A search for guidance in the multifaceted problem of low back pain

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Chapter 1

General Introduction

"As a physical therapist, I often experience the gap between guideline recommendations and the individual needs and preferences of people with low back pain."

BACKGROUND

Low back pain is a dominant health issue, with a lifetime prevalence between 50% and 85% and a point prevalence of 15% to 30% in modern countries.[1,2] Between 1990 and 2015, the number of years lived with disability due to low back pain increased by 54% worldwide.[3] Most episodes of low back pain are brief and have little or no lasting impact.[4] Recurrent episodes are common, however, and low back pain is increasingly recognized as a chronic condition with a variable course rather than a series of unrelated occurrences.[5] Low back pain is a multifaceted problem that is influenced by multiple psychosocial and physical prognostic factors.[6] For the majority of people suffering from low back pain, it is currently impossible to pinpoint the precise nociceptive source.[7] Lifestyle factors, such as smoking, obesity, and a lack of physical activity—all of which are associated with poorer overall health—are linked to the occurrence of low back pain episodes.[7] The precise role of these prognostic factors is unknown. This lack of knowledge limits healthcare professionals in care for low back pain to adjust treatments based on available evidence.

Non-evidence-based practice can be found in every country.[8,9] Visits to emergency departments are common, as is the liberal use of imaging, opioids, spinal injections, and surgery.[8,10,11,12,13,14] Healthcare professionals frequently struggle to make and justify decisions about the best care for people suffering from low back pain.[15,16,17,18,19,20,21,22,23] Clinical guidelines are available to aid a variety of healthcare professionals dealing with low back pain.[24,25,26] Although national and international guidelines provide guidance, scientific support for multiple recommendations remains scarce, and healthcare professionals have difficulty adjusting these recommendations to the individual needs of people experiencing low back pain.[15,16,17,18,19,20,21,22,23] Healthcare professionals might benefit from more supportive guideline recommendations and more detailed information on prognostic factors to allow them to adjust treatment strategies to the needs and values of individual people with low back pain.

In this introduction, we highlight and elaborate on the most common bottlenecks in clinical practice for low back pain based on the recommendations of the Royal Dutch Society for Physical Therapy (KNGF) guideline (2021);[27] the guideline published by the British National Institute for Health and Care Excellence (NICE) for low back pain and sciatica in adults older than 16 years of age (2016);[28] an updated overview of clinical practice guidelines by Oliveira et al. (2018);[24] *The Lancet* series on low back pain (2018);[7,8] a report for the Dutch Healthcare Institute describing an analysis of 16 national and international guidelines on low back pain by Staal et al. (2019);[25] and a systematic review of clinical practice guidelines by Zaina et al. (2023).[26]

Medical Imaging

Imaging (X-ray, CT, and MRI) provides no health benefits for patients with low back pain, and it is not recommended in clinical practice guidelines.[7,8,24,25] According to recommendations in the NICE guideline,[28] *The Lancet* series,[7,8] Staal et al.,[25] and Oliveira et al.,[24] imaging should not be routinely offered in non-specialist settings for people with low back pain (with or without sciatica); that it should be explained to people with low back pain (with or without sciatica) that imaging may not be needed if they are being referred for a specialist opinion; and that imaging should be considered in specialist healthcare settings only if the result is likely to change management. Despite this knowledge, in the United States (US), imaging is performed in as much as 21.7%– 28.8% of the population of patients with acute low back pain during the first 4–6 weeks, even in the absence of an indication for such techniques.[29,30] The value of imaging in low back pain is questionable, as degenerative, congenital, and postural abnormalities are also prevalent in people without low back pain.[31] These imaging findings are only vaguely correlated with symptoms of back pain, and they are not associated with future low back pain.[31,32] Moreover, imaging does not seem to lead to any improvement in terms of pain or function, and negative consequences have been reported. For example, imaging has been identified as increasing the number of spinal surgeries, exposing patients to unnecessary harm, and contributing to the increase in healthcare expenditures.[30,33,34] Scholars have suggested that medical imaging without a clinical indication is often prompted by the physician's need for reassurance of diagnosis, as well as to specify anatomical defects, to meet the expectations of patients, or for financial incentives.[35,36,37] The reasons why general practitioners make referrals for imaging and the manner in which they do so remain unclear.[38,39] Given that referrals for imaging increase costs, reducing the amount of imaging performed could offer a means of saving money.[40] Although it has been established that imaging in low back pain does not lead to better patient outcomes,[33,41] its effects on costs, healthcare utilization, and absence from work have not been reviewed before. These effects thus remain unclear.

Guideline Adherence

Rates of adherence to guidelines show room for improvement, and an increase in adherence to guidelines could potentially lead to better outcomes and reduced costs of treatment.[15,17,18,19,20,21,42,43] The KNGF guideline,[27] the NICE guideline,[28] *The Lancet* series,[7,8] Staal et al.,[25] Oliveira et al.,[24] and Zaina et al.[26] recommend providing advice and information to people with low back pain, helping them to self-manage their low back pain, providing information on the nature of low back pain, and encouraging people to continue with normal activities. Previous research on Dutch general practitioners has revealed that perceived barriers to and facilitators of using these guidelines were patient-related, thus suggesting that current guidelines do not always adequately incorporate the preferences, needs, and abilities of patients.[22] Within the context of physical therapy, studies have shown that the beliefs and treatment expectations of people with low back pain are often in conflict with guideline recommendations.[23,44] In addition, physical therapists often struggle to adjust guideline recommendations to the specific needs of people with low back pain.[20,45,46] The considerations of Dutch physical therapists regarding adherence to the KNGF low back pain (LBP) guideline[27] have not previously been investigated through qualitative research. To improve adherence to guidelines, it is essential to understand the considerations of physical therapists regarding the assessment and management of low back pain.

Lifestyle: Physical Activity and Sedentary Behavior

Low back pain is a multifaceted problem, and multiple prognostic factors could potentially affect the recovery process.[7] The course of low back pain differs substantially between patients.[7,47]

The NICE guideline,[28] *The Lancet* series,[7,8] Staal et al.,[25] Oliveira et al.,[24] and Zaina et al.[26] recommend considering a group exercise program (biomechanical, aerobic, mind–body, or a combination of approaches) and returning to normal activities for people with specific episodes or flare-ups of low back pain (with or without sciatica). Bed rest is not recommended. These guidelines contain no specific recommendations on lifestyle factors (e.g., sedentary behavior and the amount and type of physical activity). Recommendations for people with low back pain in other guidelines include the advice to remain physically active, as a prolonged period of inactivity has an adverse effect on recovery.[7,8,24,25,48] Furthermore, physical activity might accelerate the recovery of low back pain.[27,49] The available scientific literature contains limited and conflicting evidence on the role of physical activity and sedentary behavior in relation to recovery from low back pain.[50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65] The identification of and increased knowledge about prognostic factors (e.g., habitual physical activity and sedentary behavior) may help to enhance understanding concerning the course of low back pain, while potentially helping healthcare professionals and patients with low back pain to facilitate recovery.

