.7)	26.3 (3.9)	26.4 (3.4)
Smoking	8 (6.8)	3 (5.1)	5 (8.5)
Missing data	1 (0.8)	1 (1.7)	0 (0.0)
Education, n (%)			
Elementary school	7 (5.9)	1 (1.7)	6 (10.2)
High school	51 (43.2)	24 (40.7)	27 (45.8)
University	42 (35.6)	23 (39.0)	19 (32.2)
Vocational education	17 (14.4)	11 (18.6)	6 (10.2)
Missing data	1 (0.8)	0 (0.0)	1 (1.7)
Sick leave, n (%)			
No sick leave	75 (63.6)	39 (66.1)	36 (61.0)
Full-time	25 (21.2)	13 (22.0)	12 (20.3)
Part-time	16 (13.6)	7 (11.9)	9 (15.3)
Missing data	2 (1.7)	0 (0.0)	2 (3.4)
Previous lumbar spine surgery, n (%)			
0 occasion (no previous back surgery)	108 (91.5)	55 (93.2)	53 (89.8)
1 occasion	7 (5.9)	4 (6.8)	3 (5.1)
2 occasions	3 (2.5)	0 (0.0)	3 (5.1)
Pain duration, back >2 years, n (%)	87 (73.7)	41 (34.7)	46 (39.0)
Pain duration, leg >2 years, n (%)	52 (44.1)	28 (47.5)	24 (40.7)
Missing data	1 (0.8)	1 (1.7)	0 (0.0)
Comorbidity, n (%)	13 (11.0)	6 (10.2)	7 (11.9)
Surgical Procedure, n (%)			
Instrumented posterior fusion	103 (87.3)	53 (89.8)	50 (84.7)
Instrumented anterior interbody fusion	1 (0.8)	1 (1.7)	0 (0.0)
Instrumented combined posterior and interbody fusion	4 (3.4)	0 (0.0)	4 (6.8)
Did not go through fusion surgery	10 (8.5)	5 (8.5)	5 (8.5)
Fusion levels, n (%)			
1 level	62 (57.4)	32 (59.3)	30 (55.6)
2 level	41 (38.0)	20 (37.0)	21 (38.9)
3 level	5 (4.6)	2 (3.7)	3 (5.6)

The recruitment started in April 2014 and the last participant was included in June 2017. All 118 participants met the independent observer 8 to 12 weeks before surgery, completed the baseline questionnaires, and were given a triaxial accelerometer (ActiGraph GT3X+; Actigraph, Pensacola, FL). The patients were advised to wear the accelerometer for seven consecutive days and to remove the device when using water and at bedtime. The device was attached to the patient's hip with a flexible band.

Study III, cross-sectional study

Study III was a cross-sectional study, and baseline data for the participants in the randomised controlled trial (RCT) (Study IV) were used.

Study IV, RCT study

Study IV was a prospective RCT. The participants were randomly allocated either to the active intervention or to conventional care. The randomisation procedure was performed after the baseline assessments. Each participant received a numbered, sealed envelope, which had information about the allocation covered on coloured paper. The envelopes were prepared by the project leader (ML) before the study started. The allocation order was 1:1 and was determined by a computerised random list, prepared by an independent statistician. The randomisation list was stored in a locked fire-proof cupboard and was kept from those who were involved in the study, only decoded for analysis until the final participant had reached the 6-month follow-up. The independent observer who was responsible for assessment of the outcome measures will be kept blind regarding the treatment allocation until the 2-year follow-up. Furthermore, the physiotherapists involved in the postoperative rehabilitation, the spinal surgeons, the hospital staff, and the statisticians were also blind. However, the physiotherapists delivering the active intervention or conventional care before surgery and the participants could not be blinded regarding the treatment allocation.

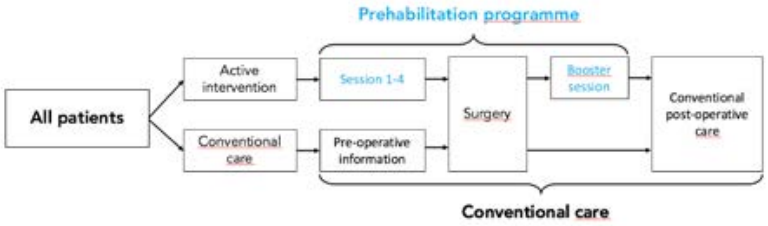

FIGURE 8. Overview of the intervention groups, Study IV.

All outcome measures were gathered at baseline and one week before surgery. After surgery, all outcome measures were gathered at 3 and 8 weeks, and at 3 and 6 months. All the data collected were registered in a coded electronic data file.

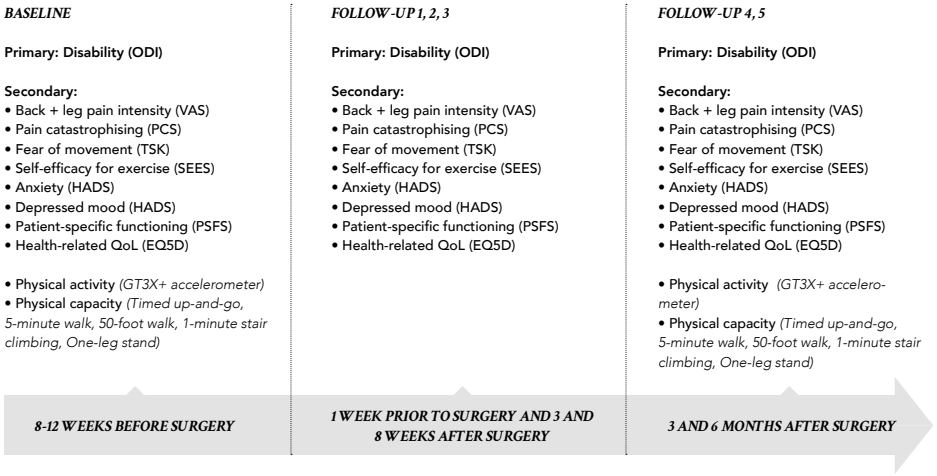

FIGURE 9. An overview of the different time points of measurement, Study IV.

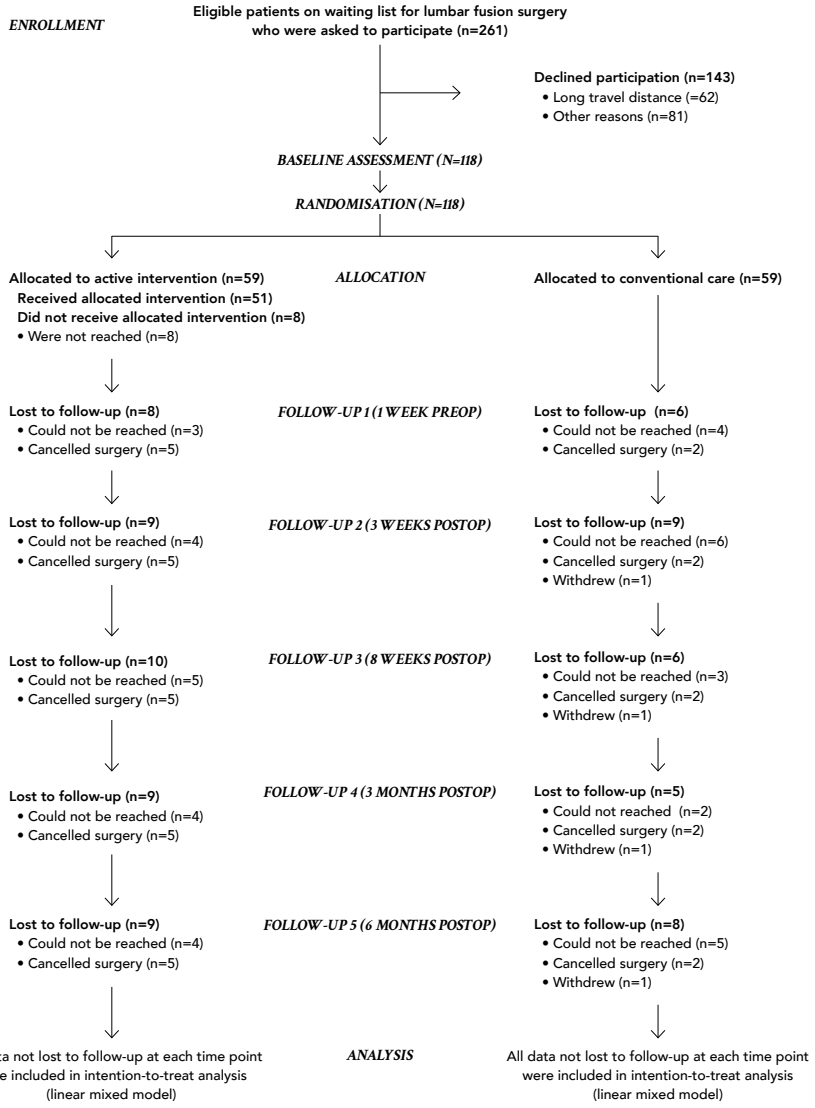

FIGURE 10. Flow chart of the patients included, according to the format of the CONSORT statement, Study IV.

Power calculation, Studies III and IV

The sample sizes for Studies III and IV were calculated using a power analysis (80% power, alpha = 0.05) with disability as the primary outcome, measured with ODI. We determined that we would require a sample size of 55 participants in each group in order to be able to show a statistically significant between-group difference of at least eight points in the ODI, with a standard deviation of 15 points, based on earlier studies (Hägg et al., 2002; Peacock et al., 2011). The difference of eight points on the ODI was established in earlier reports of a minimal clinically important difference in the range of 5.2 to 16.3 on ODI in a similar population (Hägg, 2002; Hägg et al., 2002).

3.5 OUTCOME MEASURES

All outcome measures in this thesis were based on the cognitive behavioural fear-avoidance model described above. Different types of outcome measures were used such as patient-reported outcome measures (PROMs), physical capacity tasks, and objectively measured physical activity. These outcome measures were included for the purpose of obtaining a comprehensive picture of the patient's level of functioning before and after the study.

TABLE 4: Overview of the outcome measures in Studies I, III and IV

Outcome measures	Study I, SSRD	Study III, Cross-sectional	Study IV, RCT
Patient-reported outcome measures			
Oswestry Disability Index (ODI)	X	X	X
Pain intensity back (VAS)	X	X	X
Pain intensity leg (VAS)	X	X	X
Pain Catastrophising Scale (PCS)	X	X	X
Fear of movement (TSK)	X	X	X
Self-Efficacy for Exercise Scale (SEE)		X	X
Anxiety (HADS)		X	X
Depressed Mood (HADS)		X	X
Health Related Quality of Life (EQ-5D index)		X	X
Health Related Quality of Life (EQ-5D VAS)			X
Patient-specific functioning (PSFS)	X		X
Physical activity measures (accelerometer)			
Steps per day		X	X
Counts per minute	X		
Time spent in MVPA (total accumulated)		X	X
Time spent in MVPA (10-minutes bouts)		X	
Time spent in light physical activity per day			X
Time spent sedentary			X
Physical capacity measures			
5-minute walking			X
50-foot fast walk			X
Timed Up-and-Go			X
1-minute stair-climbing			X
One-Leg stand Test, eyes open			X
One-Leg stand Test, eyes closed			X

Demographic data

Demographic data were collected by using the baseline questionnaire of Swespine, (www.4s.nu), including age, gender, self-reported weight and height (body mass index (BMI) in kg/m2), smoking status (yes/no), level of education, sick-leave status, previous spine surgery, duration of pain (back and leg), intensity of pain (back and leg), and comorbidity. Type of surgical procedure of the spine and number of fusion levels was obtained from the participant's medical file (see Table 2 and 3).

3.5.1 Primary outcome

Disability

The Oswestry Disability Index 2.0 (ODI) was used to measure disability. The ODI is a back pain-specific outcome measure of disability and is recommended for assessment of chronic LBP (Deyo et al., 1998; Fairbank et al., 2000). It is a widely used measure for people with severe LBP and disability (Fairbank et al., 2000; Grotle et al., 2005). ODI version 2.0 covers 10 items (intensity of pain, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and travelling). Each item is measured on a scale from 0 to 5, were 5 indicates the most severe disability. The score is summed and multiplied by two to generate a total score from 0 (representing no disability) to 100 (maximum disability). Values on the ODI of 21–40 points represent moderate disability; 41–60 points mean severe disability; 61–80 points mean incapacitating disability; and 81–100 points mean being restricted to bed (Fairbank et al., 1980; Fairbank et al., 2000).

The minimal important change (MIC) ranged from 5.2 to 16.3 points, and the MIC value of 8 points was used in this thesis (Hägg, 2002; Hägg et al., 2002; Strömqvist et al., 2009). The English version of the ODI has been shown to have high internal consistency (Fairbank et al., 2000), high test-retest reliability (Davidson et al., 2002) adequate content validity, and adequate responsiveness (Smeets et al., 2011) for patients with chronic LBP.

3.5.2 Secondary outcomes

Pain

The level of intensity of back and leg pain over the previous week was measured using a 100-mm horizontal VAS with the endpoints no pain (0 mm) and worst pain (100 mm) (Price et al., 1983). An intensity score of 0 to 4 mm indicates no pain; 5 to 44 mm indicates mild pain; 45 to 74 mm moderate pain; and 75 to 100 mm

severe pain (Jensen et al., 2003). The MIC value for intensity of back pain has been reported to be 15 mm and that for leg pain intensity 17 mm (Asher et al., 2018) in patients undergoing lumbar fusion surgery. There is adequate support for the validity and reliability of the VAS in patients with chronic pain (Carlsson, 1983).

Pain catastrophising

The Pain Catastrophising Scale (PCS) was used to measure the degree of pain catastrophising. The PCS has 13 items and the total score ranges from 0 to 52, with 0 points indicating no pain catastrophising (Sullivan et al., 1995). A cutoff score of 20 points indicates a moderate level of pain catastrophising (Sullivan et al., 2006). The MIC value for pain catastrophising with a reduction of 38% points has been reported (Scott et al., 2014). The PCS has shown adequate internal consistency and high construct validity in a Swedish population sample (Kemani et al., 2018).

Kinesiophobia

Fear of movement was measured using the Tampa Scale for Kinesiophobia (TSK). The TSK has 17 items. The total score ranges from 17 to 68, with higher scores indicating a higher degree of kinesiophobia. A cutoff score of > 37 points has been defined as indicating kinesiophobia (Lundberg, 2006). The MIC value for kinesiophobia has been reported to be 6 points in patients undergoing lumbar fusion surgery (Monticone et al., 2017). The TSK scale has been found to have high test-retest reliability and internal consistency, and adequate support for face validity, content validity and construct validity in patients with LBP (Lundberg et al., 2004).

The Self-Efficacy for Exercise Scale

Self-efficacy related to exercise was measured using the Self-Efficacy for Exercise Scale (SEES) (Resnick et al., 2000). The SEES consists of nine items that measure how confident the person is in exercising three times per week (20 minutes each session) under certain conditions–for example, "whether you had to exercise alone" or "whether you were busy with other things". The total score ranges from 0 to 90 points, with higher scores indicating a higher degree of self-efficacy for exercise. The SEES has shown substantial test-retest reliability, and satisfactory internal consistency and content validity with older adults (Rydwik et al., 2014).

Anxiety and depression

Anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (HADS) (Zigmond et al., 1983). The HADS contains 14 items altogether: seven items measure anxiety and seven items measure depressed mood. The total score for each subscale ranges from 0 to 21, with a higher score indicating a greater level of anxiety or depressed mood. Values of 0 points to 7 points indicate no anxiety or no depressed mood; 8 to 10 points indicate mild anxiety or mild depressed mood: 11 to 14 points indicate moderate anxiety or moderate depressed mood; and 12 to 21 points indicate severe anxiety or severe depressed mood (Snaith, 2003). A MIC value of –1.5 points has been reported for both anxiety and depressed mood in a similar population (Lindback et al., 2017). HADS has shown moderate internal consistency and high construct validity in a Swedish general population sample (Lisspers et al., 1997).

Health-Related Quality of Life

Health-Related Quality of Life was assessed using the European Quality of Life 5 Dimensions questionnaire (EQ-5D) ("EuroQol," 1990). The EQ-5D has two parts that measure health-related quality of life ("EuroQol," 1990). The first part includes a classification of the health status, with five items relating to mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. The response alternatives range from 1 (= no problems) through 2 (= moderate problems) to 3 (=severe problems). The response alternative was calculated to form a health state index for each participant. Each health state has a preference value that ranges from –0.59 to 1.0, where 1.0 means optimal health. The MIC value has been reported to be 0.17 in a similar population (Johnsen et al., 2013).

The second part of the EQ-5D is a vertical Visual Analogue Scale (EQ-5D VAS) that measures the participant's general health on a particular day, with the response alternatives ranging from 0 points (= the worst possible health state) to 100 points (= the best possible health state). The EQ-5D VAS is not used when calculating the health state index. A MIC value of 4.4 points has been reported in a similar population (Asher et al., 2018). The English version of the EQ-5D questionnaire has acceptable test-retest reliability and recent findings support its construct validity for patients with chronic musculoskeletal pain (Conner-Spady et al., 2015).

Patient-specific functioning

Patient-specific functioning was assessed using the Patient-Specific Functional Scale (PSFS). The participant lists three important activities that are difficult to perform due to his/her LBP condition. He/she rates how difficult it is to perform the activity on a scale from 0 to 10 points. Zero points indicate that the participant cannot perform the activity at all. The three separate scores are averaged to generate a total score. A MIC value of 2.0 points has been reported in a similar population (Maughan et al., 2010). The English version of the PSFS is responsive to clinically important changes over time (Maughan et al., 2010) and shows good test-retest reliability and strong criterion validity (Stratford, 1995) for patients with chronic LBP.

3.5.3 Physical activity measures

Physical activity was measured objectively using a digital triaxial accelerometer (ActiGraph GT3X+; ActiGraph, Pensacola, FL). The variables of physical activity used in this thesis were steps per day, time spent with at least moderate-intensity physical activity (total accumulated or in 10-minute bouts), time spent with light physical activity, time spent sedentary, and mean counts per minute.

The device measures acceleration in three planes and the raw output is called "counts". The raw data from the accelerometer were checked for wear time using Actilife v6.13.0 software. Wear time was calculated by subtracting non-wear time from 24 hours. Non-wear time was set to an interval of at least 60 consecutive minutes of zero activity counts, with allowance for one to two minutes of counts between 0 and 100 (Troiano et al., 2008).

A dataset for a particular participant was valid if the participant had worn the accelerometer for at least 10 hours per day for a minimum of four days (Choi et al., 2011; Trost et al., 2005). To classify physical activity into different intensities and time spent sedentary, the number of "counts" per minute was used. Data were analysed on a minute-by-minute basis in the software. The threshold for the different intensity variables recommended by Troiano et al. was set to counts per minute on the vertical axis for sedentary (0 to 99 counts per minute); light (100 to 2,019 counts per minute); moderate (2,020 to 5,998 counts per minute); and vigorous (5,999 to ∞ counts per minute) (Troiano et al., 2008).

The intensity variable "at least moderate-intensity physical activity" included the two variables "moderate intensity" and "vigorous intensity". The variable "at least moderate-intensity physical activity" was calculated both in total time accumulated per week (every minute over the threshold was counted) and as minutes per week accumulated, in at least in 10-minute bouts (periods). The intensity variable in "at least moderate-intensity physical activity" in 10-minute bouts was calculated and defined as a 10-minute period with an allowance of an interruption of no more than two minutes under the threshold of 2,020 counts (Troiano et al., 2008).

The variable "steps per day" was derived from the output data using the same software the (Actilife v6.13.0). Steps per day is an easy variable to understand in terms of total physical activity, and a cutoff point of ≥7,500 has been reported to be comparable to the WHO recommendations for health (Tudor-Locke et al., 2004).

The device was attached to the participant's dominant hip with an elastic band, and he/she was instructed to wear the accelerometer during waking hours for 7 days. It was removed at bedtime, and during contact with water. The GT3X+ accelerometer has shown high construct validity when measuring intensity levels of physical activity (Kelly et al., 2013) and excellent criterion validity when measuring the number of steps in healthy people (Gatti et al., 2015).

FIGURE 11. Accelerometer used in Studies I, III and IV.

3.5.4 Physical capacity

Five different tests were used to measure physical capacity:

- Five-minute walk (the distance the participant could walk was measured) (Simmonds et al., 1998; Smeets et al., 2006). A MIC value of 21.4 metres has been reported for people with LBP (Andersson et al., 2010).
- Fifty-foot fast walking (the time in seconds that it takes to walk 50 feet) (Simmonds et al., 1998; Smeets et al., 2006). A MIC value of –0.7 seconds has been reported for people with LBP (Andersson et al., 2010).
- Timed up-and-go (the time in seconds that it takes to rise from a chair, walk three metres, turn around and walk back to the chair, and sit down) (Simmonds et al., 1998; Smeets et al., 2006). A MIC value of –3.4 seconds has been reported for people undergoing lumbar spinal surgery (Gautschi et al., 2017).
- One-minute stair climbing (the number of steps the participants can walk in one minute) (Simmonds et al., 1998; Smeets et al., 2006). A MIC value of 14.5 steps has been reported for people with LBP (Andersson et al., 2010).
- One-Leg Stand Test (the time in seconds that a participant can stand on one leg with eyes open or eyes closed) (Maribo et al., 2009).