Psychosocial factors and type of leg pain

People with low back pain constitute a heterogeneous population with substantial variability in prognosis where psychosocial and physical prognostic factors are explicitly mentioned in guidelines concerning low back pain.[8] Although the KNGF guideline,[27] the NICE guideline,[28] and Staal et al.[25] recommend considering the use of risk-stratification tools to inform shared decision-making about stratified management, scientific evidence is scarce. Stratification is not mentioned in *The Lancet* series,[7,8] Oliveira et al.,[24] or Zaina et al.[26] The Subgroups for Targeted Treatment (STarT) Back Screening Tool (SBST) is a prognostic tool measuring five psychosocial items, which have a great influence on the risk score, and four physical items that may support prognosis and clinical decision-making.[66] In several randomized controlled trials, people with back pain have been separated into distinct categories of risk for persistent disabling back pain.[67,68,69,70] Multiple cohort studies have reported that some SBST subgroups are at greater risk for poorer clinical outcomes.[71,72,73,74,75,76,77,78] According to a recent meta-analysis, however, with regard to patient-reported pain intensity and disability, there is insufficient evidence to support the preference for classification systems above generalized interventions when managing low back pain.[79]

Another prognostic factor is the presence of leg pain, which can be of either radicular or non-radicular origin.[27,28] The KNGF guideline,[27] the NICE guideline,[28] *The Lancet* series,[7,8] and Zaina et al.[26] no longer distinguish between low back pain with or without leg pain, as there is conflicting evidence on the course of low back pain with or without leg pain. While Staal et al.[25] and Oliveira et al.[24] do recommend neurological testing to identify radicular pain, there is no difference between the treatment strategies for radicular and non-specific low back pain. Several systematic reviews and cohort studies have reported less favorable outcomes for people with low back pain including radicular complaints in the leg, as compared to those with other types of low back pain.[80,81,82,83,84,85] In contrast, however, other systematic reviews have reported no differences or an unclear association in the recovery trajectory between people with and people without radicular complaints in the leg.[86,87,88] Classification systems used in these studies vary widely, and few focus on distinguishing different types of leg pain. This highlights the need for further research into subgroups of leg-pain types: non-radiating low back pain, non-radicular referred low back pain, and radicular radiating low back pain.[86,89]

There is uncertainty about the long-term low back pain trajectory according to SBST risk score and type of leg pain. Greater clarity about the association of SBST risk score and type of leg pain with the course of low back pain could help to enhance knowledge concerning the course of low back pain and treatment adjustments, in addition to informing future guidelines.

Trajectories of disability and pain

People with low back pain constitute a heterogeneous group, and there is a need for more evidence to enhance understanding the different trajectories applying to individuals within this population.[54,90] Such knowledge could help to improve the ability of healthcare professionals to identify and predict patient-specific needs and perform adjusted treatment.[91] A more sophisticated research technique might be beneficial in revealing these strategies.[92] To this end, latent class growth analysis (LCGA) and growth mixture modeling (GMM) are being increasingly recognized for their usefulness in identifying homogeneous subpopulations within heterogeneous populations.[93] The KNGF guideline,[27] the NICE guideline,[28] *The Lancet* series,[7,8] Staal et al.,[25] Oliveira et al.,[24] and Zaina et al.[26] recommend providing people with advice and information adjusted to their individual needs and capabilities. Increased knowledge concerning the different trajectories of people with low back pain could help to improve the ability of healthcare professionals to identify and predict patient-specific needs and perform adjusted treatment interventions. Given the scarcity of evidence concerning disability and pain trajectories of people with low back pain in primary care, such knowledge could be useful in the identification of pain and disability trajectories, as well as in the identification of predictors of class membership in adults with low back pain in primary care.

OBJECTIVE

The objective of this thesis is to provide further substantiation for aspects of guideline-informed low back pain care, thereby assisting healthcare professionals by developing better support for guideline recommendations and by providing more detailed information on prognostic factors that could allow them to adjust treatment strategies to the needs and values of individuals with low back pain.

RESEARCH QUESTIONS

- How is imaging in patients who have no symptoms suggestive of serious low back pain associated with increased costs, healthcare utilization, and absence from work?
- What reasons do Dutch physical therapists have for deviating from guideline recommendations in the treatment of patients with low back pain?
- How are habitual physical activity levels and sedentary behavior measured at the start of physical therapy treatment associated with disability trajectories in adults with low back pain?
- How are the STarT Back Screening Tool risk score and the type of leg pain associated with disability trajectories in adults with low back pain seeking primary care?
- Is it possible to identify and describe different pain and disability trajectories in adults with low back pain in primary care?

THESIS OUTLINE

Chapter 2 describes a systematic review in which low back pain treatments involving imaging are compared to those not involving imaging. The outcome measures addressed in this review are costs, healthcare utilization, and absence from work.

Chapter 3 reports on reasons that physical therapists have for deviating from guideline recommendations in the treatment of patients with low back pain. This qualitative study is based on interviews with physical therapists in primary care.

Chapter 4 describes the association between physical activity and sedentary behavior and the disability trajectories of people with low back pain, based on a prospective cohort study.

Chapter 5 describes the association between the STarT Back Screening Tool risk score and the type of leg pain with the disability trajectories of people with low back pain, based on a prospective cohort study.

Chapter 6 defines various trajectories of disability and pain for low back pain patients in primary care, based on a latent class growth analysis and growth mixture modelling.

Chapter 7 contains a general discussion of the studies included in this thesis. The results of all chapters are discussed and placed within a broader theoretical and practical perspective. This chapter also contains conclusions and recommendations for future research.

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Chapter 2

Imaging versus no imaging for low back pain: a systematic review, measuring costs, healthcare utilization and absence from work

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ABSTRACT

Purpose: Routine imaging (x-ray, CT, MRI) provides no health benefits for low back pain (LBP) patients and is not recommended in clinical practice guidelines. Whether imaging leads to increased costs, healthcare utilization or absence from work is unclear. Therefore, this study systematically reviews if imaging in patients with LBP leads to an increase on these outcomes.

Methods: We searched PubMed, CINAHL, EMBASE, Cochrane Library and Web of Science until October 2017 for randomized controlled trials (RCTs) and observational studies (OSs), comparing imaging versus no imaging on targeted outcomes. Data extraction and quality assessment was performed independently by two reviewers. The quality of the body of evidence was determined using GRADE methodology.

Results: Moderate quality evidence (1 RCT; n=421) supports that direct costs increase for patients undergoing x-ray. Low quality evidence (3 OSs; n=9,535) supports that early MRI leads to an increase in costs. There is moderate quality evidence (2 RCTs, 6 OSs; n=19,392) that performing MRI, x-ray, or imaging (MRI or CT) leads to an increase of healthcare utilization (e.g., future injections, surgery, medication etc.). Two RCTs (n=667) showed no significant differences between x-ray or MRI groups compared with no imaging groups on absence from work. However, the results of two observational studies (n=7,765) did show significantly greater mean absence from work in the imaging groups in comparison with the no imaging-groups.

Conclusions: Imaging in low back pain is associated with higher medical costs and increased healthcare utilization. There are indications that it also leads to higher absence from work.

INTRODUCTION

Low back pain (LBP) is a dominant health issue with a lifetime prevalence between 50% and 85% and a point prevalence of 15% to 30% in modern countries.[1,2] It also contributes to healthcare consumption and is the main determinant of years lived with disability.[3,4] Worldwide costs of treating low back pain are very high and increasing over time.[5,6] In the United States, direct and indirect healthcare costs are associated with the treatment of low back pain and add up to between 85 and 238 billion dollars every year.[7,8] In the Netherlands, the indirect costs account for 88% of the total costs of low back pain.[9] These indirect costs consist mainly of costs associated with absence from work.[10] According to most guidelines for low back pain, objectives of conservative treatment are to reduce medication use, decrease pain and disability, and prevent surgery.[11,12,13]

Lumbar imaging (x-ray, MRI or CT) is not recommended in these guidelines, except when malignant low back problems are suspected,[14] although recent research has shown that empirical support for most red flags is lacking.[15] Adherence to guidelines may contribute to a reduction in costs and healthcare utilization[16], as overdiagnosis is a widespread problem.[17] The value of imaging in low back pain is questionable, as degenerative, congenital and postural abnormalities are prevalent in people without low back pain.[18,19] These imaging findings are only vaguely correlated with symptoms from back pain and are not associated with future low back pain.[20,21,22,23]

Despite this knowledge, in the United States (U.S.) imaging is performed in as much as 21.7% to 28.8% of the population with acute LBP in the first 4-6 weeks in the absence of an indication for such imaging techniques.[24,25] X-ray was used in 12.0% to 32.2% of patients with LBP, magnetic resonance imaging (MRI) in 16.0% to 21.0%, and computed tomography (CT) in 1.4% to 3.0%.[26] The use of CT and MRI in low back pain patients increased in the U.S. between 1999 (7.2%) and 2010 (11%), while the use of X-rays remained stable over that period.[27] Moreover, imaging does not seem to improve pain or function and negative consequences have been reported: it increases the number of spinal surgery, exposes patients to unnecessary harms, and contributes to the increase of healthcare expenditures.[25,28,29,30]

It has been suggested that medical imaging without a clinical indication is prompted by the physician's need for reassurance of diagnosis, to specify an anatomical defect, to meet the expectations of patients or for financial incentives.[31,32,33] However, why and how general practitioners refer to imaging, remains unclear.[34,35] Referral to imaging increases costs. Reducing the amount of imaging is a possible way to save money.[36] Imaging in low back pain does not lead to better patient outcomes, but the effects on costs, healthcare utilization, and absence from work have not been reviewed before.[29,37] Therefore, the aim of this systematic review is to determine if imaging in patients without red flags suggesting serious low back pain is associated with increased costs, healthcare utilization or absence from work.

METHODS

For this systematic review, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA statement) was used.[38]

Data Sources and Searches

The following databases were searched: PubMed, CINAHL, EMBASE, Cochrane Library and Web of Science up to October 2017. Appendix 1 shows the complete search strategy with the keywords used (MeSH, EMTREE and text words). All articles published in English were eligible. Two independent reviewers (GL, WvL) screened the results of the database search on title, abstract and keywords for the eligibility of the study population, intervention, comparison, and outcome.

Study Selection

Eligible studies included both randomized controlled trials (RCTs) and observational studies, comparing imaging (x-ray, CT, MRI) versus no imaging on targeted outcomes. The studies had to meet the following criteria: (1) they included patients with LBP with or without sciatica, (2) participants were older than 18 years of age and (3) outcome measures contained costs, healthcare utilization or absence from work.

Studies were excluded when imaging was aimed at examining the presence of a specific pathology (e.g., spondyloarthropathies, oncological disease, systemic diseases, fractures or dislocation) in the presence of red flags symptoms.

Data Extraction and Quality Assessment

Quality assessment of the selected studies was based on data extraction performed by two independent reviewers (GL, WvL). Data were extracted for design, study population, setting, intervention, follow-up period, costs, healthcare utilization and absence from work. Costs were expressed in USD or GBP. Healthcare utilization was expressed as relative risk, odds ratio or likelihood ratio for receiving future treatment.

The methodological quality of each randomized controlled trial was appraised using the Cochrane risk of bias tool.[39]

The methodological quality of each included observational study was appraised using the National Institutes of Health (NIH) Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies.[40] The tool was designed to assist with the appraisal of internal validity (potential risk of measurement-, selection-, or information bias, or confounding) of cohort and cross-sectional studies and was, therefore, appropriate for this systematic review. Due to the expected scarceness of data regarding the targeted outcomes, poor or very poor studies were not excluded based on quality score.

The methodological quality of the included studies was independently assessed by both reviewers. Disagreements were discussed until consensus was reached. The reviewers were not blinded to the authors or the journal name.

Data Synthesis and Analysis

An overview for the randomized trials and a separate overview for all observational studies is presented summarizing number of studies, study design, type of imaging, number of patients, exclusion criteria, duration of low back pain, follow-up and primary outcome measures.

Conclusions concerning differences between imaging and non-imaging for costs, healthcare utilization and absence from work were formulated using the GRADE methodology separately for randomized controlled trials and observational studies.[41,42,43,44]

The quality of the evidence from RCTs was rated as high and downgraded to moderate, low or very low evidence when one or more quality criteria were not met. Factors that may downgrade the quality of the evidence were limitations in study design and execution, inconsistency, indirectness of evidence, and imprecision.[39,45,46]

Evidence coming from observational studies was rated as low and upgraded if there was a large magnitude of an effect. When the relative risk was greater than 2, the magnitude of the effect was rated as large.[39,47]

RESULTS

11,112 references were retrieved. After removing 3,426 duplicates, 7,686 titles and abstracts were screened for eligibility. 82 full-text articles were retrieved. Finally, 14 studies were included for this review. The flowchart of reference selection is shown in figure 1.