The construct validity of these tests has been shown, and they have adequate test-retest reliability for patients with chronic LBP (Maribo et al., 2009; Simmonds et al., 1998; Smeets et al., 2006).

FIGURE 12. One-minute stair climbing.

3.6 THE ACTIVE INTERVENTION

The active intervention involved four individual sessions before surgery, and one booster session 2 weeks after surgery. The active intervention started 8–12 weeks before surgery. Every session lasted one hour, and the post-surgery booster session that was held over the phone was about 30 minutes long. One physiotherapist performed all sessions for all participants who took part in the active intervention.

The main aim of the active intervention was to encourage the participant to stay active regardless of the severe LBP that he/she was seeking help for.

Several cognitive behavioural techniques were used to target fear-avoidance beliefs and self-efficacy, and they included goal setting for physical activity before and after surgery, pain education, a behavioural experiment, and homework after each session.

Session 1 – Person-centred analysis of functioning

Cognitive interview with a Socratic approach

A cognitive interview with a Socratic question technique was used, which means that the physiotherapist used open-ended questions with the aim of helping the participant to start reflecting about his/her thoughts, feelings, body sensations, and behaviours in relation to pain and functioning (Kåver, 2006). The focus of this discussion was about functioning rather than pain.

Modified PHODA – analysis of activity behaviour

To investigate the individual's activity behaviour, a modified series of PHODA with 27 photographs of daily activities was used (Leeuw et al., 2007b).

The physiotherapist discussed the activity hierarchy with the participant and the underlying motives, cognitions, and feelings related to different activities. The activity hierarchy helped the participant and the physiotherapist to understand the impact that LBP had in daily life. In addition to PHODA, photographs of leisure-based activities were added in order to gain an overview of how that participant could handle more strenuous activities and the extent to which the participant engaged in any leisure-based activities. A functional activity goal that the participant wanted to reach after the operation was decided upon. Such a goal could be starting with cross-country skiing again, riding a horse, or being able to drive a car to France.

FIGURE 13. Photographs of daily activities (PHODA).

FIGURE 14. Functional activity goal.

Homework 1

The aim of the homework was to help the participant learn to be aware of cognitions, feelings, behaviour, and body sensations related to a physical activity, and to increase or maintain his/her physical activity level.

The participant made a list of physical activities that he/she would still like to do but had stopped performing, or had performed less often or less intensely due to the LBP. The participant selected one of these physical activities and monitored his/her cognitions, feelings, behaviours, and body sensations related to that physical activity–as homework until session 2.

Identification of psychological risk factors

To identify psychological risk factors for low functioning, the participant completed

the Pain Catastrophising Scale (Sullivan et al., 1995), the Tampa Scale for Kinesiophobia (Lundberg et al., 2004), and the Self-Efficacy for Exercise Scale (Resnick et al., 2000) before session 2.

Session 2 – Educational session

Follow-up of homework 1

The physiotherapist discussed the physical activity that the participant had done as homework and concentrated on cognitions, feelings, behaviours, and body sensations that might have occurred before and after the activity.

Pain education

An educational session about acute and chronic pain was held (Moseley, 2003; Moseley et al., 2004). The underlying theoretical model for the pain education was the fear-avoidance model, which served as a basis for explaining the rationale for being active despite the LBP (Vlaeyen et al., 1995; Woby et al., 2007). The pain education session was in the form of a discussion between the physiotherapist and the participant. The participant's thoughts, beliefs, and knowledge– and also what he/she wanted to know about staying active despite the LBP–were discussed in detail. The participant's answers to the questionnaires completed after session 1 and information from the homework assignment were used as a basis in this session. After this, a health plan was formed together.

Goal setting – short-term goal before surgery

A person-centred short-term physical activity goal that he/she wanted to reach before surgery was decided upon. This short-term goal was specific, measurable, achievable, realistic, and time-targeted (a SMART goal) (Bovend'Eerdt et al., 2009). For example, a short-term goal could be to "go for a walk in the nearby forest for 30 minutes every day". The participant was encouraged to work towards that goal in gradual steps to enhance self-efficacy related to that physical activity.

Homework 2

The aim of the homework assignment was threefold: to learn to be aware of cognitions, feelings, behaviours, and body sensations related to a physical activity; to increase the physical activity level; and to help the participant to reach his/her short-term goal before surgery.

The participant chose this physical activity from the list of physical activities that was established during session 1.

Session 3 – Cognitive behavioural experiment

Follow-up of homework 2 and short-term goal before surgery

The physiotherapist and the participant discussed the progress towards the short-term goal, as well as cognitions, feelings, body sensations, and behaviours related to the physical activity that had been performed as homework.

Cognitive behavioural experiment

A behavioural experiment was performed, which had a twofold aim: to enhance inhibitory learning by testing and violating negative expectations that the participant might have regarding a physical activity, and to explore avoidance behaviour. For the behavioural experiment, the participant selected one physical activity from the list of physical activities established during session 1. The activity had to be an activity that the participant had stopped performing due to his/her back problem. Before the behavioural experiment, the participant was asked about what cognitions he/she had about the activity and what he/she expected would happen when performing that physical activity. After the physical activity was performed, the validity of the participant's thoughts and the participant's level of self-efficacy was discussed in terms of both short- and long-term consequences.

Homework 3

The aim of the homework assignment was threefold: to learn to be aware of cognitions, feelings, behaviours, and body sensations related to physical activity; to increase the level of physical activity; and to help the participant to reach his/her short-term goal before surgery.

The homework was either the same physical activity selected during session 2 or a new physical activity from the list of physical activities established during session 1.

Session 4 – Goal setting after surgery

Follow-up of homework 3 and short-term goal before surgery

The physiotherapist and the participant discussed the progress in achieving his/her short-term goal and the cognitions, feelings, and behaviours related to the physical activity that had been performed as homework.

Goal setting – 4 and 8 weeks after surgery

The participant chose two functioning-related goals to be reached at 4 and 8 weeks after surgery, which should involve a physical activity that was important to him/her. These goals were set as SMART goals (Bovend'Eerdt et al., 2009).

Enhancement of self-efficacy related to the short-term goal before surgery

The participant was encouraged to continue working towards his/her short-term goal and was advised to take gradual steps towards enhancing his/her self-efficacy related to that goal. If the participant had already reached the short-term goal, the goal was modified by increasing the intensity, duration, or frequency of the physical activity, or by choosing another physical activity that he/she considered to be important.

Session 5 – Booster session after surgery

Cognitive interview with a Socratic approach

The aim of the booster session was to capture the participant's cognitions and feelings regarding physical activities – particularly activities of daily living. The physiotherapist identified tendencies towards fear-avoidance beliefs and encouraged the participant to keep active.

Follow-up of goals 4 and 8 weeks after surgery

The participant's goals were discussed and were adjusted with regard to duration, intensity, or frequency in accordance with his/her current medical status.

Enhancement of self-efficacy related to goals 4 and 8 weeks after surgery

The participant was encouraged to continue with his/her progress towards the goals and was advised to take gradual steps towards enhancing his/her self-efficacy related to that physical activity.

3.7 CONVENTIONAL CARE INTERVENTION

Conventional care included one single session with a physiotherapist. In this session, the patient received information about the details of the postoperative mobilization routine, and was introduced to a core exercise programme, to be initiated on the day after surgery. Furthermore, the patient was encouraged to keep active and to start performing the recommended exercises before surgery.

3.8 STATISTICAL ANALYSIS

TABLE 5. Statistical methods used in Studies III and IV

Methods	Study III	Study IV
Descriptive statistics		
Frequency (n), proportion (%)	X	X
Mean, standard deviation (SD)	X	X
Regression models		
Univariate regression analyses	X	
Multiple linear regression model	X	
Linear mixed model		X
Physical activity measures		
Steps per day	X	X
Physical activity intensity (accumulated per week)	X	X
Physical activity intensity (10-minutes bouts)	X	
Effect size		
Hedge's g		X

Study I

Demographic variables collected at baseline are presented separately for each of the 11 participants (Table 2). The daily dependent outcome measures, four items of TSK, four items of PCS, three activities using PSFS, and physical activity (variable "mean counts per minute") were analysed visually, describing the daily changes in level, trend, and variability (Lundervold et al., 2000). To evaluate the effect of the pilot intervention, the daily changes in phase B1 and B2 were compared to those in phase A for each participant separately.

The dependent outcomes measured before the study started and at follow-up (TSK, PCS, VAS back/leg, ODI) were evaluated and analysed. The score for each outcome measure was calculated for the 11 participants, and the change from baseline to

point C of each score is presented in Table 6. The numerical score for each participant was analysed in relation to the cutoff points described under outcome measures.

Study III

In Study III statistical analysis was performed using the statistical software SPSS version 24 (IBM Corporation, Armonk, NY). Descriptive statistics were used for demographic data and all variables are presented as frequencies (proportions) or means with standard deviation (SD). The numbers of internal missing data are shown in the tables separately. Statistical significance was assumed at any p-value of ≤ 0.05, and– where appropriate –95% confidence intervals (CIs) are given (Table 3) (Study III).

The physical activity data from the accelerometer were calculated using Actilife v6.13.0 software. Two variables were calculated: "steps per day" and "at least moderate-intensity physical activity". The intensity variable "at least moderate-intensity physical activity in 10-minute bouts" was used to calculate the proportions of patients who reached the physical activity recommendations for health, as put forward by the WHO (WHO, 2009). The variable "steps per day" was divided into three subgroups: ≥ 7,500 steps per day (physically active lifestyle), 5,000-7,499 steps per day (low active lifestyle), and < 5,000 steps per day (sedentary lifestyle) (Tudor-Locke et al., 2011, 2013). The proportions of patients who reached each level were calculated.

In Study III, two different multiple linear regression models were used to investigate the association between the fear-avoidance factors and the physical activity variables. The variable "steps per day" and the intensity variable "at least moderate physical activity in 10-minute-bouts" were used as dependent variables. To choose the independent variables for the final multiple regression model, a purposeful selection method was used (Bursac et al., 2008).

The first step included univariate regression analyses and independent variables were excluded if they were associated with the dependent variable with a p-value > 0.25. Independent variables were excluded irrespective of whether they were fear-avoidance factors or potential confounders (age, gender, BMI).

The second step in the analysis included a backward multiple regression analysis where the remaining independent variables were excluded if they were associated with the dependent variable with a p-value of > 0.15. The independent variables were only excluded if the beta coefficient of the remaining independent variables in the model did not change more than 15%.

The third step in the analysis was performed by adding the independent variables that were excluded in the initial univariate regression analysis one by one and the variable was only kept in the multiple regression model if it had a p-value of ≤ 0.15 (Bursac et al., 2008). The confounders (age, gender, or BMI), if they remained in the final model, were not interpreted in the results since they were only added to adjust the model. The variables in the final model were controlled for multicollinearity, and the standardised residuals from the model were checked for normality and heteroscedasticity.

The standardised residuals in the multiple linear regression analysis of the variable "steps per day" and the intensity variable "at least moderate physical activity in 10-minute bouts" were not normally distributed, and the variables were therefore transformed into their natural logarithms. After the transformation, the standardised residuals of the intensity variable "at least moderate physical activity in 10-minute bouts" were still not normally distributed and the variable was therefore not investigated further.

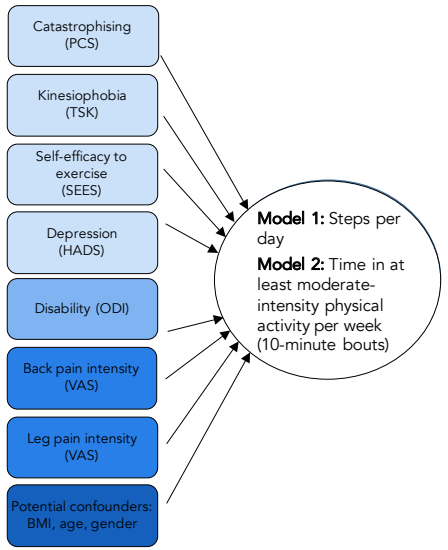

FIGURE 15. Overview of the variables in the regression models. PCS, pain catastrophising Scale; TSK, Tampa Scale for Kinesiophobia; SEES, Self-Efficacy for Exercise Scale; HADS, Hospital Anxiety and Depression Scale; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale.

Study IV

Data analysis was performed with SAS 9.4 (SAS Institute, Cary, NC) and SPSS version 22. All outcome measure values were interpreted in relation to reference values and to the minimal important change (MIC) (Vet et al., 2011). If a MIC value was not available for the same study population, we used a value that was as close as possible.

Statistical analysis used to respond to the first hypotheses

We used an "intention-to-treat" (ITT) approach to compare the effects of the different treatment conditions on the primary (ODI) and secondary outcomes from baseline to the 6-month follow-up. For subjects who were lost to follow-up, all the available data were used. A linear mixed model with a heterogeneous Toeplitz covariance matrix was used to evaluate the effect of the different interventions for the various time points. This takes the correlated nature of repeated measures for the same participant into account while allowing for missing observations. Each outcome had a separate model that included the change scores as the dependent variable. These were calculated by subtracting the baseline value for each outcome from its follow-up values. Fixed factors were set to, time, treatment group, and the baseline value of each dependent variable, and treatment centre was set as a random factor. To detect differences in treatment effect between time points, an interaction term for group and time was included as fixed factors. Confounding factors (depressive symptoms, gender, and steps per day) was set a priori on the basis of available evidence, and the baseline values of these factors were added to the model as fixed factors (Adogwa et al., 2013; LaCaille et al., 2005; Mannion et al., 2006; Pearson et al., 2013).

Statistical analysis used to respond to the second hypotheses

Hedge's g for between-group effect sizes of the primary and secondary outcomes at each time point was computed using standard errors from the mixed-model output to derive pooled and weighted standard deviations (Hedges, 2007). Effect sizes (ESs) were categorized as small ($d \approx 0.20$ to $d < 0.50$), medium ($d \geq 0.50$ to $d < 0.80$), and large ($d \geq 0.80$) (Cohen, 1992) and are presented with 95% confidence intervals (Hedges et al., 1985). ESs at each time point (1 week before surgery and 3 weeks, 8 weeks, and 3 months after surgery) were compared with that at 6 months.

Per-protocol analysis

All participants included in the per-protocol analysis had to have undergone lumbar fusion surgery. Furthermore, participants in the active intervention needed to have received it in at least four out of five sessions. In the sensitivity analysis, per-protocol data and ITT data were compared.

4

SUMMARY OF RESULTS

HANNA LOTZKE

Department of Ortopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden, 2019

4. SUMMARY OF RESULTS

Study I

Study I was a feasibility study with the aim of describing the process of developing a physiotherapeutic prehabilitation programme based on a cognitive behavioural approach, using a Single-Subject Research Design (SSRD).

Results regarding daily changes in the dependent variables measured on a daily basis after the pilot or the conventional care intervention

Throughout the pilot intervention (B1), a decrease was seen in kinesiophobia (two participants) and pain catastrophising (three participants) out of six participants compared to in phase A. An example of such decrease is shown in Figure 16. Throughout the conventional care intervention (B2), none of the participants had any change in kinesiophobia and one participant had a lower level in pain catastrophising out of five participants compared to in phase A.

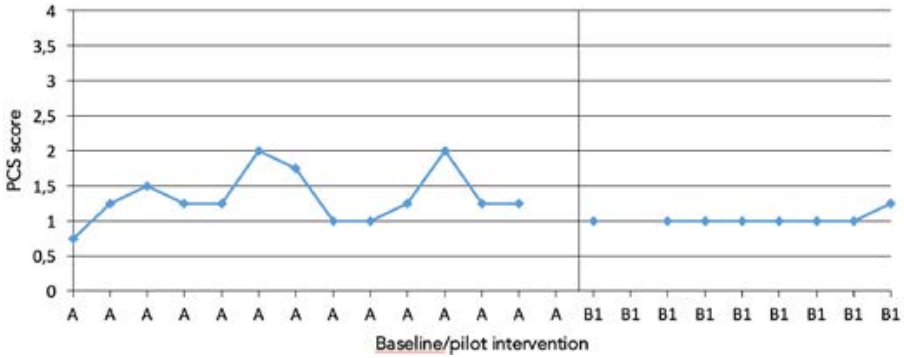

FIGURE 16. Participant P6, daily measures of mean pain catastrophising (PCS), during Phases A and B1 (pilot intervention).

Throughout the pilot intervention (B1), one participant out of five improved in all three important daily activities (PSFS), and one participant improved in two activities compared to in phase A. Throughout the conventional care intervention (B2), one participant out of five improved in two activities compared to in phase A.

Throughout the pilot intervention (B1), three participants out of six became more physically active compared to in phase A. Throughout the conventional care intervention (B2), one participant out of four became more physically active compared to in phase A. One participant's physical activity level measured on a daily basis was lost due to a computer problem.

The daily physical activity patterns showed a high degree of variation among the participants included in the pilot study.

Results concerning whether a cognitive shift could be detected in the dependent variable PCS measured on a daily basis after the pilot or conventional care intervention

Throughout the pilot intervention (B1), a cognitive shift in pain catastrophising could be seen in three participants out of six. The change that occurred was detected after the first two sessions. Throughout the conventional care intervention (B2), a cognitive shift could be seen in one out of five participants.

The daily dependent outcome measures showed some changes in those participants who received the pilot intervention first, but the changes were small.

Results regarding whether a change occurred in the dependent outcome measures after the SSRD study

Six of the 11 participants reported a lower score on TSK and two participants reached a minimal important change (MIC = –6 points reduction). Five of 11 participants had a lower score on PCS and three participants reached a minimal important change (MIC = 38% reduction). Two participants had a lower score in intensity of back pain (VAS) and two participants had a lower leg pain intensity (VAS). One participants reached a minimal important change in intensity of back pain (MIC = –15 mm reduction). Eight participants had a lower score on the ODI and three participants reached a minimal important change (MIC = –8 points reduction) (Table 6). The dependent outcome measures were suitable for detection of changes after the SSRD study, but the changes were small.

TABLE 6. Descriptive scores for the variables fear of movement, pain catastrophising, pain intensity and disability at baseline and after completion of the pilot study. Change scores are shown within parantheses.

Patient	Kinesiophobia (TSK)	Pain Catastrophising (PCS)	Pain Intensity – back pain (VAS)	Pain Intensity – leg pain (VAS)	Disability (ODI)
	Baseline – End (Change)	Baseline – End (Change)	Baseline – End (Change)	Baseline – End (Change)	Baseline – End (Change)
1	55-51 (-4)	32-20 (-12)	60-60 (0)	35-35 (0)	34-34 (0)
2	50-40 (-10)	40-35 (-5)	72-87 (+15)	0-0	44-42 (-2)
3	31-33 (+2)	5-10 (+5)	68-80 (+12)	58-67 (+9)	68-58 (-10)
4	34-30 (-4)	23-25 (+2)	68-68 (0)	65-62 (-3)	50-50 (0)
5	36-32 (-4)	28-28 (0)	78-72 (-6)	46-67 (+21)	46-40 (-6)
6	33-36 (+3)	10-9 (-1)	40-43 (+3)	2-4 (+2)	44-30 (-14)
7	42-45 (+3)	37-49 (+12)	80-86 (+6)	50-72 (+22)	36-44 (+8)
8	31-28 (-3)	14-9 (-5)	61-44 (-17)	31-45 (+14)	44-36 (-8)
9	32-35 (+3)	24-24 (0)	41-61 (+20)	2-0 (-2)	38-34(-4)
10	48-52 (+4)	7-20 (+13)	70- missing	0- missing	44- missing
11	40-27 (-13)	32-21 (-11)	60-75 (+15)	0-7 (+7)	30-28 (-2)

TSK=Tampa Scale for Kinesiophobia, range 17-68; PCS=Pain Catastrophising Scale, range 0-52; VAS=Visual Analogue Scale, range 0-100 mm; ODI= Oswestry Disability Index, range 0-100.

Important lessons were learned from delivering the pilot intervention and based on this, the research team decided to modify the theoretical framework and the pilot intervention.

The treatment integrity and treatment differentiation aspects of the pilot intervention were evaluated. A new treatment manual (Study Protocol 3) was written for the active intervention, to be used in the RCT (Study IV).

Modification of theoretical framework: the two pathways of the cognitive fear-avoidance with self-efficacy as a mediating factor and physical activity were added to the original fear-avoidance model; a person-centred approach to address

fluctuations in kinesiophobia and pain catastrophising, and to support self-efficacy was included as the overall philosophy of the intervention.

Changes made in the cognitive behavioural techniques: more intense physical activities were added to the PHODA photographs; specific SMART goals were added as homework after each session; session 3 was changed to a behavioural experiment instead of an in vivo exposure experiment; a booster session was added to follow up SMART goals and enhance self-efficacy in relation to these goals after surgery.

Finally, the content of session 4 was adjusted to include goal setting 4 and 8 weeks after surgery.

These modifications were made to strengthen the feasibility of the pilot intervention and to contextually adjust the active intervention to the context of spinal surgery, see Table 7.

TABLE 7. Changes made after the pilot intervention.