The 14 included studies consisted of 6 RCTs and 8 observational studies. Characteristics of the RCTs are shown in table 1 and quality assessment of the RCTs are shown in table 2. Those of the observational studies are reported in table 3 and 4. Due to substantial differences in study design, outcome, follow-up and population, a meta-analysis or another form of subgroup analysis or data pooling could not be performed for any of the included studies. Results for the outcome measures are presented per type of imaging (i.e., MRI, x-ray, MRI or CT), starting with the RCT's followed by the observational studies. Cochrane reporting recommendations were applied.[48,49]

Figure 1. Reference selection according to the reporting style of the PRISMA Statement.

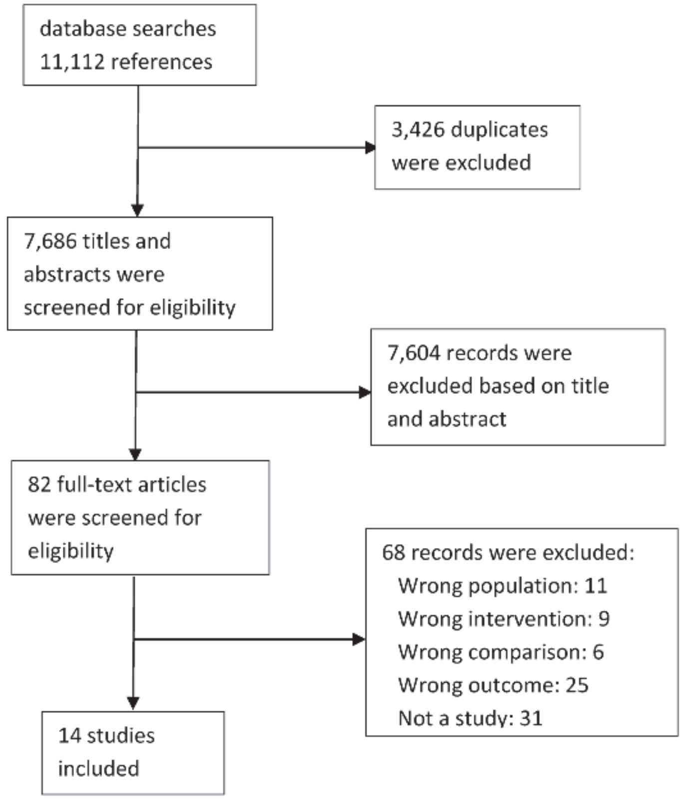

Table 1. Characteristics of Randomized Controlled Trials

Author, Year	Populaton	Intervention	Control	Outcome	Follow-up
Ash et al. 2008 [60]	246 patients with acute (3 weeks) LBP and/or radiculopathy (150 LBP and 96 radiculopathy patients) recruited from Spine Center, primary care units or Emergency Department Country: United States	MRI blinded	MRI unblinded (pt+ph)	no effect of blinding of the result of the MRI to the patient and health care provider for the mean number of sick days	2, 4, 6, and 8 weeks 6, 12, and 24 months
Cohen et al. 2012 [41]	132 patients With Lumbosacral Radiculopathy Referred for Epidural Steroid Injections Country: United States	MRI blinded	MRI unblinded (ph)	blinding of the physician lead to a significant increase in medication use at one-month follow-up no significant difference at 3-month follow-up	1 and 3 months
Gilbert et al. 2004 [63]	782 participants who had been referred by their general practitioner to a consultant orthopaedic specialist or neurosurgeon because of symptomatic lumbar spine disorders. Country: United Kingdom	early imaging (MRI or CT)	delayed, selective imaging	0-8 months: early imaging-group had significantly more expenses on imaging and physical therapy compared with the group of delayed, selective imaging 9-24 months: early imaging-group had significantly higher costs of hospital admissions Differences in other outcome measures, no significancy	8 and 24 months

Table 1. Continued

Author, Year	Populaton	Intervention	Control	Outcome	Follow-up
Kendrick et al. 2001 [40]	421 patients with low back pain of a median duration of 10 weeks from 52 general practices Country: United Kingdom	radiography of lumbar spine	no Rx / usual care	relative risk of 1.62 (p<0.01) for the radiography-group to have visited a doctor in the past 3 months compared with the control group. Other forms of healthcare utilization showed no significant differences between groups no significant influence on taken time off work and median number of days off work	3 and 9 months
Kerry et al. 2002 [62]	139 Patients consulting their general practitioner (GP) with low back pain at first presentation Country: United Kingdom	X-ray	no X-ray	odds ratios of 1.6-2.4 for the radiography-group to consult their GP subsequently for back pain and for referral to another healthcare provider at recruitment	6 weeks and 1 year
Miller et al. 2002 [61]	421 patients with low back pain of at least 6 weeks' duration from 52 general practices Country: United Kingdom	radiography of lumbar spine	no Rx / usual care	Direct costs are higher (p<0.001) for the radiography-group No significant difference was found for the indirect costs	3 and 9 months

Table 2. Assessment of Randomized Controlled Trials

	Ash et al. 2007 GL	Ash et al. 2007 WvL	Cohen et al. 2012 GL	Cohen et al. 2012 WvL	Gilbert et al. 2004 GL	Gilbert et al. 2004 WvL	Kendrick et al. 2011 GL	Kendrick et al. 2011 WvL	Kerry et al. 2002 GL	Kerry et al. 2002 WvL	Miller et al. 2002 GL	Miller et al. 2002 WvL
1 Was the assignment of the intervention randomized to the patients?	+	+	+	+	+	+	+	+	+	+	+	+
2 The person who includes patients should not be aware of the randomization sequence. Was that the case here?	+	+	+	+	+	+	+	+	+	+	+	+
3 Were the patients and the practitioners blinded for the treatment?	+	?	+	+	?	-	-	-	-	-	?	?
4 Were the outcome assessors blinded for treatment?	+	?	+	+	?	-	?	-	?	?	?	?
5 Were the groups comparable at the beginning of the trial?	+	+	+	-	+	-	+	+	+	+	+	+
If no: has this been corrected in the analyzes?				+								
6 Is a complete follow-up available from a sufficient proportion of all included patients?	+	+	+	+	+	+	+	+	?	?	+	+

Table 2. Continued

	Ash et al. 2007 GL	Ash et al. 2007 WvL	Cohen et al. 2012 GL	Cohen et al. 2012 WvL	Gilbert et al. 2004 GL	Gilbert et al. 2004 WvL	Kendrick et al. 2011 GL	Kendrick et al. 2011 WvL	Kerry et al. 2002 GL	Kerry et al. 2002 WvL	Miller et al. 2002 GL	Miller et al. 2002 WvL
If no: can selective loss-to-follow-up sufficiently be ruled out?												
7 Have all the included patients been analyzed in the group in which they were randomized?	+	+	+	+	+	+	+	+	+	+	+	+
8 Have the groups been treated equally, apart from the intervention?	+	+	+	+	+	?	+	+	+	+	+	+
9 Can selective publication of results sufficiently be ruled out?	+	+	+	+	+	+	+	+	+	+	+	+
10 Can unwanted influence of sponsors sufficiently be ruled out?	+	+	+	+	+	+	+	+	+	+	+	+

Table 3. Characteristics of Observational Studies

Author, Year	Population	Intervention	Control	Outcome	Follow-up
Aaronson et al. 2017 [64]	6094 patients with uncomplicated back pain visiting ED Country: United States	MRI	no MRI	patients who had an MRI were more likely to be admitted to observation (74.2% vs 10.8%; p<0.0001) and had a longer ED LOS (median 4.8 hours vs 2.7; p<0.0001)	1 week
Carey et al. 2015 [65]	872 general practice patients of which 551 (63%) reported that they had experienced lower back pain Country: Australia	Imaging (radiograpy, MRI or CT)	non imaging	referred for imaging (radiography, MRI or CT) were prescribed medication (70%) compared with those not referred (39%, p<0.001)	12 months
Fritz et al. 2015 [47]	2893 patients with a new LBP-related primary care consultation Country: United States	Advanced imaging (MRI or CT)	phys. ther.	higher odds ratios (3.67-5.47) for the advanced imaging-group (MRI or CT) for surgery, injections, spine surgeon visit, any spine specialist visit and emergency department visit compared with physical therapy group	12 months
Graves et al. 2014 [43]	1770 workers (age >18) with work-related LBP using administrative claims Country: United States	no early MRI	early MRI	differences (p<0.001) between the nonadherent group and the guideline adherent group for receiving an injection (40.8% vs 6.9%), surgery (19.9% vs 2.5%) and mean visits of physical therapy/osteopathy (18.4 vs 6.8) and outpatient (12.2 vs 4.3) higher costs (p<0.001) on all outcomes for the nonadherent group vs the adherent group. Mean total costs are $22,151 vs $6,640	12 months

Table 3. Continued

Author, Year	Population	Intervention	Control	Outcome	Follow-up
Kerry et al. 2002 [62]	419 Patients consulting their general practitioner (GP) with low back pain at first presentation Country: United Kingdom	X-ray	no X-ray	odds ratios of 1.6-2.4 for the radiography-group to consult their GP subsequently for back pain and for referral to another healthcare provider at recruitment	6 weeks and 1 year
Webster et al. 2010 [28]	A total of 7210 LBP claims with paid lost time were identified by body part Country: United States	early MRI	no MRI	higher mean total medical costs for the early MRI group ($21,921) compared to the no-MRI group ($2,779). % to undergo surgery for no-MRI group was 0.8% vs 22.0% for the early MRI group. Mean first disability period of 134 vs 23 (no MRI) days	24 months
Webster et al. 2013 [42]	555 workers with acute, disabling, work-related low back pain (LBP) with and without radiculopathy. Country: United States	early MRI	no MRI	Total medical costs were lower in the no-MRI group. $4,100 and $2,306 for radiculopathy and nonspecific LBP in the no-MRI group vs $22,339 and $17,028 for radiculopathy and nonspecific LBP in the early MRI group nonspecific LBP in the early MRI-group had on average 165 sick days no-MRI group only had 44.4 sick days on average	24 months
Webster et al. 2014 [46]	A total of 7210 LBP claims with paid lost time were identified by body part Country: United States	early / timely MRI	no MRI	no-MRI group vs early or timely MRI for receiving injections (25.17-32.70), EMG/NCV (35.13-54.89), advanced imaging (13.04-20.53) and surgery (6.48-33.80) (p=0.001)	3, 6, 9, and 12 months

2

Table 4. Assessment of Observational Studies

1	Was the research question or objective in this paper clearly stated?
2	Was the study population clearly specified and defined?
3	Was the participation rate of eligible persons at least 50%?
4	Were all the subjects selected or recruited from the same or similar populations (including the same time period)?
	Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?
5	Was a sample size justification, power description, or variance and effect estimates provided?
6	For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?
7	Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?
8	For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?
9	Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?
10	Was the exposure(s) assessed more than once over time?
11	Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?
12	Were the outcome assessors blinded to the exposure status of participants?
13	Was loss to follow-up after baseline 20% or less?
14	Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?

Table 4. Continued

	Aaronson et al. 2017		**Carey et al. 2015**		**Fritz et al. 2015**		**Graves et al. 2014**		**Kerry et al. 2002**		**Webster et al. 2010**		**Webster et al. 2013**		**Webster et al. 2014**	
	GL	WvL	GL	WvL	GL	WvL	GL	WvL	GL	WvL	GL	WvL	GL	WvL	GL	WvL
1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2	+	+	+	-	+	+	+	+	+	+	+	-	+	-	+	-
3	+	+	NR	NR	+	+	+	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-
6	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+
7	-	CD	NR	NR	+	+	+	+	+	+	+	+	+	+	+	+
8	NA	NA	+	+	+	+	+	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	+	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+
12	NA	NA	NR	NR	-	-	-	-	-	-	NR	CD	-	-	+	+
13	NA	NA	NR	NR	NR	+	+	+	+	+	+	+	+	+	+	+
14	-	-	-	-	CD	CD	+	+	-	-	+	+	+	+	+	+

2

RANDOMIZED CONTROLLED STUDIES

MRI and costs
No studies were found that report on this possible relationship.

MRI and healthcare utilization
One study[50] (n=132) compared two groups of physicians composing a treatment plan. One group was blinded to the results of the MRI. The other group was not blinded to the results. This study was conducted within a very specific population: patients who were diagnosed with radiculopathy and referred for epidural steroid injection. At one-month follow-up, 27% of the blinded group achieved a 20% or greater reduction in medication use versus 48% in the group where the physician was not blinded to the result of the MRI. This study did not report about other forms of costs.
This study provides moderate quality evidence (imprecision) that blinding of the physician to the results of the MRI leads to a significantly smaller decrease in medication use by patients at one-month follow-up. This difference was no longer present at the 3-month follow-up.

MRI and absence from work
One study[51] (n=246) compared a group where patients and healthcare providers were blinded to the result of the MRI with a non-blinded group. There were no significant differences in the mean number of sick days measured at 6 weeks and 1 year.
There is moderate quality evidence (imprecision) that there is probably no difference in the mean number of sick days between blinded and non-blinded groups to MRI results.