	Study Protocol 2.0 (tested in SSRD)	**Identified threats to treatment fidelity**	**Study Protocol 3.0 Contextual change**
Theoretical framework	Cognitive behavioural fear-avoidance theory.	Hard to establish a fear hierarchy (not all fearful) – exposure in vivo not possible Patients had "normal" physical activity level, but fluctuating physical activity pattern	Using the two arms (avoidance – confrontation) of the Cognitive behavioural fear-avoidance theory, with self-efficacy as a mediating factor. Person-centred approach to address fluctuations and support self-efficacy Adding physical activity to the theoretical model
Assessment	The original version of the PHODA was used. The phrasing of the question was contextually adjusted	The activities included in the original PHODA did not cover intense physical activities Hard to establish a fear hierarchy	PHODA was adjusted to include more intense physical activities
Treatment integrity was the treatment delivered as intended?	Detailed treatment manual used Same treatment "dose" (same number, frequency and length of contact)	Patients set up personal goals which demands person centred approach	Treatment manual adjusted Detailed study protocol
Treatment differentiation was the active intervention strong enough to detect a change?	Based on previous studies and clinical experiences it was assumed that the pilot intervention should lead to a cognitive shift as reflected in PCS, whereas such a shift should not be detected in conventional care intervention	A change was detected in PCS, but it was considered to be weak	**The behavioural change techniques were strengthened by:** a) Refining the SMART goal to be specific b) Using Cognitive behavioural experiment instead of exposure in vivo c) Using well-defined and specified home work after each session d) Adding a Booster session post-operatively
Content of the intervention	**Session 4** Pre-op information the same as the one session in conventional care intervention	**Session 4** Preoperative information needed to be personalised	**The content of Session 4 was adjusted** • Follow-up of home work and SMART goal • Goal setting • Enhance self-efficacy in relation to SMART goal

Study II, Study protocol

The theoretical framework and content of active intervention was described in detail and published in the format of a study protocol (Study II). The active intervention is presented in Figure 17 and the modified version of the cognitive fear-avoidance model is presented in Figure 18.

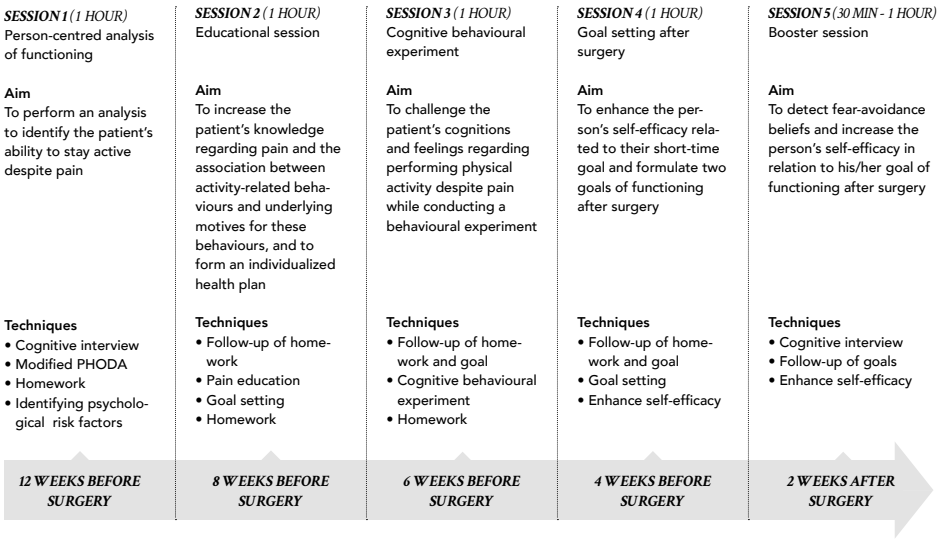

FIGURE 17. Schematic overview of the active intervention.

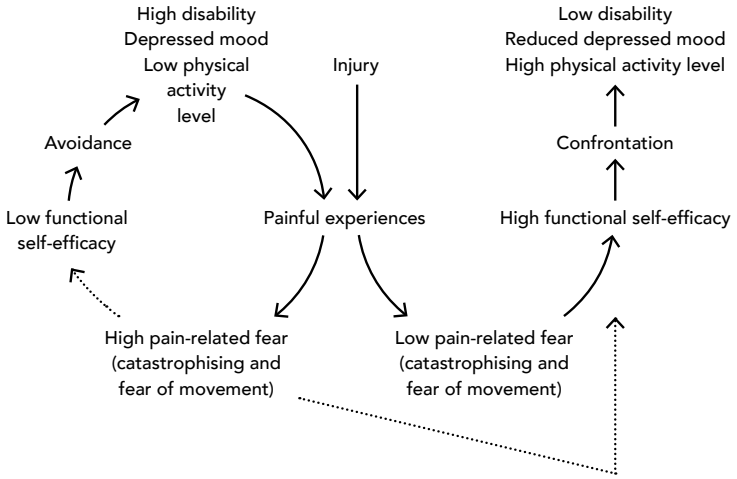

FIGURE 18. Modified Cognitive behavioural fear-avoidance model with self-efficacy (Vlaeyen 1995, Woby 2007).

Study III, Cross-sectional study

Study III was a cross-sectional study with the aim of investigating the preoperative level of objectively measured physical activity, and of exploring associations with the level of physical activity in the fear-avoidance model.

Demographics

One hundred and sixteen patients participated. At baseline, the participants had a moderate level of disability, a moderate level of back pain, kinesiophobia (TSK), moderate pain catastrophising thoughts (PCS), and reduced health-related quality of life (EQ-5D index) (Table 8).

Preoperative level of intensity of physical activity in relation to WHO health recommendations

Only 20 participants (17%) fulfilled the WHO recommendations on physical activity for health (≥ 150 minutes per week in 10-minute bouts). Consequently, 96 participants (83%) did not fulfil the recommendations, and out of those 32 patients (28%) spent 0 minutes per week on "at least moderate-intensity physical activity" (10-minute bouts) (Figure 19).

TABLE 8. Values for accelerometer data and fear-avoidance factors for all patients.

	All n = 118	Women n = 63	Men n = 55
Accelerometer data[1]			
Time spent in MVPA per week (10-minute bouts)	81.7 (116.9)	87.4 (107.9)	75.1 (127.1)
Time spent in MVPA per week (total accumulated)	197.6 (141.3)	187.6 (134.1)	209.1 (149.7)
Steps/day	7493.5 (2645.4)	7553.6 (2728.0)	7424.4 (2571.0)
Pain intensity – back (VAS)	61.1 (19.4)	63.3 (17.7)	58.7 (21.0)
Pain intensity – leg (VAS)[2]	35.4 (29.7)	36.0 (28.8)	34.7 (30.9)
Disability (ODI)	37.8 (12.4)	38.2 (11.7)	35.3 (13.0)
Pain catastrophising (PCS)	22.8 (8.1)	22.7 (8.1)	22.9 (8.2)
Fear of movement (TSK)	38.1 (8.4)	35.9 (7.7)	40.6 (8.6)
Self-efficacy for exercise (SEES)	61.2 (20.5)	62.6 (20.1)	59.5 (20.9)
Depression (HADS)	5.4 (3.6)	5.4 (2.9)	5.4 (4.3)
Anxiety (HADS)	6.6 (3.7)	6.5 (3.7)	6.7 (3.7)
Health related quality of life (EQ5D index)[2]	0.49 (0.29)	0.51 (0.28)	0.47 (0.30)

[1] n = 116, [2] n = 117. Values correspond to mean (SD). MVPA, physical activity of least moderate-intensity; VAS, Visual Analogue Scale; ODI, Oswestry Disability Index; PCS, Pain Catastrophising Scale; TSK, Tampa Scale for Kinesiophobia; SEES, Self-efficacy for Exercise Scale; HADS, Hospital Anxiety and Depression Scale; EQ5D index, Health Related Quality of Life.

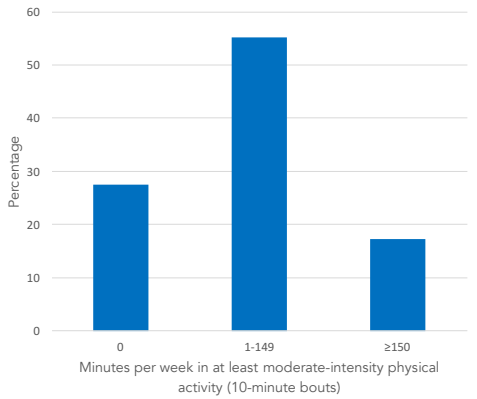

FIGURE 19. Histogram of "at least moderate-intensity physical activity".

Preoperative level of total physical activity measured with the variable "steps per day"

Nineteen patients (16%) were categorized as having a sedentary lifestyle, 44 patients (38%) had a low active lifestyle, and 53 patients (46%) had a physically active lifestyle (Figure 20).

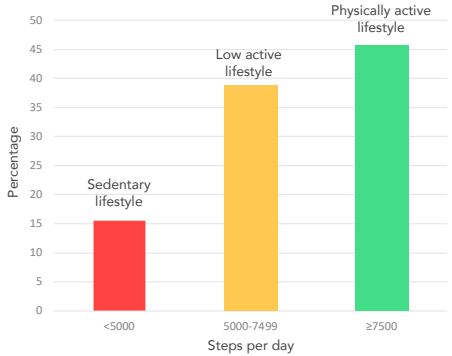

FIGURE 20. Histogram of "steps per day".

Association between factors in the fear-avoidance model and "steps per day" (dependent variable)

In the final multiple linear regression model, the dependent variable "step per day" (log-transformed) was found to be associated with both fear of movement (TSK) and disability (ODI). After the variable "steps per day" was back-transformed, a 10-point lower level of fear of movement (TSK) was associated with an 8.6% greater number of steps per day, and a 10-point lower level of disability (ODI) was associated with an 8.6% greater number of steps per day.

Study IV, Randomised controlled trial

Study IV, was an RCT with the aim of investigating whether a person-centred physiotherapeutic prehabilitation programme based on a cognitive behavioural approach would reduce disability and improve functioning after lumbar fusion surgery in patients with degenerative disc diseases (DDDs) to a greater extent than conventional care.

Out of the 59 participants included in the active intervention, 46 participants (78%) attended four or more sessions. Eight participants declined participation in the intervention for individual reasons such as: lack of time for the intervention; long travelling distance; difficulty with transportation. The compliance with the intervention was high, and no adverse events were reported during the active intervention.

Comparison between the active intervention and conventional care after surgery

In the ITT analysis, no statistically significant difference in the primary outcome disability (ODI) was found between the active intervention group and the conventional care group (see Table 9 "Group x Time").

TABLE 9. BASELINE scores, change scores from baseline and Hedge's effect sizes for between-group differences between active intervention and conventional care in all patients by intention-to-treat analysis*

		Baseline values	Change: baseline to 1 week prior to surgery	Change: baseline to 3 weeks postop	Change: baseline to 8 weeks postop	Change: baseline to 3 months postop	Change: baseline to 6 months postop	Group effect	Time effect	Interaction Group* Time
Disability (ODI)	Active intervention	35.7 (32.3 – 39.0)	0.8 (-3.7 – 5.3)	4.1 (-2.2 – 10.4)	-10.8 (-16.0 – -5.6)	-13.4 (-18.4 – -8.3)	-14.5 (-19.8 – -9.3)	p = 0.98	p < 0.001	p = 0.16
	Conventional care	38.0 (35.1 – 40.9)	2.9 (-1.5 – 7.3)	2.3 (-3.9 – 8.5)	-8.6 (-13.6 – -3.6)	-12.6 (-17.5 – -7.8)	-17.5 (-22.7 – -12.4)			
	Between-group ES	–	0.13 (-0.26 – 0.51)	-0.08 (-0.47 – 0.31)	0.12 (-0.27 – 0.50)	0.04 (-0.34 – 0.43)	-0.16 (-0.55 – 0.23)			
Pain intensity – back (VAS)	Active intervention	57.3 (51.7 – 62.9)	-1.0 (-5.8 – 3.7)	-13.6 (-21.1 – -6.1)	-28.3 (-34.4 – -22.2) [a]	-30.8 (-37.0 – -24.7)	-29.2 (-36.7 – -21.7)	p = 0.99	p < 0.001	p = 0.19
	Conventional care	65.0 (61.0 – 68.9)	2.5 (-2.1 – 7.1)	-19.6 (-27.2 – -12.0)	-23.1 (-29.1 – -17.1) [a]	-30.7 (-36.7 – -24.8)	-31.8 (-39.2 – -24.4)			
	Between-group ES	–	0.21 (-0.18 – 0.59)	-0.22 (-0.62 – 0.17)	0.24 (-0.16 – 0.63)	0 (-0.38 – 0.39)	-0.10 (-0.49 – 0.29)			
Pain intensity – leg (VAS)	Active intervention	37.3 (29.3 – 45.3)	3.0 (-10.9 – 17.0)	-16.6 (-30.7 – -2.6)	-19.4 (-32.7 – -6.0) [a]	-24.4 (-37.2 – -11.6)	-17.6 (-30.9 – -4.2)	p = 0.47	p < 0.001	p = 0.90
	Conventional care	33.5 (26.3 – 40.7)	-1.3 (-15.1 – 12.4)	-16.5 (-30.5 – -2.5)	-19.0 (-32.2 – -5.8) [a]	-26.2 (-38.8 – -13.6)	-21.6 (-34.8 – -8.4)			
	Between-group ES	–	-0.09 (-0.47 – 0.30)	0.00 (-0.39 – 0.40)	0.01 (-0.39 – 0.40)	-0.04 (-0.43 – 0.35)	-0.08 (-0.47 – 0.31)			
Pain catastrophising (PCS)	Active intervention	22.5 (20.5 – 24.4)	-4.4 (-6.4 – -2.3)	-10.1 (-12.0 – -8.1)	-11.3 (-13.2 – -9.3) [a]	-10.8 (-12.5 – -9)	-11.8 (-13.8 – -9.8)	p = 0.47	p < 0.001	p = 0.20
	Conventional care	23.1 (20.9 – 25.3)	-2.2 (-4.3 – -0.2)	-10.3 (-12.3 – -8.3)	-9.4 (-11.3 – -7.5) [a]	-11.3 (-12.9 – -9.6)	-11.6 (-13.6 – -9.7)			
	Between-group ES	–	0.29 (-0.11 – 0.69)	-0.03 (-0.43 – 0.36)	0.27 (-0.12 – 0.67)	-0.08 (-0.47 – 0.30)	0.02 (-0.37 – 0.42)			
Fear of movement (TSK)	Active intervention	37.8 (35.6 – 40.1)	-3.4 (-5.0 – -1.8)	-3.4 (-5.1 – -1.7)	-5.2 (-7.0 – -3.4)	-5.3 (-7.3 – -3.4)	-7.8 (-9.5 – -6.0)	p = 0.79	p < 0.001	p = 0.22
	Conventional care	38.5 (36.4 – 40.7)	-1.7 (-3.3 – -0.1)	-4.2 (-5.9 – -2.5)	-5.8 (-7.5 – -4.2)	-6.3 (-8.1 – -4.5)	-8.3 (-10.1 – -6.6)			
	Between-group ES	–	0.30 (-0.10 – 0.70)	-0.13 (-0.53 – 0.27)	-0.10 (-0.50 – 0.30)	-0.14 (-0.53 – 0.25)	-0.09 (-0.49 – 0.3)			
Self-efficacy for exercise (SEES)	Active intervention	61.5 (56.4 – 66.6)	0.6 (-6.1 – 7.3)	6.8 (-0.5 – 14.2)	5.3 (-1.6 – 12.1)	6.1 (-0.8 – 12.9)	4.9 (-2.5 – 12.4)	p = 0.54	p = 0.02	p = 0.30
	Conventional care	60.8 (55.4 – 66.3)	-0.4 (-6.9 – 6.1)	0.5 (-6.7 – 7.7)	6.6 (0.0 – 13.1)	5.1 (-1.4 – 11.6)	3.4 (-3.8 – 10.6)			
	Between-group ES	–	0.04 (-0.35 – 0.44)	0.25 (-0.16 – 0.65)	-0.05 (-0.45 – 0.34)	0.04 (-0.35 – 0.43)	0.06 (-0.34 – 0.46)			
Anxiety (HADS)**	Active intervention	6.9 (5.9 – 7.9)	-0.3 (-1.4 – 0.8)	-2.2 (-3.1 – -1.2)	-2.3 (-3.3 – -1.3) [a]	-2.5 (-3.4 – -1.6)	-2.7 (-3.5 – -1.8)	p = 0.43	p < 0.001	p = 0.85
	Conventional care	6.3 (5.5 – 7.2)	0.3 (-0.7 – 1.4)	-1.8 (-2.7 – -0.9)	-1.7 (-2.7 – -0.8) [a]	-2.4 (-3.3 – -1.6)	-2.6 (-3.5 – -1.8)			
	Between-group ES	–	0.16 (-0.23 – 0.56)	0.11 (-0.30 – 0.51)	0.17 (-0.23 – 0.58)	0.03 (-0.37 – 0.42)	0.01 (-0.39 – 0.41)			
Depressed mood (HADS)	Active intervention	5.1 (4.2 – 6)	-0.5 (-1.5 – 0.6)	-1.0 (-2.1 – 0.1)	-1.3 (-2.4 – -0.2)	-1.6 (-2.7 – -0.6)	-1.8 (-2.9 – -0.8)	P = 0.84	p < 0.001	p = 0.34
	Conventional care	5.7 (4.8 – 6.6)	0.5 (-0.6 – 1.5)	-1.0 (-2.0 – 0.1)	-1.4 (-2.4 – -0.3)	-1.8 (-2.8 – -0.8)	-2.1 (-3.1 – -1.1)			
	Between-group ES	–	0.25 (-0.14 – 0.65)	0.00 (-0.40 – 0.40)	-0.02 (-0.42 – 0.37)	-0.05 (-0.44 – 0.34)	-0.07 (-0.47 – 0.33)			

CONT. TABLE 9.

Health related quality of life **(EQ-5D index)**	Active intervention	0.51 (0.44 – 0.58)	0.09 (0.02 – 0.16)	0.02 (-0.05 – 0.1)	0.19 (0.13 – 0.25) [a]	0.20 (0.14 – 0.25)	0.21 (0.15 – 0.27)	p = 0.52	p < 0.001	p = 0.01
	Conventional care	0.47 (0.40 – 0.55)	-0.05 (-0.12 – 0.02)	0.07 (0 – 0.14)	0.14 (0.08 – 0.20)	0.20 (0.15 – 0.26)	0.26 (0.21 – 0.32)			
	Between-group ES	–	0.57 (0.16 – 0.98)	-0.18 (-0.57 – 0.22)	0.23 (-0.16 – 0.63)	-0.03 (-0.42 – 0.35)	-0.25 (-0.64 – 0.14)			
Health related quality of life **(EQ-5D VAS)**	Active intervention	46.1 (41.6 – 50.7)	-1.6 (-9.0 – 5.8)	5.4 (-3.1 – 14.0)	18.8 (11.3 – 26.2) [a]	24.2 (17.4 – 31.1)	23.2 (15.9 – 30.6)	p = 0.50	p < 0.001	p = 0.53
	Conventional care	46.1 (41.5 – 50.8)	-2.3 (-9.4 – 4.9)	10.7 (2.4 – 19.1)	20.0 (12.9 – 27.2) [a]	24.1 (17.5 – 30.6)	26.4 (19.2 – 33.5)			
	Between-group ES	–	0.02 (-0.37 – 0.41)	-0.18 (-0.58 – 0.22)	-0.05 (-0.44 – 0.35)	0.01 (-0.38 – 0.4)	-0.12 (-0.52 – 0.27)			
Patient-reported functioning **(PSFS)**	Active intervention	2.8 (2.4 – 3.3)	0.2 (-0.3 – 0.7)	0.2 (-0.5 – 0.9)	1.5 (0.8 – 2.2)	2.0 (1.3 – 2.6)	2.9 (2.2 – 3.6)	p = 0.13	p < 0.001	p = 0.83
	Conventional care	2.9 (2.4 – 3.5)	-0.2 (-0.7 – 0.3)	-0.1 (-0.8 – 0.5)	0.7 (0.1 – 1.4)	1.3 (0.6 – 1.9)	2.5 (1.8 – 3.2)			
	Between-group ES	–	0.23 (-0.19 – 0.65)	0.15 (-0.27 – 0.57)	0.35 (-0.06 – 0.76)	0.30 (-0.10 – 0.70)	0.17 (-0.25 – 0.59)			
Steps/day	Active intervention	7811.8 (7088.3 – 8535.4)	–	–	–	-88.5 (-687.2 – 510.2)	180.5 (-421.7 – 782.7)	p = 0.77	p = 0.91	p = 0.20
	Conventional care	7175.2 (6544.3 – 7806)	–	–	–	42.3 (-549.3 – 633.8)	-183.8 (-780.1 – 412.6)			
	Between-group ES	–	–	–	–	-0.09 (-0.50 – 0.32)	0.25 (-0.16 – 0.66)			
Time spent in MVPA per day (total accumulated)***	Active intervention	29.9 (24.8 – 35)	–	–	–	3.7 (-1.3 – 8.8)	2.5 (-2.2 – 7.3)	p = 0.22	p = 0.07	p = 0.33
	Conventional care	26.5 (21.3 – 31.8)	–	–	–	1.7 (-3.3 – 6.7)	-2.2 (-6.8 – 2.4)			
	Between-group ES	–	–	–	–	0.16 (-0.25 – 0.57)	0.42 (0.00 – 0.83)			
Time spent in light physical activity per day	Active intervention	276.4 (254.3 – 298.4)	–	–	–	-23.6 (-43.3 – -3.9)	-7.1 (-28.8 – 14.6)	p = 0.80	p = 0.03	p = 0.98
	Conventional care	279.8 (264.2 – 295.5)	–	–	–	-27.1 (-46.7 – -7.5)	-10.3 (-31.8 – 11.3)			
	Between-group ES	–	–	–	–	0.07 (-0.33 – 0.48)	0.06 (-0.35 – 0.47)			
Time spent sedentary	Active intervention	550.1 (524.0 – 576.2)	–	–	–	27.9 (-13.9 – 69.8)	19 (-24.9 – 63)	p = 0.39	p = 0.82	p = 0.23
	Conventional care	543.3 (521.5 – 565.1)	–	–	–	27.8 (-12.8 – 68.3)	40.9 (-1.8 – 83.7)			
	Between-group ES	–	–	–	–	0.00 (-0.41 – 0.4)	0.21 (-0.21 – 0.62)			

CONT. TABLE 9.

5-minute walk	Active intervention	427.5 (405.6 – 449.3)	–	–	–	47.0 (-0.3 – 94.2)	58.8 (10.7 – 106.8)	p = 0.75	p = 0.01	p = 0.62
	Conventional care	409.9 (389.9 – 429.9)	–	–	–	41.5 (-4.8 – 87.9)	58.3 (10.9 – 105.6)			
	Between-group ES	–	–	–	–	0.05 (-0.35 – 0.45)	0 (-0.40 – 0.41)			
50-foot walk	Active intervention	8.9 (8.2 – 9.6)	–	–	–	-0.9 (-1.6 – -0.1)	-0.9 (-1.7 – -0.1)	p = 0.57	p = 0.36	p = 0.39
	Conventional care	9.6 (8.9 – 10.3)	–	–	–	-1.0 (-1.7 – -0.2)	-1.1 (-1.9 – -0.4)			
	Between-group ES	–	–	–	–	-0.04 (-0.44 – 0.36)	-0.12 (-0.53 – 0.28)			
Timed up-and-go	Active intervention	8.0 (7.1 – 8.9)	–	–	–	-1.5 (-2.1 – -0.8)	-1.7 (-2.4 – -1.1)	p = 0.44	p < 0.001	p = 0.21
	Conventional care	7.8 (7.3 – 8.3)	–	–	–	-1.2 (-1.8 – -0.6)	-1.7 (-2.3 – -1)			
	Between-group ES	–	–	–	–	0.19 (-0.21 – 0.59)	0.05 (-0.35 – 0.46)			
1-min stair climbing	Active intervention	107.1 (100.3 – 113.9)	–	–	–	15.2 (10.6 – 19.8)	19.2 (13.7 – 24.6)	p = 0.71	p < 0.001	p = 0.37
	Conventional care	101.1 (95.4 – 106.8)	–	–	–	15.0 (10.6 – 19.5)	21.6 (16.2 – 27)			
	Between-group ES	–	–	–	–	0.02 (-0.38 – 0.42)	-0.18 (-0.59 – 0.23)			
One-Leg Stand Test. eyes open	Active intervention	44.1 (38.6 – 49.6)	–	–	–	5.1 (0.3 – 9.8)	7.0 (3.0 – 11.1)	p = 0.97	p = 0.016	p = 0.29
	Conventional care	38.7 (33.1 – 44.3)	–	–	–	3.5 (-1.2 – 8.1)	8.4 (4.3 – 12.6)			
	Between-group ES	–	–	–	–	0.14 (-0.26 – 0.54)	-0.14 (-0.54 – 0.27)			
One-Leg Stand Test. eyes closed	Active intervention	4.7 (3.0 – 6.4)	–	–	–	0.5 (-0.7 – 1.7)	2.1 (-0.1 – 4.2)	p = 0.14	p = 0.34	p = 0.49
	Conventional care	2.8 (2.3 – 3.2)	–	–	–	-0.1 (-1.3 – 1.1)	0.1 (-2.1 – 2.3)			
	Between-group ES	–	–	–	–	0.23 (-0.17 – 0.63)	0.36 (-0.05 – 0.77)			

* Fixed factors used in the linear mixed model analysis: Treatment group, time, Group*Time interaction term, confounding factors (baseline values of depression, baseline steps per day and gender) and the baseline value of the dependent variable. Random factor: Treatment center.

** Depression not used as a confounding factor due to multicollinearity.

*** Steps per day not used as a confounding factor due to multicollinearity.

[a] Indicates that the change score reached the minimal important change 8 weeks postop.

Numbers are presented as means (95% confidence interval).

EQ-5D, EuroQol-5D; HADS, Hospital Anxiety and Depression Scale; MVPA, moderate- to-vigorous-intensity physical activity; ODI, Oswestry Disability Index 2.0; PCS, Pain Catastrophizing Scale; PSFS, Patient-Specific Functional Scale; SEES, Self-Efficacy for Exercise Scale; TSK, Tampa Scale for Kinesiophobia; VAS, visual analogue scale

Among the secondary outcome measures, a statistically significant difference between groups in favour of the active intervention was only found in the EQ-5D index in the ITT analysis (see Group x Time, Table 9).

Small effect sizes (ESs) could be seen at separate time points; the between-group differences were not statistically significant and therefore the ESs must be treated with caution. At six months after surgery, the largest ESs were seen in the variable "at least moderate-intensity physical activity" (time spent in MVPA) (ES = 0.42, 95% CI: 0.00 to 0.83), one-leg stand test (ES = 0.36, 95% CI: –0.05 to 0.77) and "steps per day" (ES = 0.25, 95% CI: –0.16 to 0.66).

Changes over time in each group separately

A statistically significant change from baseline to 6 months for each group separately was seen in the primary outcome (ODI) (see Table 9 "Time").

From baseline to one week before surgery, changes were seen in health-related quality of life index (ES = 0.57, 95% CI: 0.16 to 0.98), pain intensity back (ES = 0.21, 95% CI: –0.18 to 0.59), catastrophising (ES = 0.29, 95% CI: –0.11 to 0.69), fear of movement (ES = 0.30, 95% CI: –0.10 to 0.70), depressed mood (ES = 0.25, 95% CI: –0.14 to 0.65), and patient-specific functioning (ES = 0.23, 95% CI: –0.19 to 0.65) in the active intervention group. The changes were small, and the between-group difference was not statistically significant and should therefore be interpreted with caution.

Both groups achieved early clinically relevant changes (MIC values) after surgery in several secondary outcome measures (Table 9 Marked a). Furthermore, at 8 weeks after surgery ODI had decreased by < 8 points (MIC = 8 points, ODI score) in both groups and the ODI score continued to decrease. At 6-month follow-up after surgery, the total ODI score of both groups was < 21.5 points. The active intervention group reached the MIC value for PSFS (MIC = 2 points, PSFS) at three months and the conventional care group reached it at six months (see Table 9).

When comparing the change score from baseline to six months in the variables "at least moderate-intensity physical activity" and "steps per day", the variables increased in the active intervention. In the conventional care intervention, the change score from baseline to six months showed a deterioration, Figure 21.

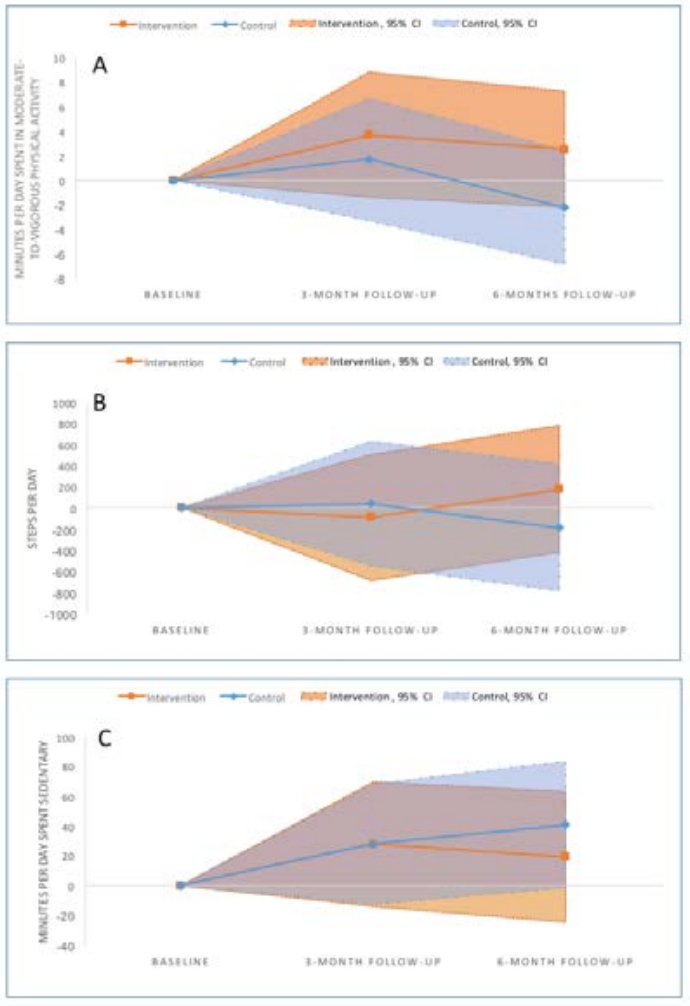

FIGURE 21. Graphs of change score of the intervention and the conventional care group of (A) minutes per day in at least moderate-intensity physical activity, (B) steps per day, and (C) minutes per day spent sedentary.

Per-protocol analysis

Forty-six patients from the active intervention and 54 participants from the conventional care intervention were included in the per-protocol analysis. No statistically significant difference between the groups using ITT analysis and per-protocol analysis was detected in the sensitivity analysis, for any outcome measure.

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

5. DISCUSSION

In the work for the studies included in this thesis, we developed and evaluated one of the first active prehabilition programmes for people with chronic severe LBP due to degenerative disc disease who were scheduled for lumbar fusion surgery. The studies discussed below contribute new knowledge about prehabilitation in the context of lumbar fusion surgery.

5.1.1 Development of an active prehabilitation intervention

The development of the active intervention was performed as a process in several steps, which finally resulted in evaluation of the active intervention in an RCT study.

In our RCT study, no statistically significant difference in the primary outcome (ODI) was found between groups, from baseline to six months after surgery (Study IV). These findings are similar to the results of other prehabilitation studies in the context of lumbar spinal surgery, which, similarly, have not shown any significant differences between groups after surgery regarding the primary outcome disability (Lindback et al., 2017; Louw et al., 2014; Nielsen et al., 2010; Rolving et al., 2015). There are several possible reasons for the lack of statistical differences between groups.

It is important to understand non-statistically significant results, especially when evaluating new interventions (Bellg et al., 2004; Moncher et al., 1991). In behavioural change interventions, it is especially important to understand the treatment fidelity. Treatment fidelity refers to the process of monitoring and improving the reliability and internal validity of the intervention, and it covers several considerations such as treatment integrity, treatment differentiation, treatment receipt, and treatment enactment (Bellg et al., 2004).

A central point in treatment fidelity is that the intervention should rests on a sound theoretical framework. The active intervention in this thesis was developed from a theoretical framework, which we developed over a period of time. After the pilot intervention, performed in Study I, we realized that some adjustments of the active intervention were needed to suit this patient group. Furthermore, Woby et al. had presented a revised fear-avoidance model including the mediational role of functional self-efficacy (Woby et al., 2007). Moreover, a person-centred approach has been shown in previous publication to have benefits for the patient's self-efficacy

(Ekman et al., 2012; Forts et al., 2016: Olsson et al., 2007). Based on this, we decided to use the revised fear-avoidance model suggested by Woby et al. and to include self-efficacy regarding exercise and physical activity in the theoretical model. Since the start of our randomised controlled trial in 2014, a few other studies have been performed to investigate a prehabilitation programme in the context of lumbar spinal surgery using a theoretical basis for their intervention (Louw et al., 2014; Rolving et al., 2015). Rolving et al. used a cognitive behavioural intervention with a bio-psychosocial basis, incorporating the original fear-avoidance model (Vlaeyen et al., 1995). Louw et al. performed a pain education intervention based on the bio-psychosocial model and on new knowledge about neurophysiology, neurobiology, and how pain is processed in the brain (Melzack, 2001; Moseley, 2003; Moseley et al., 2015). Rolving et al. specified a priori that the aim of their intervention was to target fear-avoidance beliefs using several behavioural and cognitive techniques (Rolving et al., 2015). Compared to the study by Rolving et al., the theoretical framework of our active intervention was contextually adjusted to be suitable in the context of orthopaedic surgery, based on the findings in Study I.

Another aspect of treatment fidelity is treatment differentiation. With no statistically significant difference between the treatment arms, an understanding of treatment differentiation is crucial for interpretation of an intervention's effectiveness, or lack of such (Bellg et al., 2004; Kazdin, 1986; Leeuw et al., 2008). This means understanding how and if the two interventions that were delivered differed from each other as intended (Bellg et al., 2004). In our study, we did not control how conventional care was delivered since we wanted to keep this treatment arm as routine preoperative conventional care. Since our study was an ongoing process over three and a half years, conventional care might have changed over this time–since several studies on prehabilitation were published in this time period and the topic was on the agenda at conferences for physiotherapists during the years that our study was performed. This may have influenced the conventional care to become gradually more active over the inclusion period. Moreover, a recent study showed that Swedish spinal surgeons recommend a faster rehabilitation regime and more activities on the first day after lumbar fusion surgery than Dutch surgeons (van Erp et al., 2017). To our knowledge, no other prehabilitation studies have specified how the content of the conventional care intervention was controlled for (Lindback et al., 2017; Louw et al., 2014; Nielsen et al., 2010; Rolving et al., 2015) in a standardised way (e.g. using audio tape recording or a treatment protocol).

Thus, it is not possible to know whether our treatment or other prehabilitation treatments differed from each other as expected. Future studies with the aim of evaluating two different interventions should therefore preferably include treatment differentiation in the protocol to reduce random variability.

Reliability of the intervention

Another consideration with treatment fidelity is to understand the aspects of reliability of the intervention delivered. Such components include the number of sessions delivered, the length of time of the sessions, and the number of professionals included in the intervention. Our active intervention included four one-hour sessions and one booster session over the phone two weeks after surgery, delivered by one physiotherapist. Roving et al. included six three-hours sessions of cognitive behavioural therapy group meetings, delivered by a multidisciplinary team (Rolving et al., 2015). Louw et al. included one session of pain education, delivered by a physiotherapist (Louw et al., 2014). Furthermore, Lindbäck et al. included 18 sessions of pre-surgical physiotherapy, delivered by several local physiotherapists (Lindback et al., 2017), and Nielsen et al. included two sessions of physical exercise delivered by a physiotherapist (Nielsen et al., 2010). None of the aforementioned studies, nor ours, had a statistically significant between-group difference in the primary outcome "disability" after surgery (Lindback et al., 2017; Louw et al., 2014; Nielsen et al., 2010; Rolving et al., 2015). Thus, based on our study and the aforementioned studies, it is difficult to evaluate how many sessions, the length of time of each session, and the number of professionals that would be sufficient to include in a prehabilitation intervention before lumbar spinal surgery.

Treatment integrity

In the work included in this thesis, we used several strategies to control that the intervention was delivered according to the treatment manual. The physiotherapist who delivered the active intervention in our RCT study (Study IV) was coached by an experienced psychologist in cognitive behavioural therapy before the study started (Study I). Together, the research team developed and prepared a treatment manual to be used in the RCT (Study I). The physiotherapist in our study followed the pre-defined treatment manual, which included the same number of sessions and treatment times for each participant. In retrospect, we could have done more to check whether the active intervention was delivered according to the treatment manual by, for example, using a recording device or an observer. This has been

reported by Boden et al., who delivered a prehabilitation intervention in another setting with a positive outcome (Boden et al., 2018). Regarding other prehabilitation studies in the context of lumbar spinal surgery, three research groups has reported how the professionals delivering the intervention was trained before the study started (Lindback et al., 2017; Louw et al., 2014; Rolving et al., 2015). To our knowledge, none of these studies has reported how the content of the intervention was controlled for or if the intervention delivered was contextually adjusted to the spinal surgery context (Lindback et al., 2017; Louw et al., 2014; Rolving et al., 2015).

In our RCT study, we used strict inclusion and exclusion criteria to keep the study group–and the surgery performed–as homogenous as possible. The rationale for this approach was that we wanted to evaluate our active intervention for one of the smallest subgroups of the degenerative spinal disorders recorded in Swespine (www.4s.nu) and learn from those results before implementation into a more heterogeneous population.

At the start of the work described in this thesis, we knew little about a prehabilitation phase for patients undergoing lumbar fusion, and only one study had been published on this topic (Nielsen et al., 2010).

5.1.2 Evaluation of the active intervention

The baseline measures in Studies III and IV showed that patients with chronic LBP scheduled for lumbar fusion surgery had kinesiophobia, moderate pain catastrophising (≤ 20 points), and reduced self-efficacy for exercise. The importance of addressing psychological risk factors before lumbar spinal surgery has been suggested elsewhere. To offer treatment before surgery for patients with a high number of psychological risk factors could be helpful instead of excluding patients from undergoing lumbar spine surgery (Abbott et al., 2010; Dorow et al., 2017; Havakeshian et al., 2013). In our RCT we found that after the intervention, but 1 week before surgery, the group receiving the active intervention reported a lower intensity of back pain; a decrease in pain catastrophising, in fear of movement, and in depressed mood; and also higher patient-specific functioning and health-related quality of life. The tendency to have a favourable change in these outcome measures seen here may have been an effect of the active intervention. However, the changes were small, and the between-group difference was not statistically significant, so this should be interpreted with caution.

Two other prehabilitation studies have evaluated the effect of their intervention phase before surgery and at discharge from hospital immediately after surgery (Lindback et al., 2017; Nielsen et al., 2010). Lindbäck et al. reported statistically significant differences between groups in several secondary outcome measures in favour of the intervention group, before surgery (Lindback et al., 2017). Moreover, Nielsen et al. showed that the group that received the physiotherapy intervention achieved the pre-defined recovery milestones faster than the control group (Nielsen et al., 2010). The difference in the results seen here between our study and the studies described above might depend on several aspects of treatment fidelity and the choice of statistical methods used.

The only statistically significant difference between the groups in our study was seen in health-related quality of life (EQ-5D index). The largest effect size was seen in EQ-5D-index one week before surgery (ES = 0.57), in favour of the active intervention group. Compared to other prehabilitation studies, no such early effect has been reported (Lindback et al., 2017; Louw et al., 2014; Rolving et al., 2015). After surgery, the group that received the active intervention reached the minimal important change value (MIC = 0.17) in the EQ-5D index as early as 8 weeks, and the conventional care group reached this MIC value at three months after surgery. At the six-month follow-up, the group difference had levelled out. This early change seen in the EQ-5D index will be interesting to follow and analyse over time, since this result could serve as a basis for future studies to improve the outcome of lumbar fusion surgery.

In our work, no statistically significant differences in ODI score between the groups were seen at any follow-up point after surgery. The only prehabilitation study that has found a statistically significant difference in disability score (ODI) in favour of the intervention group 3 months after surgery was the study by Rolving et al. (Rolving et al., 2015). For the secondary outcome measures in our study, no statistically significant difference between the groups was seen, except for in EQ-5D index in the ITT analysis, and nearly all outcome measures reached a stable plateau in both groups already at 3 months after surgery. In accordance with our findings, no other prehabilitation studies have found any significant differences between groups in secondary outcome measures after surgery (Lindback et al., 2017; Louw et al., 2014; Rolving et al., 2015). Furthermore, no such stable plateau in secondary outcomes at this time point have been reported in other prehabilitation studies (Nielsen et al.,

2010; Rolving et al., 2015). Nevertheless, Louw et al. found a statistically significant between-group difference in healthcare saving in favour of the group that received a pain education programme one year after surgery (Louw et al., 2014).

In our study, already 8 weeks after surgery ODI had decreased > 8 points (MIC=8, ODI score reduction) (Strömqvist et al., 2009) in both groups, and at 6 months after surgery the ODI score was < 21.5 points, which was interpreted as showing almost no disability (Fairbank et al., 2000). None of the prehabilitation studies including mixed spinal surgical diagnoses have reported such an early decrease in both groups regarding disability (Lindback et al., 2017; Louw et al., 2014; Rolving et al., 2015). The change in score from baseline to six months in our study was statistically significant for almost all secondary outcome measures in both groups separately (Table 9 Study IV, time x effect). Furthermore, both groups had reached the minimal important change in most of the secondary outcome measures by the 6-months follow-up. This suggests that spinal fusion in conjunction with both the active intervention and the conventional care intervention led to important improvements for the patients. The result of surgery without preoperative care was not studied, so no conclusions how much this influenced the outcome is unknown.