X-ray and costs
One study[52] (n=421) compared patients with low back pain that received x-ray to a group that received usual care without x-ray. Direct mean costs were $250 in the x-ray-group compared to $180 in the usual care group without x-ray. Indirect mean costs were $748 in the x-ray-group compared to $653 in the usual care group without x-ray. Observed differences were significant for direct mean costs, but not for the indirect costs.

There is moderate quality evidence (serious limitations) that direct costs are probably higher for the x-ray-group. There is probably no difference in the indirect costs.

X-ray and healthcare utilization
Two studies[53,54] compared patient groups who received x-ray with control groups that did not receive x-ray.
The study of Kendrick et al. (n=421) reported a relative risk of 1.62 (CI 1.33-1.97) for the x-ray-group to have visited a doctor in the past 3 months compared with the control group. Relative risks for other forms of healthcare utilization, like physical therapy, osteopathy, and medication use, showed no significant differences between groups.[53]
Kerry et al. (n=139) reported no significant differences in the RCT-section of the study between the x-ray-group and the no x-ray-group in any of the outcome measures. This study also contains an observational arm of which the results are shown in the results of the observational studies.[54]
There is low quality evidence (serious limitations, imprecision) from two studies that there may be no association between performing x-ray and the amount of healthcare utilization.

X-ray and absence from work
One study[53] (n=421) showed that performing x-ray has no significant influence on taken time off work and the median number of days off work.
There is moderate quality evidence (serious limitations) that there is probably no influence of performing x-ray on absence from work.

Imaging studies (MRI or CT) and costs
One study[55] (n=782) compared early imaging with delayed, selective imaging.
In the period of 0-8 months, the early imaging-group had significantly more mean expenses on imaging ($139.95) and physical therapy ($57.45), compared with the group of delayed, selective imaging (resp. $44.79 and $41.44). In the period of 9-24 months, the early imaging-group had significantly higher mean costs of hospital admissions ($100.13) compared with the group of delayed, selective imaging ($62.79). Outcome measures (outpatient consultations, surgery, injections, back support/corset/brace, GP consultations, prescription

medicines, non-prescription medicines, and special tests) showed differences, but were not statistically significant.
There is very low quality evidence (very serious limitations, inconsistency) to support that we are uncertain that imaging can lead to higher costs.

Imaging studies (MRI or CT) and healthcare utilization
No studies were found that report on this possible relationship.

Imaging (x-ray, MRI or CT) and absence from work
No studies were found that report on this possible relationship.

OBSERVATIONAL STUDIES

MRI and costs
Three studies[25,56,57] compared early MRI versus no MRI in low back pain patients. Webster et al. 2010 (n=7210) found significantly higher mean total medical costs for the early MRI group ($21,921) compared to the no-MRI group ($2,779).[25]
The study of Webster et al. 2013 (n=555) showed that total medical costs were significantly lower in the no-MRI group compared to the early MRI group. $4,100 and $2,306 for radiculopathy and nonspecific LBP in the no-MRI group versus $22,339 and $17,028 for radiculopathy and nonspecific LBP in the early MRI group.[57]
Graves et al. (n=1770) report significantly higher costs (outpatient services, inpatient services, non-medical, and disability compensation) for the early MRI group versus the no-MRI group. Mean total costs were $22,151 versus $6,640.[56]
There is low quality evidence that early MRI may lead to an increase in costs.

MRI and healthcare utilization
Four studies[25,56,58,59] compared patients with low back pain who received MRI, with patients who did not receive MRI.
Webster et al. 2010 revealed that the percentage to undergo surgery for the no-MRI group was 0.8% versus 22.0% for the early MRI group.[25] This difference was significant.
Graves et al. reported significant differences between the early MRI group and the no MRI group for receiving an injection (40.8% versus 6.9%), surgery (19.9% versus 2.5%) and mean visits of physical therapy/osteopathy (18.4 versus 6.8) and outpatient (12.2 versus 4.3) at 12 months. The number of mean visits chiropractic did not differ between groups.[56]
Webster et al. 2014 revealed relative risks for the early or timely MRI group versus the no-MRI group for receiving injections (25.17-32.70), EMG/NCV (35.13-54.89), advanced imaging (13.04-20.53) and surgery (6.48-33.80) at 6 months. Results were displayed in a range, because groups were divided into more or less severe, and into early or timely MRI.[58]
Aaronson et al. found with univariate analysis that patients who had an MRI were significantly more likely to be admitted to observation (74.2% versus 10.8%) and had a longer Emergency Department length of stay (median 4.8 hours versus 2.7).[59]
Overall, there is low quality evidence (large magnitude of an effect, indirectness of evidence) that receiving an early MRI may lead to an increase in healthcare utilization.

MRI and absence from work
Two studies[25,57] compared early MRI versus no MRI in low back pain patients.
Webster et al. 2010 reported a mean first absence from work period of 133.6 (CI 120.5-146.7) days for the early MRI-group versus 22.9 (CI 19.5-26.2) days for the no MRI group.[25]
Webster et al. 2013 reported a significantly longer length of mean first absence from work period for the early MRI-group, regardless of radiculopathy. Patients with nonspecific LBP in the early MRI-group had on average 165 (CI 128.5-201.5) sick days, where the no-MRI group only had 44.4 (CI 37.5-51.4) sick days on average. The rate of absence of work was 72% lower in no-MRI groups for the radiculopathy cases and 68% lower for the patients with nonspecific LBP cases.[57]
Low quality evidence supports that patients with low back pain who receive early MRI probably have a longer mean first absence from work period compared to the no-MRI group. There is low quality evidence that patients who receive early MRI may have a higher rate of absence from work compared to the no-MRI group.

X-ray and costs
No studies were found that report on this possible relationship.

X-ray and healthcare utilization

One study[54] (n=419) compared a patient group who received x-ray with a group that did not receive x-ray.
In the observational arm of their study, Kerry et al. reported odds ratios of 1.6-2.4 for the x-ray-group to consult their GP subsequently for back pain (within six weeks: OR 2.1; CI 1.2-3.5, six weeks to one year: OR 1.6; CI 0.95-2.7) and for referral to another healthcare provider at recruitment (OR 1.8; CI 1.0-3.2), within six weeks (OR 2.4; CI 1.4-3.9) and in the period from six weeks to 1 year (OR 1.9; CI 1.2-3.2).
There is low quality evidence that performing x-ray for patients with low back pain may lead to an increase in healthcare utilization.

X-ray and absence from work

No studies were found that report on this possible relationship.