One interesting finding in our work was the difference in change scores at six months in the variables "at least moderate-intensity physical activity" and "steps per day" in favour of the active intervention group. The level of physical activity was measured objectively with an accelerometer which is considered to be one of the most valid ways to measure physical activity (Slootmaker et al., 2009) The change scores showed an increase in both variables. The change scores of these variables in the conventional care group showed a deterioration. No statistically significant between-group differences were seen in either back pain intensity (VAS) or disability level (ODI) at this time point. This might indicate that the active intervention with personalised physical activity goals before and after surgery had an impact on the physical activity level 6 months after surgery. This will be analysed further and investigated at the 1-year follow-up. One prehabilitation study has evaluated the level of physical activity at one-year follow-up. The authors found a statistically significant between-group difference in self-reported physical activity in favour of the physiotherapy group (Lindback et al., 2017).

5.1.3 Physical activity before lumbar fusion surgery

In study III, we found that a high proportion of the participants were not sufficiently active. Only 17% of the study group adhered to the health-enhancing physical activity recommendations of the WHO (WHO, 2009), as measured by the variable "at least moderate intensity physical activity" (10-minute bouts). Furthermore, more than half of the participants (54%) measured by the variable "steps per day" did not reach the level of having a physically active lifestyle, which has also been found elsewhere (Mobbs et al., 2016).

To our knowledge, these results are some of the first results regarding the level of physical activity, measured objectively, in participants scheduled for lumbar fusion surgery. No other prehabilitation study has assessed the physical activity level before surgery objectively, and has made comparisons with the health recommendations put forward by the WHO (Lindback et al., 2017; Louw et al., 2014; Nielsen et al., 2010; Rolving et al., 2015; WHO, 2009).

Our results showed that 83% of our study group did not adhere to the WHO health recommendations regarding physical activity, and they are therefore at risk of developing additional disease, which may increase the risk of reduced health status over time (WHO, 2009, 2010). Others have shown that one quarter of the healthy European population does not adhere to the WHO recommendations regarding physical activity (Gerovasili et al., 2015). This indicates that the patients in our study had an even lower physical activity level than the healthy population. In a population with spinal stenosis, Norden et al. showed that only 4% of the patients met the WHO physical activity recommendations in the variable "at least moderate physical activity" (Norden et al., 2017). This difference between our studies is most probably due to the difference in the study populations. Patients with spinal stenosis report having a lower walking capacity than patients with degenerative disc disease (Fritzell et al., 2016). Furthermore, in patients with lumbar degenerative disorders, Mobbs et al. found that their study group had a mean value of steps per day that was beneath the threshold for a physically active lifestyle (Mobbs et al., 2016). These findings, together with the findings from our study, indicate that patients planned for lumbar spinal surgery or lumbar fusion surgery have a low level of physical activity, which should be considered in any prehabilitation phase.

It has been suggested that the largest health effect can be gained by stimulating this subgroup of people into being more physically active (Haskell et al., 2007). If these participants with the lowest physical activity levels remain physically inactive after surgery, they may develop additional disease due to inactivity. This could lead to a poorer health status and a reduced quality of life. Moreover, in a narrative review including studies on patients undergoing lumbar spinal fusion surgery (Gaudin et al., 2017), the authors found an association between the patient's own positive impression of good health and low cardiovascular comorbidity with better functional capacity and greater patient satisfaction after fusion surgery (Gaudin et al., 2017).

In addition, both fear of movement and disability were found to be negatively associated with the variable "steps per day". Since factors such as fear of movement and low self-efficacy have been found to influence physical activity (Lundberg et al., 2011; Woby et al., 2007) one of the aims of Study III was to investigate the relationship between these factors. None of the studies that have investigated the preoperative physical activity in patients undergoing lumbar spinal surgery (Lindback et al., 2017; Mobbs et al., 2016; Norden et al., 2017; Rolving et al., 2013) have explored the association between the level of physical activity in relation to factors in the fear-avoidance model (Vlaeyen et al., 1995; Woby et al., 2007) in patients with chronic LBP.

We found that the variable "steps per day" showed a negative association with both fear of movement (TSK) and disability (ODI). In other words, this suggests that if the patient's disability and fear of movement decrease, the number of steps per day might increase. Similar results have been reported for patients undergoing decompression and lumbar fusion surgery (Donnarumma et al., 2017). These authors found a significant correlation between a low physical activity level (collected by questionnaire) and higher levels of disability, and also a higher level of fear of movement. It has been suggested elsewhere that predictive psychological factors should be considered before surgery, to improve the outcome of lumbar fusion surgery (Abbott et al., 2011; Gaudin et al., 2017). A better understanding of factors that contribute to outcomes after lumbar fusion surgery is certainly needed. Identification of patients with a low physical activity level and fear-avoidance factors in the prehabilitation phase could be of importance for patients awaiting lumbar fusion surgery, for a better outcome of surgery. In a recent systematic review, the authors concluded that more information regarding psychosocial and physical

conditions for patients who are scheduled for first time lumbar fusion surgery is needed. Without such information, it will not be possible to improve the pre- and post-rehabilitation in the context of lumbar fusion surgery (Koenders et al., 2018).

6

STRENGTHS AND LIMITATIONS

HANNA LOTZKE

Department of Ortopaedics, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden, 2019

6. STRENGTHS AND LIMITATIONS

A major strength of our prehabilitation study was that we used the cognitive behavioural fear-avoidance model as a theoretical basis and we used several cognitive behavioural techniques in our active intervention. Furthermore, we developed our intervention in several steps and the treatment manual was adjusted to patients in the setting of lumbar spinal surgery. In addition, we used a person-centred approach and by doing so the active intervention was adjusted to the patient's specific needs and goals. In retrospect, however, we should have used a standardised protocol to check whether the active intervention and the conventional care intervention differed in an important manner during our randomised controlled trial, which is a limitation.

Another strength (Study III) was that we used an objective way of measuring physical activity before lumbar fusion surgery. A movement device such as an accelerometer is considered to be one of the most valid ways to measure daily physical activity correctly (Slootmaker et al., 2009). The accelerometer provides more accurate estimates of physical activity than self-reported questionnaires, since recall and response bias is reduced (Prince et al., 2008). However, some activities such as swimming or group water exercise are difficult to measure, since the accelerometer should be removed before such activities. Furthermore, an accelerometer worn on the hip measures ambulatory activity and some activities may not be accurately measured, such as cycling. Thus, for some participants the accelerometer data could have been underestimated (Ham et al., 2007), which is a limitation.

Another strength (Study IV) is that we used a mixed model to evaluate all the outcome measures between the two groups. This statistical analysis takes the correlated nature of repeated measures for the same individual into account while allowing for missing observations, thus keeping high power at each follow-up time point. We used a structured protocol for collecting all outcome measures for each time point, and the missing rate of our primary outcome at six-month follow up was ≤ 15% and internal missing items of the PROMs was < 5% (see flow chart, Study IV). A "missing rate" below < 5% is considered to lead to little bias, and rates > 20% may lead to serious threats to internal validity (Schulz et al., 2002). The outcome measures that were used were reliable and have been validated for participants with chronic LBP.

During the active intervention, no adverse events were reported, which means that the intervention was well tolerated. We had high compliance with the active intervention and 78% of the participants had four or more out of five sessions included in the active intervention. This shows that the number of sessions was feasible for the participants.

It has been suggested that more active and healthier people are more likely to take part in an active intervention (Martin et al., 2000). Selection bias in a randomised controlled trial can produce a cohort of relatively healthy patients excluding non-active patients with high comorbidities (Eisman et al., 2018). One hundred and forty-three participants who were on the waiting list declined participation in our study due to having a long distance to travel and due to other personal reasons such as "not having time to participate" (see flow chart, Study IV). We did not follow these participants, so we cannot present any data on these people–which is a limitation.

7

CONCLUSIONS

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

7. CONCLUSIONS

The work in this thesis has shown that a physiotherapeutic person-centred prehabilitation programme based on a cognitive behavioural approach did not improve functioning at six months after spinal fusion surgery relative to conventional care.

No statistically significant between-group differences were seen in the primary outcome "disability" from baseline to six months after surgery. However, a statistically significant between group difference was found in health-related quality of life (EQ-5D index) from baseline to six months after surgery. Both the active intervention group and conventional care intervention had achieved clinically relevant changes already at 3 months after surgery. Based on our findings, we cannot confirm what kind of intervention programme would be the most effective in improving outcome of surgery in this patient group. Whether or not physiotherapeutic prehabilitation would have any effect on the long-term follow-up or on subgroups of patients remains to be investigated.

The compliance with the active intervention was high and 78% of the participants randomised to the active intervention completed at least four out of five sessions. No adverse event was reported which indicates that the active intervention was well tolerated by the participants.

This thesis also showed that patients who were planned for lumbar fusion surgery had a low level of physical activity compared to the WHO recommendations on physical activity for health benefits. Moreover, more than half of the study population had a low active lifestyle as measured by "steps per day". This group of participants is therefore at risk of poor health due to insufficient physical activity. The variable "step per day" was found to be associated with both fear of movement (TSK) and disability (ODI). This suggests that if the patient's disability level and fear of movement decrease, the variable "steps per day" might increase in value. We also found that there was a high variability both in psychological factors and in level of physical activity among the participants before surgery. These findings support the use of a person-centred approach in the prehabilitation phase.

Moreover, the change score in physical activity measured by "at least moderate-intensity physical activity" and "steps per day" increased from baseline to six months after surgery in favour for the group receiving the active intervention. In the group

receiving conventional care a deterioration in change score from baseline to six months were seen.

To further evaluate the prehabilitation programme presented in this thesis, we will continue to monitor all outcome measures at 1-and 2- year follow-up.

8

FUTURE WORK

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

8. FUTURE WORK

The findings in this thesis have given rise to several more questions that could lead to further studies.

Our active intervention programme included a person-centred cognitive behavioural approach that possibly would have had a larger impact on patients with high fear-avoidance beliefs or other psychological risk factors undergoing lumbar fusion surgery. We found that the patients in our RCT had a high degree of variability in disability level, fear-avoidance beliefs and in the level of self-efficacy for exercise. However, in the present RCT, the number of patients did not allow us to study any sub-groups of patients. It would in the future be interesting to evaluate our prehabilitation programme specifically on patients with a high psychological risk profile for a poor outcome of lumbar spine surgery. For future studies, the long-term aim would be to develop guidelines based on different risk factors with a person-centred approach for this patient group, and the active intervention in our study together with the interventions presented in the other prehabilitation studies discussed in this thesis could be a foundation for such guidelines.

More than half of the patients who were asked to participate in the RCT were not able to take part in the study according to practical issues such as, long travelling distance sometimes in combination with difficulties to sit in a car, strong analgesics preventing car driving, or difficulties to take time off from work. This may have added bias to our study group together with other factors such as willingness to participate in a study with an active intervention arm. To develop a person-centred internet-based prehabilitation intervention based on our programme would be of interest to evaluate and further study the effect of such a programme in a wider setting.

Before lumbar fusion surgery, the variability of the level of physical activity and several psychological factors that could be barriers to physical activity was shown to be high. Being physically active affects one's general health and people who have a low level of physical activity can develop additional diseases if they remain physically inactive after surgery. In future studies it would be interesting to use physical activity as an outcome measure both in studies, evaluating the effect of prehabilitation but also surgical interventions.

We did not include a qualitative study in this work, we therefore cannot tell what the patients experienced as the most important in the prehabilitation phase. In order to gather more knowledge about the patient's point of view in the prehabilitation phase, the aforementioned study is just to be initiated.

In our work, we did not monitor or include a uniform post-surgery rehabilitation programme. All the patients were encouraged to make contact with a local physiotherapist 4 weeks following the surgery, in order to start the postoperative rehabilitation. It would be interesting to further investigate the prehabilitation phase in conjunction with the postoperative phase in order to develop an evidence-based treatment protocol including both preoperative and postoperative rehabilitation guidelines for this patient group.

When economic resources are scarce, it is very important not only to investigate the effect of a new intervention but also to take into account the economical aspects of such an intervention. This would help the decision makers to allocate resources to treatments that are cost-effective. From an overall societal point of view, the loss of productivity for chronic LBP patients is the largest expense. Health is a function of length of life and quality of life, and an index "quality-adjusted life-year index" (QALY) has been developed in an attempt to combine the value of these attributes into a single index number. We are currently collecting data to evaluate at what time-point the patients in our RCT started to work as well as costs for health care resources, and prescribed drugs after surgery. The cost-effectiveness and the cost-utility analysis will be included in the evaluation of our RCT (about the prehabilitation intervention) at the 1 year and 2 years follow-up.

PERSON-CENTRED PREHABILITATION PROGRAM TO IMPROVE FUNCTIONING

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

9. ACKNOWLEDGEMENTS

Först av allt vill jag av hela mitt hjärta tacka alla de patienter som deltagit i studierna. Ni har varit fantastiska som har tagit er tid att komma på alla uppföljningar och utan knorr burit accelerometer till vardag som till fest. Utan alla er hade det aldrig gått att genomföra någon av dessa studier. Tack för att jag har fått ta del av alla era erfarenheter vilket har gett mig en djupare kunskap om hur det är at leva med svår ländryggssmärta.

I would like to thank and express my gratitude to everyone who made it possible to finish the work included in this thesis. In particular, I want to thank:

My main supervisor and co-author, Associate Professor Mari Lundberg, PT, PhD. Thank you for introducing me to research and broadening my perspective. Without you, it would have been impossible to come this far. Thanks for always being there when I needed you most, and for guiding me, encouraging me, and believing in me. Thank you for being so generous in sharing your deep knowledge of research with me. We have been working hard, have travelled to several conferences, and have laughed a lot. Most of all, I would like to thank you for being such a fantastic friend and mentor through all these years.

Professor Helena Brisby, MD, PhD, co-supervisor and co-author. Thank you for inspiring me, giving me excellent scientific support, believing in me, and encouraging me during my work for this thesis. Thank you for sharing your deep knowledge of research and most of all for being such a dear friend, sharing your energy and positive attitudes of life with me. I also want to thank you as Head of the Department of Ortopaedics, Institution of Clinical Sciences at Sahlgrenska Academy, University of Gothenburg, for giving me the opportunity to conduct research at your department.

Professor Rob Smeets, MD, PhD, co-supervisor and co-author. Thank you for your positive attitude to research and for always challenging me to think outside the box. Thank you for your hospitality when I've been visiting the rehabilitation centre in Maastricht and for introducing me to your research team. I really appreciate your wise and straightforward approach when discussing research with you. Thank you for being such a good friend.

Max Jakobsson, PT, BSc. We have travelled a long way and have shared a lot of happy memories together. Thank you for your kindness, your patience with all my questions, and all those fruitful discussions about research and life. I will always remember the summer of 2018 when we struggled with all our manuscripts in the heat. Thank you for being such a good friend and for always being ready to help. You are next!

Annelie Gutke, PT, PhD, and co-author. Thank you for sharing your knowledge of research, for your constructive feedback, and for your patience in guiding me through the work for my thesis. Most of all, I would like to thank you for being such a good friend and I hope that our friendship and our collaboration in research will continue.

Olle Hägg, MD, PhD, co-author. It's been a pleasure to work with you–both clinically and on my research questions. I thank you for sharing your deep knowledge of spinal surgery and of clinical matters. Thank you for your strong support during my work on these studies. I miss our interesting conversations at work, about research and life in general.

Maria Hagströmer, PT, Associate Professor, co-author, for your positive attitude, for highly scientific discussions, for your willingness to share your deep knowledge about physical activity, and for your quick response to questions regarding our work together. Good luck with your new job.

Marlies den Hollander, Psychologist, PhD, co-author, for your kindness, for your hospitality during my stay in Maastricht, for giving me excellent advice, and for sharing your great knowledge about pain. Thank you for your warm friendship.

Co-author Lars-Eric Olsson, Associate Professor, Nurse, PhD, for sharing your great scientific knowledge and your impressive experience concerning person-centred care.

Christer Söderling, PT, BSc, independent observer. Without you, I would not have managed to finish this project. Thank you for always being positive, flexible, professional, helpful, and a true friend

Åke Blixt, MD, PhD, my former boss who made it possible to start this journey. Thank you for always encouraging me, believing in me, and sharing your knowledge about life, research, and other important things. Thank you for being such a dear friend and for your support during the work for my thesis.

Bengt Lind, MD, Associate Professor, PhD. I would like to thank you for your support and for sharing your great knowledge about science–always being willing to discuss important and interesting questions about research and clinical matters.

Lillemor Ödman and Barbro Wilhelmson, a special thanks to both of you for helping me to include all the patients in the studies. Without you, it would have taken even longer with the inclusion procedure. Thank you for your excellent help and for being so supportive. I will always remember your small coloured notes!

All my fantastic physiotherapy colleagues at the Spine Center/Spine Rehab, Gothenburg. Anna-Karin Sundin, Johanna Esebrant, Christian Ernest, Maria Nilsson, Anna Fredlund, Christer Söderling, and Yvonne Berg. Without your support I would not have been able to come this far. Thank you for always cheering me up, giving me energy, showing interest in my research, and taking care of all the patients when I'm been busy with research. Thank you for being such excellent friends!

I would like to thank all my colleagues and co-workers at the Spine Center Gothenburg, for showing interest in my research, and for always being positive and supportive during the years. Thank you all!

Cina Holmer, for your invaluable help with all administrative matters and for your patience with all my questions. Without you, I would have been lost.

All colleagues at R-huset, floor 7 and 6, thank you for interesting discussions about life and research. Thank you for your support, your kindness, and good laughs around the lunch table.

All the members of the Back in Motion Research Group for fruitful and interesting discussions about life and science. You have all contributed with your unique knowledge to help me finish this work. Thank you for being such good friends.

Mattias Sundén and Anna Ekman for statistical support, and for sharing your knowledge about regression models, mixed models, and other statistical issues.

Nina Barne, illustrator of the cover page, for your excellent skills in taking photographs–and most of all, thank you for being such an invaluable friend.

All my dear friends outside the scientific world, who have shown an interest in my research, inviting me for dinner and believing in me. Thank you for being such wonderful people.

Ina and Susanne, my sisters in law and their families, for your support, for showing such an interest in my research work, and for being such wonderful friends.

My brother Johan and my sisters, Maria, Katarina, Magdalena, Rut, and Rode and their families for your never ending support, for believing in me, and for showing me your love. Thank you for always being there.

Elisabet and Jean-Erik, my parents. Thank you for believing in me, for loving me, and for showing me what is important in life.

Most of all, my beloved Magnus and my wonderful children Emma, Filip, and Moa. Thank you for your never ending love, your understanding, your great support, and all the joy you bring to my life. Without you, there is nothing!

Funding

The work in this thesis has been supported by funding from AFA Research Funding, Eurospine Research, the Swedish Research Council (VR), the Health and Medical Care Executive Board of the Västra Götaland Region (VGR), and Doctor Felix Neubergh grants.

HANNA LOTZKE

Department of Ortopaedics,
Institute of Clinical Sciences,
Sahlgrenska Academy,
University of Gothenburg,
Gothenburg, Sweden, 2019

10. REFERENCES

Abbott, A. D., Tyni-Lenne, R., & Hedlund, R. (2010). The influence of psychological factors on pre-operative levels of pain intensity, disability and health-related quality of life in lumbar spinal fusion surgery patients. *Physiotherapy, 96*(3), 213-221. doi:10.1016/j.physio.2009.11.013

Abbott, A. D., Tyni-Lenne, R., & Hedlund, R. (2011). Leg pain and psychological variables predict outcome 2-3 years after lumbar fusion surgery. *European Spine Journal, 20*(10), 1626-1634. doi:10.1007/s00586-011-1709-6

Abtahi, A. M., Brodke, D. S., Lawrence, B. D., Zhang, C., & Spiker, W. R. (2015). Association between patient-reported measures of psychological distress and patient satisfaction scores after spine surgery. *Journal of Bone and Joint Surgery (American Volume), 97*(10), 824-828. doi:10.2106/jbjs.n.00916

Adams, M. A., & Roughley, P. J. (2006). What is intervertebral disc degeneration, and what causes it? *Spine, 31*(18), 2151-2161. doi:10.1097/01.brs.0000231761.73859.2c

Adogwa, O., Parker, S. L., Shau, D. N., Mendenhall, S. K., Bydon, A., Cheng, J. S., Asher, A. L., & McGirt, M. J. (2013). Preoperative Zung depression scale predicts patient satisfaction independent of the extent of improvement after revision lumbar surgery. *Spine J, 13*(5), 501-506. doi:10.1016/j.spinee.2013.01.017

Adogwa, O., Verla, T., Thompson, P., Penumaka, A., Kudyba, K., Johnson, K., Fulchiero, E., Miller, T. J., Hoang, K. B., Cheng, J., & Bagley, C. A. (2014). Affective disorders influence clinical outcomes after revision lumbar surgery in elderly patients with symptomatic adjacent-segment disease, recurrent stenosis, or pseudarthrosis: clinical article. *Journal of Neurosurgery: Spine, 21*(2), 153-159. doi:10.3171/2014.4.spine12668

Airaksinen, O., Brox, J. I., Cedraschi, C., Hildebrandt, J., Klaber-Moffett, J., Kovacs, F., Mannion, A. F., Reis, S., Staal, J. B., Ursin, H., & Zanoli, G. (2006). Chapter 4. European guidelines for the management of chronic nonspecific low back pain. *European Spine Journal, 15 Suppl 2*, S192-300. doi:10.1007/s00586-006-1072-1

Allen, R. T., Rihn, J. A., Glassman, S. D., Currier, B., Albert, T. J., & Phillips, F. M. (2009). An evidence-based approach to spine surgery. *American Journal of Medical Quality, 24*(6 Suppl), 15s-24s. doi:10.1177/1062860609348743

Anderson, J. A. (1986). Epidemiological aspects of back pain. *Journal of the Society of Occupational Medicine, 36*(3), 90-94.

Andersson, E. I., Lin, C. C., & Smeets, R. J. (2010). Performance tests in people with chronic low back pain: responsiveness and minimal clinically important change. *Spine, 35*(26), E1559-1563. doi:10.1097/BRS.0b013e3181cea12e

Andersson, G. B. (1999). Epidemiological features of chronic low-back pain. *Lancet, 354*(9178), 581-585. doi:10.1016/s0140-6736(99)01312-4

Archer, K. R., Seebach, C. L., Mathis, S. L., Riley, L. H., 3rd, & Wegener, S. T. (2014). Early postoperative fear of movement predicts pain, disability, and physical health six months after spinal surgery for degenerative conditions. *Spine J, 14*(5), 759-767. doi:10.1016/j.spinee.2013.06.087

Archer, K. R., Wegener, S. T., Seebach, C., Song, Y., Skolasky, R. L., Thornton, C., Khanna, A. J., & Riley, L. H., 3rd. (2011). The effect of fear of movement beliefs on pain and disability after surgery for lumbar and cervical degenerative conditions. *Spine, 36*(19), 1554-1562. doi:10.1097/BRS.0b013e3181f8c6f4

Asher, A. L., Kerezoudis, P., Mummaneni, P. V., Bisson, E. F., Glassman, S. D., Foley, K. T., Slotkin, J., Potts, E. A., Shaffrey, M. E., Shaffrey, C. I., Coric, D., Knightly, J. J., Park, P., Fu, K. M., Devin, C. J., Archer, K. R., Chotai, S., Chan, A. K., Virk, M. S., & Bydon, M. (2018). Defining the minimum clinically important difference for grade I degenerative lumbar spondylolisthesis: insights from the Quality Outcomes Database. *Neurosurgical Focus, 44*(1), E2. doi:10.3171/2017.10.focus17554

Axelsson, P., & Karlsson, B. S. (2004). Intervertebral mobility in the progressive degenerative process. A radiostereometric analysis. *European Spine Journal, 13*(6), 567-572. doi:10.1007/s00586-004-0713-5

Ayre, M., & Tyson, G. A. (2001). The role of self-efficacy and fear-avoidance beliefs in the prediction of disability. *Australian Psychologist, 36*(3), 250-253. doi:10.1080/00050060108259663

Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavioral change. *Psychological Review, 84*(2), 191-215.

Battie, M. C., Videman, T., Gibbons, L. E., Fisher, L. D., Manninen, H., & Gill, K. (1995). 1995 Volvo Award in clinical sciences. Determinants of lumbar disc degeneration. A study relating lifetime exposures and magnetic resonance imaging findings in identical twins. *Spine, 20*(24), 2601-2612.

Battie, M. C., Videman, T., & Parent, E. (2004). Lumbar disc degeneration: epidemiology and genetic influences. *Spine, 29*(23), 2679-2690.

Bauman, A. E., Reis, R. S., Sallis, J. F., Wells, J. C., Loos, R. J., & Martin, B. W. (2012). Correlates of physical activity: why are some people physically active and others not? *Lancet, 380*(9838), 258-271. doi:10.1016/s0140-6736(12)60735-1

Beck, J. S. (1995). *Cognitive therapy : basics and beyond*. New York: Guilford Press.

Bekelis, K., Desai, A., Bakhoum, S. F., & Missios, S. (2014). A predictive model of complications after spine surgery: the National Surgical Quality Improvement Program (NSQIP) 2005-2010. *Spine J, 14*(7), 1247-1255. doi:10.1016/j.spinee.2013.08.009

Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., Ogedegbe, G., Orwig, D., Ernst, D., & Czajkowski, S. (2004). Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23*(5), 443-451. doi:10.1037/0278-6133.23.5.443

Boden, I., El-Ansary, D., Zalucki, N., Robertson, I. K., Browning, L., Skinner, E. H., & Denehy, L. (2018). Physiotherapy education and training prior to upper abdominal surgery is memorable and has high treatment fidelity: a nested mixed-methods randomised-controlled study. *Physiotherapy, 104*(2), 194-202. doi:10.1016/j.physio.2017.08.008

Boden, S. D., Davis, D. O., Dina, T. S., Patronas, N. J., & Wiesel, S. W. (1990). Abnormal magnetic-resonance scans of the lumbar spine in asymptomatic subjects. A prospective investigation. *Journal of Bone and Joint Surgery (American Volume), 72*(3), 403-408.

Boonstra, A. M., Schiphorst Preuper, H. R., Balk, G. A., & Stewart, R. E. (2014). Cut-off points for mild, moderate, and severe pain on the visual analogue scale for pain in patients with chronic musculoskeletal pain. *Pain, 155*(12), 2545-2550. doi:10.1016/j.pain.2014.09.014

Borenstein, D. G. (2001). Epidemiology, etiology, diagnostic evaluation, and treatment of low back pain. *Current Opinion in Rheumatology, 13*(2), 128-134.

Bovend'Eerdt, T. J., Botell, R. E., & Wade, D. T. (2009). Writing SMART rehabilitation goals and achieving goal attainment scaling: a practical guide. *Clinical Rehabilitation, 23*(4), 352-361. doi:10.1177/0269215508101741

Brinjikji, W., Diehn, F. E., Jarvik, J. G., Carr, C. M., Kallmes, D. F., Murad, M. H., & Luetmer, P. H. (2015). MRI Findings of Disc Degeneration are More Prevalent in Adults with Low Back Pain than in Asymptomatic Controls: A Systematic Review and Meta-Analysis. *AJNR: American Journal of Neuroradiology, 36*(12), 2394-2399. doi:10.3174/ajnr.A4498

Buchbinder, R., van Tulder, M., Oberg, B., Costa, L. M., Woolf, A., Schoene, M., & Croft, P. (2018). Low back pain: a call for action. *Lancet*. doi:10.1016/s0140-6736(18)30488-4

Bursac, Z., Gauss, C. H., Williams, D. K., & Hosmer, D. W. (2008). Purposeful selection of variables in logistic regression. *Source Code for Biology and Medicine, 3*, 17. doi:10.1186/1751-0473-3-17

Cabilan, C. J., Hines, S., & Munday, J. (2016). The Impact of Prehabilitation on Postoperative Functional Status, Healthcare Utilization, Pain, and Quality of Life: A Systematic Review. *Orthopaedic Nursing, 35*(4), 224-237. doi:10.1097/nor.0000000000000264

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ : British Medical Journal, 321*(7262), 694-696.

Carli, F., & Zavorsky, G. S. (2005). Optimizing functional exercise capacity in the elderly surgical population. *Current Opinion in Clinical Nutrition and Metabolic Care, 8*(1), 23-32.

Carlsson, A. M. (1983). Assessment of chronic pain. I. Aspects of the reliability and validity of the visual analogue scale. *Pain, 16*(1), 87-101.

Carreon, L. Y., Glassman, S. D., Kantamneni, N. R., Mugavin, M. O., & Djurasovic, M. (2010). Clinical outcomes after posterolateral lumbar fusion in workers' compensation patients: a case-control study. *Spine, 35*(19), 1812-1817. doi:10.1097/BRS.0b013e3181c68b75

Caspersen, C. J., Powell, K. E., & Christenson, G. M. (1985). Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. *Public Health Reports, 100*(2), 126-131.

Celestin, J., Edwards, R. R., & Jamison, R. N. (2009). Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: a systematic review and literature synthesis. *Pain Medicine, 10*(4), 639-653. doi:10.1111/j.1526-4637.2009.00632.x

Choi, L., Liu, Z., Matthews, C. E., & Buchowski, M. S. (2011). Validation of accelerometer wear and nonwear time classification algorithm. *Medicine and Science in Sports and Exercise, 43*(2), 357-364. doi:10.1249/MSS.0b013e3181ed61a3

Chotai, S., Devin, C. J., Archer, K. R., Bydon, M., McGirt, M. J., Nian, H., Harrell, F. E. J., Dittus, R. S., & Asher, A. L. (2017). Effect of patients' functional status on satisfaction with outcomes 12 months after elective spine surgery for lumbar degenerative disease. *Spine J, 17*(12), 1783-1793. doi:10.1016/j.spinee.2017.05.027

Chou, R., & Shekelle, P. (2010). Will this patient develop persistent disabling low back pain? *JAMA, 303*(13), 1295-1302. doi:10.1001/jama.2010.344

Christensen, F. B., Laurberg, I., & Bunger, C. E. (2003). Importance of the back-cafe concept to rehabilitation after lumbar spinal fusion: a randomized clinical study with a 2-year follow-up. *Spine, 28*(23), 2561-2569. doi:10.1097/01.brs.0000097890.96524.a1

Cloward, R. B. (1963). Lesions of the intervertebral disks and their treatment by interbody fusion methods. The painful disk. *Clinical Orthopaedics and Related Research, 27*, 51-77.

Cohen, J. (1992). A power primer. *Psychological Bulletin, 112*(1), 155-159.

Conner-Spady, B. L., Marshall, D. A., Bohm, E., Dunbar, M. J., Loucks, L., Khudairy, A. A., & Noseworthy, T. W. (2015). Reliability and validity of the EQ-5D-5L compared to the EQ-5D-3L in patients with osteoarthritis referred for hip and knee replacement. *Quality of Life Research*. doi:10.1007/s11136-014-0910-6

Costa Lda, C., Maher, C. G., Hancock, M. J., McAuley, J. H., Herbert, R. D., & Costa, L. O. (2012). The prognosis of acute and persistent low-back pain: a meta-analysis. *CMAJ: Canadian Medical Association Journal, 184*(11), E613-624. doi:10.1503/cmaj.111271

Costa Lda, C., Maher, C. G., McAuley, J. H., Hancock, M. J., & Smeets, R. J. (2011). Self-efficacy is more important than fear of movement in mediating the relationship between pain and disability in chronic low back pain. *European Journal of Pain (London, England), 15*(2), 213-219. doi:10.1016/j.ejpain.2010.06.014

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ, 337*, a1655. doi:10.1136/bmj.a1655

Davidson, M., & Keating, J. L. (2002). A Comparison of Five Low Back Disability Questionnaires: Reliability and Responsiveness. *Physical Therapy, 82*(1), 8-24.

de Jong, J. R., Vangronsveld, K., Peters, M. L., Goossens, M. E., Onghena, P., Bulte, I., & Vlaeyen, J. W. (2008). Reduction of pain-related fear and disability in post-traumatic neck pain: a replicated single-case experimental study of exposure in vivo. *Journal of Pain, 9*(12), 1123-1134. doi:10.1016/j.jpain.2008.06.015

de Jong, J. R., Vlaeyen, J. W., Onghena, P., Goossens, M. E., Geilen, M., & Mulder, H. (2005). Fear of movement/(re)injury in chronic low back pain: education or exposure in vivo as mediator to fear reduction? *Clinical Journal of Pain, 21*(1), 9-17; discussion 69-72.

de Moraes Vieira, E. B., de Goes Salvetti, M., Damiani, L. P., & de Mattos Pimenta, C. A. (2014). Self-efficacy and fear avoidance beliefs in chronic low back pain patients: coexistence and associated factors. *Pain Management Nursing, 15*(3), 593-602. doi:10.1016/j.pmn.2013.04.004

de Schepper, E. I., Overdevest, G. M., Suri, P., Peul, W. C., Oei, E. H., Koes, B. W., Bierma-Zeinstra, S. M., & Luijsterburg, P. A. (2013). Diagnosis of lumbar spinal stenosis: an updated systematic review of the accuracy of diagnostic tests. *Spine, 38*(8), E469-481. doi:10.1097/BRS.0b013e31828935ac

DeBerard, M. S., Masters, K. S., Colledge, A. L., Schleusener, R. L., & Schlegel, J. D. (2001). Outcomes of posterolateral lumbar fusion in Utah patients receiving workers' compensation: a retrospective cohort study. *Spine, 26*(7), 738-746; discussion 747.

den Boer, J. J., Oostendorp, R. A., Beems, T., Munneke, M., & Evers, A. W. (2006). Continued disability and pain after lumbar disc surgery: the role of cognitive-behavioral factors. *Pain, 123*(1-2), 45-52. doi:10.1016/j.pain.2006.02.008

den Hollander, M., de Jong, J. R., Volders, S., Goossens, M. E., Smeets, R. J., & Vlaeyen, J. W. (2010). Fear reduction in patients with chronic pain: a learning theory perspective. *Expert Review of Neurotherapeutics, 10*(11), 1733-1745. doi:10.1586/ern.10.115

den Hollander, M., Goossens, M., de Jong, J., Ruijgrok, J., Oosterhof, J., Onghena, P., Smeets, R., & Vlaeyen, J. W. (2016). Expose or protect? A randomized controlled trial of exposure in vivo vs pain-contingent treatment as usual in patients with complex regional pain syndrome type 1. *Pain, 157*(10), 2318-2329. doi:10.1097/j.pain.0000000000000651

Denison, E., Asenlof, P., & Lindberg, P. (2004). Self-efficacy, fear avoidance, and pain intensity as predictors of disability in subacute and chronic musculoskeletal pain patients in primary health care. *Pain, 111*(3), 245-252. doi:10.1016/j.pain.2004.07.001

Deyo, R. A., Battie, M., Beurskens, A. J., Bombardier, C., Croft, P., Koes, B., Malmivaara, A., Roland, M., Von Korff, M., & Waddell, G. (1998). Outcome measures for low back pain research. A proposal for standardized use. *Spine, 23*(18), 2003-2013.

Deyo, R. A., Gray, D. T., Kreuter, W., Mirza, S., & Martin, B. I. (2005). United States trends in lumbar fusion surgery for degenerative conditions. *Spine, 30*(12), 1441-1445; discussion 1446-1447.

Deyo, R. A., Mirza, S. K., Martin, B. I., Kreuter, W., Goodman, D. C., & Jarvik, J. G. (2010). Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA, 303*(13), 1259-1265. doi:10.1001/jama.2010.338

Deyo, R. A., & Weinstein, J. N. (2001). Low back pain. *New England Journal of Medicine, 344*(5), 363-370. doi:10.1056/nejm200102013440508

Dohnke, B., Knauper, B., & Muller-Fahrnow, W. (2005). Perceived self-efficacy gained from, and health effects of, a rehabilitation program after hip joint replacement. *Arthritis and Rheumatism, 53*(4), 585-592. doi:10.1002/art.21324

Donnarumma, P., Presaghi, F., Tarantino, R., Fragale, M., Rullo, M., & Delfini, R. (2017). The impact of pelvic balance, physical activity, and fear-avoidance on the outcome after decompression and instrumented fusion for degenerative lumbar stenosis. *European Spine Journal, 26*(2), 428-433. doi:10.1007/s00586-016-4644-8

Dorow, M., Lobner, M., Stein, J., Konnopka, A., Meisel, H. J., Gunther, L., Meixensberger, J., Stengler, K., Konig, H. H., & Riedel-Heller, S. G. (2017). Risk Factors for Postoperative Pain Intensity in Patients Undergoing Lumbar Disc Surgery: A Systematic Review. *PloS One, 12*(1), e0170303. doi:10.1371/journal.pone.0170303

Eccleston, C., Williams, A. C., & Morley, S. (2009). Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev*(2), Cd007407. doi:10.1002/14651858.CD007407.pub2

Eisman, J. A., Geusens, P., & van den Bergh, J. (2018). The Emperor's New Clothes: What Randomized Controlled Trials Don't Cover. *Journal of Bone and Mineral Research, 33*(8), 1394-1396. doi:10.1002/jbmr.3539

Ekman, I., Swedberg, K., Taft, C., Lindseth, A., Norberg, A., Brink, E., Carlsson, J., Dahlin-Ivanoff, S., Johansson, I. L., Kjellgren, K., Liden, E., Ohlen, J., Olsson, L. E., Rosen, H., Rydmark, M., & Sunnerhagen, K. S. (2011). Person-centered care--ready for prime time. *European Journal of Cardiovascular Nursing, 10*(4), 248-251. doi:10.1016/j.ejcnurse.2011.06.008

Ekman, I., Wolf, A., Olsson, L. E., Taft, C., Dudas, K., Schaufelberger, M., & Swedberg, K. (2012). Effects of person-centred care in patients with chronic heart failure: the PCC-HF study. *European Heart Journal, 33*(9), 1112-1119. doi:10.1093/eurheartj/ehr306

Engel, G. (1977). The need for a new medical model: a challenge for biomedicine. *Science, 196*(4286), 129-136. doi:10.1126/science.847460

EuroQol. (1990). *Health Policy, 16*(3), 199-208.

Fairbank, J. C., Couper, J., Davies, J. B., & O'Brien, J. P. (1980). The Oswestry low back pain disability questionnaire. *Physiotherapy, 66*(8), 271-273.

Fairbank, J. C., & Pynsent, P. B. (2000). The oswestry disability index. *Spine, 25*(22), 2940-2953.

Fardon, D. F., Williams, A. L., Dohring, E. J., Murtagh, F. R., Gabriel Rothman, S. L., & Sze, G. K. (2014). Lumbar disc nomenclature: version 2.0: Recommendations of the combined task forces of the North American Spine Society, the American Society of Spine Radiology and the American Society of Neuroradiology. *Spine J, 14*(11), 2525-2545. doi:10.1016/j.spinee.2014.04.022

Ferreira, P. H., Beckenkamp, P., Maher, C. G., Hopper, J. L., & Ferreira, M. L. (2013). Nature or nurture in low back pain? Results of a systematic review of studies based on twin samples. *European Journal of Pain (London, England), 17*(7), 957-971. doi:10.1002/j.1532-2149.2012.00277.x

Fordyce, W. E., Lansky, D., Calsyn, D. A., Shelton, J. L., Stolov, W. C., & Rock, D. L. (1984). Pain measurement and pain behavior. *Pain, 18*(1), 53-69.

Fordyce, W. E., Shelton, J. L., & Dundore, D. E. (1982). The modification of avoidance learning pain behaviors. *Journal of Behavioral Medicine, 5*(4), 405-414.

Fors, A., Taft, C., Ulin, K., & Ekman, I. (2016). Person-centred care improves self-efficacy to control symptoms after acute coronary syndrome: a randomized controlled trial. *European Journal of Cardiovascular Nursing, 15*(2), 186-194. doi:10.1177/1474515115623437

Fritzell, P., Hagg, O., Gerdhem, P., Abbott, A., Songsong, A., Parai, C., & Strömqvist, B. (2016). *Swespine: the Swedish spine register: the 2016 report.* Retrieved from http://www.4s.nu/

Fritzell, P., Hagg, O., Wessberg, P., & Nordwall, A. (2001). 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine, 26*(23), 2521-2532; discussion 2532-2524.

Gatti, A. A., Stratford, P. W., Brenneman, E. C., & Maly, M. R. (2015). GT3X+ accelerometer placement affects the reliability of step-counts measured during running and pedal-revolution counts measured during bicycling. *Journal of Sports Sciences*, 1-8. doi:10.1080/02640414.2015.1096018

Gatzounis, R., Schrooten, M. G., Crombez, G., & Vlaeyen, J. W. (2012). Operant learning theory in pain and chronic pain rehabilitation. *Curr Pain Headache Rep, 16*(2), 117-126. doi:10.1007/s11916-012-0247-1

Gaudin, D., Krafcik, B. M., Mansour, T. R., & Alnemari, A. (2017). Considerations in Spinal Fusion Surgery for Chronic Lumbar Pain: Psychosocial Factors, Rating Scales, and Perioperative Patient Education-A Review of the Literature. *World Neurosurgery, 98*, 21-27. doi:10.1016/j.wneu.2016.10.124

Gautschi, O. P., Stienen, M. N., Corniola, M. V., Joswig, H., Schaller, K., Hildebrandt, G., & Smoll, N. R. (2017). Assessment of the Minimum Clinically Important Difference in the Timed Up and Go Test After Surgery for Lumbar Degenerative Disc Disease. *Neurosurgery, 80*(3), 380-385. doi:10.1227/neu.0000000000001320

GBD 2016 Collaborators. (2017). Global Burden of Disease Study 2016. *Lancet, 390*(10100), 1211-1259. doi:10.1016/s0140-6736(17)32154-2

Gerovasili, V., Agaku, I. T., Vardavas, C. I., & Filippidis, F. T. (2015). Levels of physical activity among adults 18-64 years old in 28 European countries. *Preventive Medicine, 81*, 87-91. doi:10.1016/j.ypmed.2015.08.005

Gilmore, S. J., McClelland, J. A., & Davidson, M. (2015). Physiotherapeutic interventions before and after surgery for degenerative lumbar conditions: a systematic review. *Physiotherapy, 101*(2), 111-118. doi:10.1016/j.physio.2014.06.007

Gometz, A., Maislen, D., Youtz, C., Kary, E., Gometz, E. L., Sobotka, S., & Choudhri, T. F. (2018). The Effectiveness of Prehabilitation (Prehab) in Both Functional and Economic Outcomes Following Spinal Surgery: A Systematic Review. *Cureus, 10*(5), e2675. doi:10.7759/cureus.2675

Grotle, M., Brox, J. I., & Vollestad, N. K. (2005). Functional status and disability questionnaires: what do they assess? A systematic review of back-specific outcome questionnaires. *Spine, 30*(1), 130-140.