Imaging studies (x-ray, MRI or CT) and costs

No studies were found that report on this possible relationship.

Imaging (x-ray, MRI or CT) and healthcare utilization

Two studies[60,61] compared groups who received imaging versus groups that did not. The study of Fritz et al. showed higher odds ratios for the advanced imaging-group (MRI or CT) for surgery (OR 5.47; CI 2.22-13.49), injections (OR 3.67; CI 2.20-6.10), spine surgeon visit (OR 4.01; CI 2.26-7.11), any spine specialist visit (OR 4.58; CI 2.95-7.11) and emergency department visit (OR 3.82; CI 1.05-13.90), compared with the group that received physical therapy.[60]
Carey et al. report a significantly larger proportion of those referred for imaging (x-ray, MRI or CT) were prescribed medication (70%) compared with those who were not referred (39%, $p<0.001$).[61]
There is moderate quality evidence (large magnitude of an effect) that imaging probably leads to an increase in healthcare utilization.

Imaging (x-ray, MRI or CT) and absence from work

No studies were found that report on this possible relationship.

DISCUSSION

Statement of principal findings

This systematic review was performed to determine whether imaging in patients without red flags suggesting serious low back pain contributes to increased costs, healthcare utilization or absence from work.
This was the first study that systematically reports about differences in costs, healthcare utilization and absence from work, while comparing imaging versus no imaging in low back pain.
Overall, imaging (x-ray, CT or MRI) in low back pain does lead to an increase in costs, healthcare utilization or absence from work.

The results of this review revealed that all studies reported higher mean costs in the imaging groups in comparison with the non-imaging groups. Except for the RCT-section of the study of Kerry et al. the average amount of healthcare utilization in all studies was significantly higher in the group that received imaging for at least one criterion (e.g., medication, injections, surgery). There is conflicting evidence for the outcome measure "absence from work". RCTs showed no significant differences between x-ray or MRI groups compared with no imaging groups. However, the results of the observational studies did show significantly greater mean absence from work in the imaging groups in comparison with the no imaging-groups.

Strengths and limitations

A strength of this review is the sensitive search method. Because of the use of a wide variety of synonyms for patients, intervention, comparison and the three different outcome measures, the chances of missing relevant studies are low. Another strength of this study is the use of the GRADE methodology and a solid rating system for the included studies. Both RCTs and observational studies were included, which resulted in a broader overview of available information compared to including RCTs only. This broad overview resulted in a wide variety of information, due to the heterogeneity in design, population, type of imaging, type of control group, follow-up periods and outcome.

All stages of low back pain were included and the study selection was not restricted to "acute", "subacute", or "chronic" low back pain.[62,63] All RCTs and observational studies had methodological shortcomings.

Comparison with other literature

Previous similar literature research, performed by Karel et al. and Chou et al., focused on pain and function as outcomes, when comparing imaging versus no imaging in patients with low back pain and musculoskeletal disorders in general.[29,37] They found no significant differences between imaging and no imaging for any of the outcome measures. Therefore, in addition to the knowledge that imaging does not improve outcome in pain or function, there is a tendency that imaging in low back pain can lead to an increase of costs, healthcare utilization and absence from work.

Meaning of the study: possible mechanisms and implications for clinicians or policymakers

Appropriate imaging seems difficult for multiple reasons, resulting in both overuse and underuse of imaging for low back pain.[64] Guidelines recommend against use of imaging for people with low back pain.[13,65,66,67] Despite these recommendations, imaging rates are high.[68,69,70] It is possible to decrease imaging rates, but results of implementation programs on changing guidelines vary.[71,72,73,74,75] For example, imaging rates did not decrease after the Choosing Wisely campaign[69], but policy-making can have a positive effect on costs and healthcare utilization.[76]

This review contributes to an increased awareness of the possible negative implications of unnecessary imaging in low back pain. Low back pain without red flag symptoms is complex, and imaging does not provide accurate guidance to the most appropriate treatment options in this group of patients. Adjusting guidelines and the rate of adherence to them could help reduce costs, healthcare utilization and absence from work.

Future research

A suggestion for future research is to look at why rates and frequency of imaging are increasing. The answers to this question might help us identify why imaging is performed and how to reverse this trend.

Another suggestion is to develop standardized guidelines reporting about costs, healthcare utilization, and absence from work to be included in all RCTs and observational studies on the effect of imaging. These effects are often not described.[17] Previous research, especially in low back pain and imaging studies, had limited attention for these effects.

CONCLUSION

This study concludes that imaging in patients with low back pain does increase costs and healthcare utilization. There are indications that it also leads to higher absence from work. This is unwarranted for both patients and society since we know that imaging in low back pain has no health benefit.

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APPENDIX A: SEARCH STRATEGY

#1 ((“Low Back pain”[mesh] OR “Diskectomy”[mesh] OR “Spinal diseases”[mesh] OR “back injuries”[mesh] OR “spinal fusion”[mesh] OR “sciatica”[mesh] OR “Sciatic Neuropathy”[mesh] OR backpain*[tiab] OR lumbar pain*[tiab] OR lumbar back pain*[tiab] OR lumbar backach*[tiab] OR lumbar spine pain*[tiab] OR lbp[tiab] OR sacral pain*[tiab] OR dorsalgia[tiab] OR backach*[tiab] OR back ach*[tiab] OR back pain*[tiab] OR radicular pain*[tiab] OR herniated dis*[tiab] OR slipped dis*[tiab] OR Lumbago*[tiab] OR back disorder*[tiab] OR back injur*[tiab] OR spinal fusion*[tiab] OR postlaminectomy*[tiab] OR post laminectomy*[tiab] OR arachnoiditis[tiab] OR failed back*[tiab] OR spondylit*[tiab] OR spondylosis[tiab] OR sciatic*[tiab] OR discitis[tiab] OR Radicular syndrom*[tiab] OR Radicular pain*[tiab] OR Spondylolisthes*[tiab] OR scoliosis[tiab] OR spinal stenosis[tiab] OR root stenosis[tiab] OR spine stenosis[tiab] OR degeneration dis*[tiab] OR degenerative dis*[tiab] OR displaced dis*[tiab] OR Disc problem*[tiab] OR disk problem*[tiab] OR back disab*[tiab] OR Piriformis Syndrome[tiab]) OR ((“pain”[mesh] OR “Pain Measurement”[Mesh] OR “Hernia”[mesh] OR pain[tiab] or ache*[tiab] OR aching*[tiab] OR Physical Suffering*[tiab] OR hernia*[tiab] OR Analges*[tiab] OR Nociception*[tiab]) AND (“Spine”[mesh] OR “back”[mesh] OR “spinal nerves”[mesh] OR “Intervertebral Disc”[mesh] OR spine*[tiab] OR spinal[tiab] OR Intervertebral Disk*[tiab] OR Lumbar Vertebra*[tiab] OR sacrum*[tiab] OR Cauda Equina*[tiab] OR facet joint*[tiab] OR coccyx[tiab] OR coccydynia[tiab] OR Ventral Root*[tiab] OR Dorsal Root*[tiab] OR anterior root*[tiab] OR posterior root*[tiab])))