Gum, J. L., Glassman, S. D., & Carreon, L. Y. (2013). Is type of compensation a predictor of outcome after lumbar fusion? *Spine, 38*(5), 443-448. doi:10.1097/BRS.0b013e318278ebe8

Ham, S. A., Reis, J. P., Strath, S. J., Dubose, K. D., & Ainsworth, B. E. (2007). Discrepancies between methods of identifying objectively determined physical activity. *Medicine and Science in Sports and Exercise, 39*(1), 52-58. doi:10.1249/01.mss.0000235886.17229.42

Harris, I. A., & Dao, A. T. T. (2009). Trends of spinal fusion surgery in Australia: 1997 to 2006. *ANZ Journal of Surgery, 79*(11), 783-788. doi:10.1111/j.1445-2197.2009.05095.x

Haskell, W. L., Lee, I. M., Pate, R. R., Powell, K. E., Blair, S. N., Franklin, B. A., Macera, C. A., Heath, G. W., Thompson, P. D., & Bauman, A. (2007). Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. *Circulation, 116*(9), 1081-1093. doi:10.1161/circulationaha.107.185649

Havakeshian, S., & Mannion, A. F. (2013). Negative beliefs and psychological disturbance in spine surgery patients: a cause or consequence of a poor treatment outcome? *European Spine Journal, 22*(12), 2827-2835. doi:10.1007/s00586-013-2822-5

Hedges, L. V. (2007). Effect Sizes in Cluster-Randomized Designs. *Journal of Educational and Behavioral Statistics, 32*(4), 341-370. doi:10.3102/1076998606298043

Hedges, L. V., & Olkin, I. (1985). *Statistical methods for meta-analysis.* Orlando: Academic Press.

Hendrick, P., Milosavljevic, S., Hale, L., Hurley, D. A., McDonough, S., Ryan, B., & Baxter, G. D. (2011). The relationship between physical activity and low back pain outcomes: a systematic review of observational studies. *European Spine Journal, 20*(3), 464-474. doi:10.1007/s00586-010-1616-2

Hoy, D., Bain, C., Williams, G., March, L., Brooks, P., Blyth, F., Woolf, A., Vos, T., & Buchbinder, R. (2012). A systematic review of the global prevalence of low back pain. *Arthritis Rheumatism, 64*(6), 2028-2037. doi:10.1002/art.34347

Hoy, D., Brooks, P., Blyth, F., & Buchbinder, R. (2010). The Epidemiology of low back pain. *Best Practice & Research: Clinical Rheumatology, 24*(6), 769-781. doi:10.1016/j.berh.2010.10.002

Hoy, D., March, L., Brooks, P., Blyth, F., Woolf, A., Bain, C., Williams, G., Smith, E., Vos, T., Barendregt, J., Murray, C., Burstein, R., & Buchbinder, R. (2014). The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. *Annals of the Rheumatic Diseases, 73*(6), 968-974. doi:10.1136/annrheumdis-2013-204428

Hägg, O. (2002). *Measurement and prediction of outcome: application in fusion surgery for chronic low back pain.* Göteborg.

Hägg, O., Fritzell, P., Ekselius, L., & Nordwall, A. (2003). Predictors of outcome in fusion surgery for chronic low back pain. A report from the Swedish Lumbar Spine Study. *European Spine Journal, 12*(1), 22-33. doi:10.1007/s00586-002-0465-z

Hägg, O., Fritzell, P., Oden, A., & Nordwall, A. (2002). Simplifying outcome measurement: evaluation of instruments for measuring outcome after fusion surgery for chronic low back pain. *Spine, 27*(11), 1213-1222.

Itz, C. J., Geurts, J. W., van Kleef, M., & Nelemans, P. (2013). Clinical course of non-specific low back pain: a systematic review of prospective cohort studies set in primary care. *European Journal of Pain (London, England), 17*(1), 5-15. doi:10.1002/j.1532-2149.2012.00170.x

Jensen, M., & Karoly, P. (2011). Self-report scales and procedures for assessing pain in adults. In D. Turk & R. Melzack (Eds.), *Handbook of pain assessment.3.* (pp. 19-44). New York: Guildford Press.

Jensen, M. C., Brant-Zawadzki, M. N., Obuchowski, N., Modic, M. T., Malkasian, D., & Ross, J. S. (1994). Magnetic resonance imaging of the lumbar spine in people without back pain. *New England Journal of Medicine, 331*(2), 69-73. doi:10.1056/nejm199407143310201

Jensen, M. P., Chen, C., & Brugger, A. M. (2003). Interpretation of visual analog scale ratings and change scores: a reanalysis of two clinical trials of postoperative pain. *Journal of Pain, 4*(7), 407-414.

Johnsen, L. G., Hellum, C., Nygaard, O. P., Storheim, K., Brox, J. I., Rossvoll, I., Leivseth, G., & Grotle, M. (2013). Comparison of the SF6D, the EQ5D, and the oswestry disability index in patients with chronic low back pain and degenerative disc disease. *BMC Musculoskeletal Disorders, 14*, 148. doi:10.1186/1471-2474-14-148

Kalichman, L., Cole, R., Kim, D. H., Li, L., Suri, P., Guermazi, A., & Hunter, D. J. (2009a). Spinal stenosis prevalence and association with symptoms: the Framingham Study. *Spine J, 9*(7), 545-550. doi:10.1016/j.spinee.2009.03.005

Kalichman, L., Kim, D. H., Li, L., Guermazi, A., Berkin, V., & Hunter, D. J. (2009b). Spondylolysis and spondylolisthesis: prevalence and association with low back pain in the adult community-based population. *Spine, 34*(2), 199-205. doi:10.1097/BRS.0b013e31818edcfd

Kalichman, L., Kim, D. H., Li, L., Guermazi, A., & Hunter, D. J. (2010). Computed tomography-evaluated features of spinal degeneration: prevalence, intercorrelation, and association with self-reported low back pain. *Spine J, 10*(3), 200-208. doi:10.1016/j.spinee.2009.10.018

Kamper, S. J., Apeldoorn, A. T., Chiarotto, A., Smeets, R. J., Ostelo, R. W., Guzman, J., & van Tulder, M. W. (2014). Multidisciplinary biopsychosocial rehabilitation for chronic low back pain. *Cochrane Database Syst Rev, 9*, Cd000963. doi:10.1002/14651858.CD000963.pub3

Kazdin, A. E. (1986). Comparative outcome studies of psychotherapy: methodological issues and strategies. *Journal of Consulting and Clinical Psychology, 54*(1), 95-105.

Kelly, L., McMillan, D., Anderson, A., Fippinger, M., Fillerup, G., & Rider, J. (2013). Validity of actigraphs uniaxial and triaxial accelerometers for assessment of physical activity in adults in laboratory conditions. *BMC Medical Physics, 13*(1), 5.

Kemani, M. K., Grimby-Ekman, A., Lundgren, J., Sullivan, M., & Lundberg, M. (2018). Factor structure and internal consistency of a Swedish version of the Pain Catastrophizing Scale. *Acta Anaesthesiologica Scandinavica.* doi:10.1111/aas.13246

Kepler, C. K., Vaccaro, A. R., Hilibrand, A. S., Anderson, D. G., Rihn, J. A., Albert, T. J., & Radcliff, K. E. (2014). National trends in the use of fusion techniques to treat degenerative spondylolisthesis. *Spine, 39*(19), 1584-1589. doi:10.1097/brs.0000000000000486

Koenders, N., Rushton, A., Verra, M. L., Willems, P. C., Hoogeboom, T. J., & Staal, J. B. (2018). Pain and disability after first-time spinal fusion for lumbar degenerative disorders: a systematic review and meta-analysis. *European Spine Journal.* doi:10.1007/s00586-018-5680-3

Koes, B. W., van Tulder, M., Lin, C. W., Macedo, L. G., McAuley, J., & Maher, C. (2010). An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *European Spine Journal, 19*(12), 2075-2094. doi:10.1007/s00586-010-1502-y

Kori, S. H., Miller, R. P., & Todd, D. D. (1990). Kinesiophobia: a new view of chronic pain behavior *Pain Management, 3* (pp. 35-43).

Kujala, U. M., Taimela, S., Viljanen, T., Jutila, H., Viitasalo, J. T., Videman, T., & Battie, M. C. (1996). Physical loading and performance as predictors of back pain in healthy adults. A 5-year prospective study. *European Journal of Applied Physiology and Occupational Physiology, 73*(5), 452-458.

Kåver, A. (2006). Några vanliga tekniker i KBT. *KBT i utveckling : en introduktion till kognitiv beteendeterapi* (pp. 238-305). Stockholm: Natur och kultur.

LaCaille, R. A., DeBerard, M. S., Masters, K. S., Colledge, A. L., & Bacon, W. (2005). Presurgical biopsychosocial factors predict multidimensional patient: outcomes of interbody cage lumbar fusion. *Spine J, 5*(1), 71-78. doi:10.1016/j.spinee.2004.08.004

Le Roy, B., Selvy, M., & Slim, K. (2016). The concept of prehabilitation: What the surgeon needs to know? *Journal of Visceral Surgery, 153*(2), 109-112. doi:10.1016/j.jviscsurg.2016.01.001

Lee, I. M., Shiroma, E. J., Lobelo, F., Puska, P., Blair, S. N., & Katzmarzyk, P. T. (2012). Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. *Lancet, 380*(9838), 219-229. doi:10.1016/s0140-6736(12)61031-9

Leeuw, M., Goossens, M. E., Linton, S. J., Crombez, G., Boersma, K., & Vlaeyen, J. W. (2007a). The fear-avoidance model of musculoskeletal pain: current state of scientific evidence. *Journal of Behavioral Medicine, 30*(1), 77-94. doi:10.1007/s10865-006-9085-0

Leeuw, M., Goossens, M. E., van Breukelen, G. J., Boersma, K., & Vlaeyen, J. W. (2007b). Measuring perceived harmfulness of physical activities in patients with chronic low back pain: the Photograph Series of Daily Activities--short electronic version. *Journal of Pain, 8*(11), 840-849. doi:10.1016/j.jpain.2007.05.013

Leeuw, M., Goossens, M. E., van Breukelen, G. J., de Jong, J. R., Heuts, P. H., Smeets, R. J., Koke, A. J., & Vlaeyen, J. W. (2008). Exposure in vivo versus operant graded activity in chronic low back pain patients: results of a randomized controlled trial. *Pain, 138*(1), 192-207. doi:10.1016/j.pain.2007.12.009

Lemanu, D. P., Singh, P. P., MacCormick, A. D., Arroll, B., & Hill, A. G. (2013). Effect of preoperative exercise on cardiorespiratory function and recovery after surgery: a systematic review. *World Journal of Surgery, 37*(4), 711-720. doi:10.1007/s00268-012-1886-4

Leplege, A., Gzil, F., Cammelli, M., Lefeve, C., Pachoud, B., & Ville, I. (2007). Person-centredness: conceptual and historical perspectives. *Disability and Rehabilitation, 29*(20-21), 1555-1565. doi:10.1080/09638280701618661

Lethem, J., Slade, P. D., Troup, J. D., & Bentley, G. (1983). Outline of a Fear-Avoidance Model of exaggerated pain perception--I. *Behaviour Research and Therapy, 21*(4), 401-408.

Lin, C. W., McAuley, J. H., Macedo, L., Barnett, D. C., Smeets, R. J., & Verbunt, J. A. (2011). Relationship between physical activity and disability in low back pain: a systematic review and meta-analysis. *Pain, 152*(3), 607-613. doi:10.1016/j.pain.2010.11.034

Lindback, Y., Tropp, H., Enthoven, P., Abbott, A., & Oberg, B. (2017). PREPARE: presurgery physiotherapy for patients with degenerative lumbar spine disorder: a randomized controlled trial. *Spine J.* doi:10.1016/j.spinee.2017.12.009

Linton, S. J., Boersma, K., Jansson, M., Overmeer, T., Lindblom, K., & Vlaeyen, J. W. (2008). A randomized controlled trial of exposure in vivo for patients with spinal pain reporting fear of work-related activities. *European Journal of Pain (London, England), 12*(6), 722-730. doi:10.1016/j.ejpain.2007.11.001

Linton, S. J., Melin, L., & Gotestam, K. G. (1984). Behavioral analysis of chronic pain and its management. *Progress in Behavior Modification, 18*, 1-42.

Linton, S. J., & Ryberg, M. (2001). A cognitive-behavioral group intervention as prevention for persistent neck and back pain in a non-patient population: a randomized controlled trial. *Pain, 90*(1-2), 83-90.

Lisspers, J., Nygren, A., & Soderman, E. (1997). Hospital Anxiety and Depression Scale (HAD): some psychometric data for a Swedish sample. *Acta Psychiatrica Scandinavica, 96*(4), 281-286.

Livshits, G., Popham, M., Malkin, I., Sambrook, P. N., Macgregor, A. J., Spector, T., & Williams, F. M. (2011). Lumbar disc degeneration and genetic factors are the main risk factors for low back pain in women: the UK Twin Spine Study. *Annals of the Rheumatic Diseases, 70*(10), 1740-1745. doi:10.1136/ard.2010.137836

Loeser, J. D., & Treede, R. D. (2008). The Kyoto protocol of IASP Basic Pain Terminology. *Pain, 137*(3), 473-477. doi:10.1016/j.pain.2008.04.025

Louw, A., Diener, I., Landers, M. R., & Puentedura, E. J. (2014). Preoperative pain neuroscience education for lumbar radiculopathy: a multicenter randomized controlled trial with 1-year follow-up. *Spine, 39*(18), 1449-1457. doi:10.1097/brs.0000000000000444

Lundberg, M. (2006) Kinesiophobia: various aspects of moving with musculoskeletal pain. Gothenburg: Department of Orthopaedics, Institute of Clinical Sciences, The Sahlgrenska Academy, University of Gothenburg.

Lundberg, M., Frennered, K., Hagg, O., & Styf, J. (2011). The impact of fear-avoidance model variables on disability in patients with specific or nonspecific chronic low back pain. *Spine, 36*(19), 1547-1553. doi:10.1097/BRS.0b013e3181f61660

Lundberg, M., Styf, J., & Carlsson, S. G. (2004). A psychometric evaluation of the Tampa Scale for Kinesiophobia - From a physiotherapeutic perspective. *Physiotherapy Theory and Practice, 20*(2), 121-133.

Lundervold, D. A., & Belwood, M. F. (2000). The Best Kept Secret in Counseling: Single-Case (N = 1) Experimental Designs. *Journal of Counseling & Development, 78*(1), 92-102. doi:doi:10.1002/j.1556-6676.2000.tb02565.x

Manchikanti, L., Singh, V., Datta, S., Cohen, S. P., & Hirsch, J. A. (2009). Comprehensive review of epidemiology, scope, and impact of spinal pain. *Pain Physician, 12*(4), E35-70.

Manchikanti, L., Singh, V., Falco, F. J., Benyamin, R. M., & Hirsch, J. A. (2014). Epidemiology of low back pain in adults. *Neuromodulation, 17 Suppl 2*, 3-10. doi:10.1111/ner.12018

Mancuso, C. A., Duculan, R., & Girardi, F. P. (2017). Healthy Physical Activity Levels Below Recommended Thresholds Two Years After Lumbar Spine Surgery. *Spine, 42*(4), E241-e247. doi:10.1097/brs.0000000000001757

Mannion, A. F., & Elfering, A. (2006). Predictors of surgical outcome and their assessment. *European Spine Journal, 15 Suppl 1*, S93-108. doi:10.1007/s00586-005-1045-9

Mannion, A. F., Elfering, A., Staerkle, R., Junge, A., Grob, D., Dvorak, J., Jacobshagen, N., Semmer, N. K., & Boos, N. (2007). Predictors of multidimensional outcome after spinal surgery. *European Spine Journal, 16*(6), 777-786. doi:10.1007/s00586-006-0255-0

Maribo, T., Iversen, E., Andersen, N. T., Stengaard-Pedersen, K., & Schiottz-Christensen, B. (2009). Intra-observer and interobserver reliability of One Leg Stand Test as a measure of postural balance in low back pain patients. *International Musculoskeletal Medicine, 31*, 172-177.

Martin, K. A., Bowen, D. J., Dunbar-Jacob, J., & Perri, M. G. (2000). Who will adhere? Key issues in the study and prediction of adherence in randomized controlled trials. *Controlled Clinical Trials, 21*(5 Suppl), 195s-199s.

Maughan, E. F., & Lewis, J. S. (2010). Outcome measures in chronic low back pain. *European Spine Journal, 19*(9), 1484-1494. doi:10.1007/s00586-010-1353-6

May, A. M., Struijk, E. A., Fransen, H. P., Onland-Moret, N. C., de Wit, G. A., Boer, J. M., van der Schouw, Y. T., Hoekstra, J., Bueno-de-Mesquita, H. B., Peeters, P. H., & Beulens, J. W. (2015). The impact of a healthy lifestyle on Disability-Adjusted Life Years: a prospective cohort study. *BMC Medicine, 13*, 39. doi:10.1186/s12916-015-0287-6

McGirt, M. J., Bydon, M., Archer, K. R., Devin, C. J., Chotai, S., Parker, S. L., Nian, H., Harrell, F. E. J., Speroff, T., Dittus, R. S., Philips, S. E., Shaffrey, C. I., Foley, K. T., & Asher, A. L. (2017). An analysis from the Quality Outcomes Database, Part 1. Disability, quality of life, and pain outcomes following lumbar spine surgery: predicting likely individual patient outcomes for shared decision-making. *Journal of Neurosurgery: Spine*, 1-13. doi:10.3171/2016.11.spine16526

McGirt, M. J., Sivaganesan, A., Asher, A. L., & Devin, C. J. (2015). Prediction model for outcome after low-back surgery: individualized likelihood of complication, hospital readmission, return to work, and 12-month improvement in functional disability. *Neurosurgical Focus, 39*(6), E13. doi:10.3171/2015.8.focus15338

Melzack, R. (2001). Pain and the neuromatrix in the brain. *Journal of Dental Education, 65*(12), 1378-1382.

Merskey, H. (1979). Pain terms: a list with definitions and notes on usage. Recommended by the IASP Subcommittee on Taxonomy. *Pain, 6*(3), 249.

Merskey, H., & Bogduk, N. (1994a). *Classification of chronic pain : descriptions of chronic pain syndromes and definitions of pain terms.* Seattle: IASP Press.

Merskey, H., & Bogduk, N. (1994b). International Association for the Study of Pain,. Retrieved from http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698&navItemNumber=576

Meyer, R., Campbell, J., & Raja, S. (1994). Peripheral neural mechanisms of nociception. In P. D. Wall & R. Melzack (Eds.), *Textbook of pain.* Edinburgh: Churchill Livingstone.

Mobbs, R. J., Phan, K., Maharaj, M., & Rao, P. J. (2016). Physical Activity Measured with Accelerometer and Self-Rated Disability in Lumbar Spine Surgery: A Prospective Study. *Global Spine J, 6*(5), 459-464. doi:10.1055/s-0035-1565259

Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical Psychology Review, 11*(3), 247-266. doi:https://doi.org/10.1016/0272-7358(91)90103-2

Monticone, M., Ambrosini, E., Rocca, B., Foti, C., & Ferrante, S. (2017). Responsiveness and minimal clinically important changes for the Tampa Scale of Kinesiophobia after lumbar fusion during cognitive behavioral rehabilitation. *European Journal of Physical and Rehabilitation Medicine, 53*(3), 351-358. doi:10.23736/s1973-9087.16.04362-8

Moseley, G. L. (2003). A pain neuromatrix approach to patients with chronic pain. *Manual Therapy, 8*(3), 130-140.

Moseley, G. L., & Butler, D. S. (2015). Fifteen Years of Explaining Pain: The Past, Present, and Future. *Journal of Pain, 16*(9), 807-813. doi:10.1016/j.jpain.2015.05.005

Moseley, G. L., Nicholas, M. K., & Hodges, P. W. (2004). A randomized controlled trial of intensive neurophysiology education in chronic low back pain. *Clinical Journal of Pain, 20*(5), 324-330.

Nielsen, P. R., Jorgensen, L. D., Dahl, B., Pedersen, T., & Tonnesen, H. (2010). Prehabilitation and early rehabilitation after spinal surgery: randomized clinical trial. *Clinical Rehabilitation, 24*(2), 137-148. doi:10.1177/0269215509347432

Nijs, J., Paul van Wilgen, C., Van Oosterwijck, J., van Ittersum, M., & Meeus, M. (2011). How to explain central sensitization to patients with 'unexplained' chronic musculoskeletal pain: practice guidelines. *Manual Therapy, 16*(5), 413-418. doi:10.1016/j.math.2011.04.005

Noorian, S., Sorensen, K., & Cho, W. (2018). A systematic review of clinical outcomes in surgical treatment of adult isthmic spondylolisthesis. *Spine J, 18*(8), 1441-1454. doi:10.1016/j.spinee.2018.04.022

Norden, J., Smuck, M., Sinha, A., Hu, R., & Tomkins-Lane, C. (2017). Objective measurement of free-living physical activity (performance) in lumbar spinal stenosis: are physical activity guidelines being met? *Spine J, 17*(1), 26-33. doi:10.1016/j.spinee.2016.10.016

Norton, P. J., & Asmundson, G. J. G. (2003). Amending the fear-avoidance model of chronci pain: What is the role of physiological arousal? *Behavior Therapy, 34*(1), 17-30. doi:https://doi.org/10.1016/S0005-7894(03)80019-9

O'Connell, N. E., Cook, C. E., Wand, B. M., & Ward, S. P. (2016). Clinical guidelines for low back pain: A critical review of consensus and inconsistencies across three major guidelines. *Best Practice & Research: Clinical Rheumatology, 30*(6), 968-980. doi:10.1016/j.berh.2017.05.001

Olsson, L. E., Karlsson, J., & Ekman, I. (2007). Effects of nursing interventions within an integrated care pathway for patients with hip fracture. *Journal of Advanced Nursing, 58*(2), 116-125. doi:10.1111/j.1365-2648.2007.04209.x

Peacock, J., & Peacock, P. J. (2011). *Oxford handbook of medical statistics.* Oxford: Oxford University Press.

Pearson, A. M., Lurie, J. D., Tosteson, T. D., Zhao, W., Abdu, W. A., & Weinstein, J. N. (2013). Who should undergo surgery for degenerative spondylolisthesis? Treatment effect predictors in SPORT. *Spine, 38*(21), 1799-1811. doi:10.1097/BRS.0b013e3182a314d0

Philips, H. C. (1987). Avoidance behaviour and its role in sustaining chronic pain. *Behaviour Research and Therapy, 25*(4), 273-279.

Phillips, F. M., Slosar, P. J., Youssef, J. A., Andersson, G., & Papatheofanis, F. (2013). Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. *Spine, 38*(7), E409-422. doi:10.1097/BRS.0b013e3182877f11

Pinheiro, M. B., Ferreira, M. L., Refshauge, K., Maher, C. G., Ordonana, J. R., Andrade, T. B., Tsathas, A., & Ferreira, P. H. (2016). Symptoms of depression as a prognostic factor for low back pain: a systematic review. *Spine J, 16*(1), 105-116. doi:10.1016/j.spinee.2015.10.037

Powell, M. C., Wilson, M., Szypryt, P., Symonds, E. M., & Worthington, B. S. (1986). Prevalence of lumbar disc degeneration observed by magnetic resonance in symptomless women. *Lancet, 2*(8520), 1366-1367.

Price, D. D., McGrath, P. A., Rafii, A., & Buckingham, B. (1983). The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. *Pain, 17*(1), 45-56.

Prince, S. A., Adamo, K. B., Hamel, M. E., Hardt, J., Connor Gorber, S., & Tremblay, M. (2008). A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. *The International Journal of Behavioral Nutrition and Physical Activity, 5*, 56. doi:10.1186/1479-5868-5-56

Rajaee, S. S., Bae, H. W., Kanim, L. E., & Delamarter, R. B. (2012). Spinal fusion in the United States: analysis of trends from 1998 to 2008. *Spine, 37*(1), 67-76. doi:10.1097/BRS.0b013e31820cccfb

Rapoport, J., Jacobs, P., Bell, N. R., & Klarenbach, S. (2004). Refining the measurement of the economic burden of chronic diseases in Canada. *Chronic Diseases in Canada, 25*(1), 13-21.

Resnick, B., & Jenkins, L. S. (2000). Testing the reliability and validity of the Self-Efficacy for Exercise scale. *Nursing Research, 49*(3), 154-159.

Rolving, N., Nielsen, C. V., Christensen, F. B., Holm, R., Bunger, C. E., & Oestergaard, L. G. (2015). Does a Preoperative Cognitive-behavioural Intervention affect disability, pain behaviour, pain and return to work the first year after Lumbar Spinal Fusion Surgery? *Spine.* doi:10.1097/brs.0000000000000843

Rolving, N., Obling, K. H., Christensen, F. B., & Fonager, K. (2013). Physical activity level, leisure activities and related quality of life 1 year after lumbar decompression or total hip arthroplasty. *European Spine Journal, 22*(4), 802-808. doi:10.1007/s00586-012-2535-1

Rushton, A., Eveleigh, G., Petherick, E. J., Heneghan, N., Bennett, R., James, G., & Wright, C. (2012). Physiotherapy rehabilitation following lumbar spinal fusion: A systematic review and meta-analysis of randomised controlled trials. *BMJ Open, 2*(4).

Rushton, A., White, L., Heap, A., & Heneghan, N. (2015). Evaluation of current surgeon practice for patients undergoing lumbar spinal fusion surgery in the United Kingdom. *World J Orthop, 6*(6), 483-490. doi:10.5312/wjo.v6.i6.483

Ryan, C. G., Grant, P. M., Dall, P. M., Gray, H., Newton, M., & Granat, M. H. (2009). Individuals with chronic low back pain have a lower level, and an altered pattern, of physical activity compared with matched controls: an observational study. *Australian Journal of Physiotherapy, 55*(1), 53-58.

Rydwik, E., Hovmoller, F., & Bostrom, C. (2014). Aspects of reliability and validity of the Swedish version of the Self-Efficacy for Exercise Scale for older people. *Physiotherapy Theory and Practice, 30*(2), 131-137. doi:10.3109/09593985.2013.838614

Sackett, D. L., Rosenberg, W. M., Gray, J. A., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't. *BMJ, 312*(7023), 71-72.

Schaller, A., Exner, A. K., Schroeer, S., Kleineke, V., & Sauzet, O. (2017). Barriers to Physical Activity in Low Back Pain Patients following Rehabilitation: A Secondary Analysis of a Randomized Controlled Trial. *Biomed Res Int, 2017*, 6925079. doi:10.1155/2017/6925079

Schulz, K. F., & Grimes, D. A. (2002). Sample size slippages in randomised trials: exclusions and the lost and wayward. *Lancet, 359*(9308), 781-785. doi:10.1016/s0140-6736(02)07882-0

Scott, W., Wideman, T. H., & Sullivan, M. J. (2014). Clinically meaningful scores on pain catastrophizing before and after multidisciplinary rehabilitation: a prospective study of individuals with subacute pain after whiplash injury. *Clinical Journal of Pain, 30*(3), 183-190. doi:10.1097/AJP.0b013e31828eee6c

Shiri, R., & Falah-Hassani, K. (2017). Does leisure time physical activity protect against low back pain? Systematic review and meta-analysis of 36 prospective cohort studies. *British Journal of Sports Medicine, 51*(19), 1410-1418. doi:10.1136/bjsports-2016-097352

Shiri, R., Karppinen, J., Leino-Arjas, P., Solovieva, S., & Viikari-Juntura, E. (2010a). The association between obesity and low back pain: a meta-analysis. *American Journal of Epidemiology, 171*(2), 135-154. doi:10.1093/aje/kwp356

Shiri, R., Karppinen, J., Leino-Arjas, P., Solovieva, S., & Viikari-Juntura, E. (2010b). The association between smoking and low back pain: a meta-analysis. *American Journal of Medicine, 123*(1), 87.e87-35. doi:10.1016/j.amjmed.2009.05.028

Simmonds, M. J., Olson, S. L., Jones, S., Hussein, T., Lee, C. E., Novy, D., & Radwan, H. (1998). Psychometric characteristics and clinical usefulness of physical performance tests in patients with low back pain. *Spine, 23*(22), 2412-2421.

Skold, C., Tropp, H., & Berg, S. (2013). Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. *European Spine Journal, 22*(10), 2288-2295. doi:10.1007/s00586-013-2926-y

Slootmaker, S. M., Schuit, A. J., Chinapaw, M. J., Seidell, J. C., & van Mechelen, W. (2009). Disagreement in physical activity assessed by accelerometer and self-report in subgroups of age, gender, education and weight status. *The International Journal of Behavioral Nutrition and Physical Activity, 6*, 17. doi:10.1186/1479-5868-6-17

Smeets, R. J., Hijdra, H. J. M., Kester, A. D. M., Hitters, M. W. G. C., & Knottnerus, J. A. (2006). The usability of six physical performance tasks in a rehabilitation population with chronic low back pain. *Clinical Rehabilitation, 20*(11), 989-998.

Smeets, R. J., Koke, A., Lin, C. W., Ferreira, M., & Demoulin, C. (2011). Measures of function in low back pain/disorders: Low Back Pain Rating Scale (LBPRS), Oswestry Disability Index (ODI), Progressive Isoinertial Lifting Evaluation (PILE), Quebec Back Pain Disability Scale (QBPDS), and Roland-Morris Disability Questionnaire (RDQ). *Arthritis Care and Research, 63 Suppl 11*, S158-173. doi:10.1002/acr.20542

Smuck, M., Muaremi, A., Zheng, P., Norden, J., Sinha, A., Hu, R., & Tomkins-Lane, C. (2018). Objective measurement of function following lumbar spinal stenosis decompression reveals improved functional capacity with stagnant real-life physical activity. *Spine J, 18*(1), 15-21. doi:10.1016/j.spinee.2017.08.262

Snaith, R. P. (2003). The Hospital Anxiety And Depression Scale. *Health and Quality of Life Outcomes, 1*, 29-29. doi:10.1186/1477-7525-1-29

Spenkelink, C. D., Hutten, M. M., Hermens, H. J., & Greitemann, B. O. (2002). Assessment of activities of daily living with an ambulatory monitoring system: a comparative study in patients with chronic low back pain and nonsymptomatic controls. *Clinical Rehabilitation, 16*(1), 16-26. doi:10.1191/0269215502cr463oa

Steffens, D., Maher, C. G., Pereira, L. S., Stevens, M. L., Oliveira, V. C., Chapple, M., Teixeira-Salmela, L. F., & Hancock, M. J. (2016). Prevention of Low Back Pain: A Systematic Review and Meta-analysis. *JAMA Intern Med, 176*(2), 199-208. doi:10.1001/jamainternmed.2015.7431

Stratford, P. (1995). Assessing Disability and Change on Individual Patients: A Report of a Patient Specific Measure. *Physiotherapy Canada, 47*(4), 258-263.

Strömqvist, B., Fritzell, P., Hägg, O., & Jönsson, B. (2009). *Swespine: the Swedish spine Register: the 2009 report.* Retrieved from http://www.4s.nu/

Sullivan, M. J., Adams, H., Rhodenizer, T., & Stanish, W. D. (2006). A psychosocial risk factor--targeted intervention for the prevention of chronic pain and disability following whiplash injury. *Physical Therapy, 86*(1), 8-18.

Sullivan, M. J., Bishop, S. R., & Pivik, J. (1995). The Pain Catastrophizing Scale: Development and validation. *Psychological Assessment, 7*(4), 524-532.

Taylor, J. B., Goode, A. P., George, S. Z., & Cook, C. E. (2014). Incidence and risk factors for first-time incident low back pain: a systematic review and meta-analysis. *Spine J, 14*(10), 2299-2319. doi:10.1016/j.spinee.2014.01.026

The Health and Social Care Information Centre. (2011). HES online. Primary. Diagnosis: 3 Character Tables. Retrieved from https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics

Trief, P. M., Ploutz-Snyder, R., & Fredrickson, B. E. (2006). Emotional health predicts pain and function after fusion: a prospective multicenter study. *Spine, 31*(7), 823-830. doi:10.1097/01.brs.0000206362.03950.5b

Troiano, R. P., Berrigan, D., Dodd, K. W., Masse, L. C., Tilert, T., & McDowell, M. (2008). Physical activity in the United States measured by accelerometer. *Medicine and Science in Sports and Exercise, 40*(1), 181-188. doi:10.1249/mss.0b013e31815a51b3

Trost, S. G., McIver, K. L., & Pate, R. R. (2005). Conducting accelerometer-based activity assessments in field-based research. *Medicine and Science in Sports and Exercise, 37*(11 Suppl), S531-543.

Trost, S. G., Owen, N., Bauman, A. E., Sallis, J. F., & Brown, W. (2002). Correlates of adults' participation in physical activity: review and update. *Medicine and Science in Sports and Exercise, 34*(12), 1996-2001. doi:10.1249/01.mss.0000038974.76900.92

Tudor-Locke, C., & Bassett, D. R. J. (2004). How many steps/day are enough? Preliminary pedometer indices for public health. *Sports Medicine, 34*(1), 1-8.

Tudor-Locke, C., Craig, C., Brown, W., Clemes, S., De Cocker, K., Giles-Corti, B., Hatano, Y., Inoue, S., Matsudo, S., Mutrie, N., Oppert, J.-M., Rowe, D., Schmidt, M., Schofield, G., Spence, J., Teixeira, P., Tully, M., & Blair, S. (2011). How many steps/day are enough? for adults. *International Journal of Behavioral Nutrition and Physical Activity, 8*(1), 79.

Tudor-Locke, C., Craig, C. L., Thyfault, J. P., & Spence, J. C. (2013). A step-defined sedentary lifestyle index: <5000 steps/day. *Applied Physiology, Nutrition, and Metabolism. Physiologie Appliquée, Nutrition et Métabolisme, 38*(2), 100-114. doi:10.1139/apnm-2012-0235

Turk, D. C. (2003). Cognitive-behavioral approach to the treatment of chronic pain patients. *Regional Anesthesia and Pain Medicine, 28*(6), 573-579.

Turk, D. C., & Flor, H. (1999). Chronic Pain: A biobehavioral perspective. In R. J. Gatchel & D. Turk (Eds.), *Psychosocial factors in pain. Critical perspectives (pp. 18-34).* New York: Guilford Press.

Turk, D. C., & Okifuji, A. (2002). Psychological factors in chronic pain: Evolution and revolution. *Journal of Consulting and Clinical Psychology, 70*(3), 678-690. doi:10.1037//0022-006X.70.3.678

Waddell, G. (2004). *The back pain revolution.* Edinburgh: Churchill Livingstone.

Wahlman, M., Hakkinen, A., Dekker, J., Marttinen, I., Vihtonen, K., & Neva, M. H. (2014). The prevalence of depressive symptoms before and after surgery and its association with disability in patients undergoing lumbar spinal fusion. *European Spine Journal, 23*(1), 129-134. doi:10.1007/s00586-013-2896-0

van Erp, R. M. A., Jelsma, J., Huijnen, I. P. J., Lundberg, M., Willems, P. C., & Smeets, R. (2017). Spinal Surgeons' Opinions on Pre- and Postoperative Rehabilitation in Patients Undergoing Lumbar Spinal Fusion Surgery: A Survey-Based Study in the Netherlands and Sweden. *Spine*. doi:10.1097/brs.0000000000002406

van Tulder, M., Becker, A., Bekkering, T., Breen, A., del Real, M. T., Hutchinson, A., Koes, B., Laerum, E., & Malmivaara, A. (2006). Chapter 3. European guidelines for the management of acute nonspecific low back pain in primary care. *European Spine Journal, 15 Suppl 2*, S169-191. doi:10.1007/s00586-006-1071-2

Wang, S. J., Han, Y. C., Liu, X. M., Ma, B., Zhao, W. D., Wu, D. S., & Tan, J. (2014). Fusion techniques for adult isthmic spondylolisthesis: a systematic review. *Archives of Orthopaedic and Trauma Surgery, 134*(6), 777-784. doi:10.1007/s00402-014-1985-9

Weinstein, J. N., Lurie, J. D., Olson, P. R., Bronner, K. K., & Fisher, E. S. (2006). United States' trends and regional variations in lumbar spine surgery: 1992-2003. *Spine, 31*(23), 2707-2714. doi:10.1097/01.brs.0000248132.15231.fe

Wertli, M. M., Eugster, R., Held, U., Steurer, J., Kofmehl, R., & Weiser, S. (2014). Catastrophizing-a prognostic factor for outcome in patients with low back pain: a systematic review. *Spine J, 14*(11), 2639-2657. doi:10.1016/j.spinee.2014.03.003

Wertli, M. M., Rasmussen-Barr, E., Weiser, S., Bachmann, L. M., & Brunner, F. (2013). The role of fear avoidance beliefs as a prognostic factor for outcome in patients with nonspecific low back pain: a systematic review. *Spine J.* doi:10.1016/j.spinee.2013.09.036

Vet, H. C. W. d., Terwee, C. B., Mokkink, L. B., & Knol, D. L. (2011). *Measurement in medicine: a practical guide*. Cambridge Cambridge University Press.

WHO. (2009). Global health risks – Mortality and burden of disease attributable to selected major risks. Retrieved from https://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf

WHO. (2010). WHO Guidelines Approved by the Guidelines Review Committee. In WHO (Ed.), *Global Recommendations on Physical Activity for Health.* Geneva: WHO.

Williams, A. C., Eccleston, C., & Morley, S. (2012). Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev, 11*, Cd007407. doi:10.1002/14651858.CD007407.pub3

Wilmot, E. G., Edwardson, C. L., Achana, F. A., Davies, M. J., Gorely, T., Gray, L. J., Khunti, K., Yates, T., & Biddle, S. J. (2012). Sedentary time in adults and the association with diabetes, cardiovascular disease and death: systematic review and meta-analysis. *Diabetologia, 55*(11), 2895-2905. doi:10.1007/s00125-012-2677-z

Vlaeyen, J. W. (2012b). *Pain-related fear: exposure-based treatment for chronic pain.* Seattle: IASP Press.

Vlaeyen, J. W., de Jong, J., Geilen, M., Heuts, P. H., & van Breukelen, G. (2001). Graded exposure in vivo in the treatment of pain-related fear: a replicated single-case experimental design in four patients with chronic low back pain. *Behaviour Research and Therapy, 39*(2), 151-166.

Vlaeyen, J. W., de Jong, J., Geilen, M., Heuts, P. H., & van Breukelen, G. (2002a). The treatment of fear of movement/(re)injury in chronic low back pain: further evidence on the effectiveness of exposure in vivo. *Clinical Journal of Pain, 18*(4), 251-261.

Vlaeyen, J. W., De Jong, J. R., Onghena, P., Kerckhoffs-Hanssen, M., & Kole-Snijders, A. M. (2002b). Can pain-related fear be reduced? The application of cognitive-behavioural exposure in vivo. *Pain Res Manag, 7*(3), 144-153.

Vlaeyen, J. W., Kole-Snijders, A. M., Boeren, R. G., & van Eek, H. (1995). Fear of movement/(re)injury in chronic low back pain and its relation to behavioral performance. *Pain, 62*(3), 363-372.

Vlaeyen, J. W., & Linton, S. J. (2000). Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain, 85*(3), 317-332.

Vlaeyen, J. W., & Linton, S. J. (2012a). Fear-avoidance model of chronic musculoskeletal pain: 12 years on. *Pain, 153*(6), 1144-1147. doi:10.1016/j.pain.2011.12.009

Woby, S. R., Urmston, M., & Watson, P. J. (2007). Self-efficacy mediates the relation between pain-related fear and outcome in chronic low back pain patients. *European Journal of Pain (London, England), 11*(7), 711-718. doi:10.1016/j.ejpain.2006.10.009

Von Korff, M., & Saunders, K. (1996). The course of back pain in primary care. *Spine, 21*(24), 2833-2837; discussion 2838-2839.

Woods, M. P., & Asmundson, G. J. (2008). Evaluating the efficacy of graded in vivo exposure for the treatment of fear in patients with chronic back pain: a randomized controlled clinical trial. *Pain, 136*(3), 271-280. doi:10.1016/j.pain.2007.06.037

Yoshiiwa, T., Miyazaki, M., Notani, N., Ishihara, T., Kawano, M., & Tsumura, H. (2016). Analysis of the Relationship between Ligamentum Flavum Thickening and Lumbar Segmental Instability, Disc Degeneration, and Facet Joint Osteoarthritis in Lumbar Spinal Stenosis. *Asian Spine J, 10*(6), 1132-1140. doi:10.4184/asj.2016.10.6.1132

Zhan, S., & Ottenbacher, K. J. (2001). Single subject research designs for disability research. *Disability and Rehabilitation, 23*(1), 1-8.

Zhang, T. T., Liu, Z., Liu, Y. L., Zhao, J. J., Liu, D. W., & Tian, Q. B. (2016). Obesity as a Risk Factor for Low Back Pain: A Meta-Analysis. *Clin Spine Surg*. doi:10.1097/bsd.0000000000000468

Zhang, T. T., Liu, Z., Liu, Y. L., Zhao, J. J., Liu, D. W., & Tian, Q. B. (2018). Obesity as a Risk Factor for Low Back Pain: A Meta-Analysis. *Clin Spine Surg, 31*(1), 22-27. doi:10.1097/bsd.0000000000000468

Zigmond, A. S., & Snaith, R. P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica, 67*(6), 361-370. doi:10.1111/j.1600-0447.1983.tb09716.x