#2 (“Magnetic Resonance Imaging”[mh] OR “magnetic resonance spectroscopy”[mh] OR magnetic resonance[tiab] OR NMR[tiab] OR MR[tiab] OR MRI[tiab] OR MRIs[tiab] OR mrs[tiab] OR MRSI[tiab] OR fMRI[tiab] OR fMRIs[tiab] OR fcmri[tiab] OR cmr[tiab] OR MRA[tiab] OR diffusion weighted[tiab] OR perfusion weighted[tiab] OR diffusion tensor[tiab] OR tractography[tiab] OR magnetization transfer*[tiab] OR zeugmatograph*[tiab] OR echo-planar[tiab] OR echoplanar[tiab] OR proton spin tomograph*[tiab] OR 1H-MR*[tiab] OR 1HMR*[tiab] OR H-MR*[tiab] OR HMR*[tiab] OR tesla[tiab] OR DWI[tiab] OR DTI[tiab] OR

2

arterial spin labelling[tiab] OR arterial spin labeling[tiab] OR current density imag*[tiab] OR MP-RAGE[tiab] OR MPRAGE[tiab] OR turbo spin echo*[tiab] OR T1weighted[tiab] OR T2weighted[tiab] OR T1-weighted[tiab] OR T2-weighted[tiab] OR t2 star[tiab] OR t2-map*[tiab] OR t2-value*[tiab] OR t2-relax*[tiab] OR t1-map*[tiab] OR t1-value*[tiab] OR t1-relax*[tiab] OR dgemric[tiab] OR ASL[tiab] OR imaging[tiab] OR "Radiography"[Mesh] OR radiograph*[tiab] OR Roentgenograph*[tiab] OR Tomography[mesh] OR tomograph*[tiab] OR "Diagnostic Imaging"[Mesh:NoExp] OR "Diagnostic Imaging"[SH] OR "Tomography, X-Ray Computed"[Mesh] OR ct[tiab] OR cts[tiab] OR cat scan*[tiab] OR catscan*[tiab] OR x ray*[tiab] OR xray*[tiab] OR scan*[tiab] OR photograph*[tiab] OR photo[tiab] OR photos[tiab] OR radiolog*[tiab] OR ACR[tiab])

#3 ("costs and cost analysis"[mesh] OR "cost of illness"[mesh] OR "Health Care Costs"[Mesh] OR "Insurance"[Mesh] OR "Referral and Consultation"[Mesh] OR Budget control*[tiab] OR Budget saving*[tiab] OR Care budget*[tiab] OR care expen*[tiab] OR Care expen*[tiab] OR Care fund*[tiab] OR Care spend*[tiab] OR champus[tiab] OR Claim analysis[tiab] OR Claim review*[tiab] OR Claims Analysis[tiab] OR Claims Review*[tiab] OR Coinsurance*[tiab] OR Competitive Health Plan*[tiab] OR Competitive Medical Plan*[tiab] OR control cost*[tiab] OR Cost allocat*[tiab] OR Cost analy*[tiab] OR Cost apportionment*[tiab] OR Cost benefit*[tiab] OR Cost compar*[tiab] OR Cost contain*[tiab] OR Cost control*[tiab] OR Cost effective*[tiab] OR Cost Efficien*[tiab] OR Cost evaluat*[tiab] OR Cost increase*[tiab] OR Cost manag*[tiab] OR Cost minimi*[tiab] OR Cost reduc*[tiab] OR Cost reduction[tiab] OR Cost saving*[tiab] OR Cost sharing[tiab] OR Cost shifting*[tiab] OR Costeffect*[tiab] OR Cost minimisation[tiab] OR Cost minimization[tiab] OR Deductible*[tiab] OR direct cost*[tiab] OR Economic evaluat*[tiab] OR Health Benefit Plan*[tiab] OR Health budget*[tiab] OR health care cost*[tiab] OR Health care saving*[tiab] OR health care spending[tiab] OR health care system*[tiab] OR health cost*[tiab] OR health expen*[tiab] OR health expenditure*[tiab] OR Health fund*[tiab] OR Health spend*[tiab] OR health spending*[tiab] OR Healthcare budget*[tiab] OR Healthcare cost*[tiab] OR healthcare expen*[tiab] OR Healthcare fund*[tiab] OR Healthcare savings[tiab] OR Healthcare spend*[tiab] OR healthcare spending*[tiab] OR healthcare system*[tiab] OR High cost*[tiab] OR High spend*[tiab] OR Increasing cost*[tiab] OR insuran*[tiab] OR Low cost*[tiab] OR managed car*[tiab] OR Medical budget*[tiab] OR Medical Care Cost*[tiab] OR medical cost*[tiab] OR Medical expen*[tiab] OR Medical fund*[tiab] OR medical saving*[tiab] OR Medical saving*[tiab] OR Medical spend*[tiab] OR medicare[tiab] OR Preferred provider*[tiab] OR Reducing cost*[tiab] OR Reimburs*[tiab] OR Rising cost*[tiab] OR Saving cost*[tiab] OR societal cost*[tiab] OR Third-Party Pay*[tiab] OR Treatment Cost*[tiab] OR Usage reduction*[tiab] OR Value Based Purchas*[tiab] OR Worker Compensation*[tiab] OR Worker s compensation*[tiab] OR Workers compensation*[tiab])

#4 ("Health Services Misuse"[Mesh] OR appropriateness criteria[tiab] OR overus*[tiab] OR over us*[tiab] OR overutili*[tiab] OR over utili*[tiab] OR misuse*[tiab] OR mis use[tiab] OR Unnecessary Surgery[tiab] OR Unnecessary procedur*[tiab] OR Unnecessary treat*[tiab] OR Unnecessary medic*[tiab] OR Overdiagno*[tiab] OR Over diagno*[tiab] OR Overmedication*[tiab] OR Over medication*[tiab] OR Misdiagnosi*[tiab] OR Mis diagnosi*[tiab] OR Unwanted Medical Car*[tiab] OR Overtreat*[tiab] OR over treat*[tiab] OR inappropriate[tiab] OR Justif*[tiab])

#5 ("absenteeism"[mesh] OR "Sick leave"[mesh] OR "Return to work"[mesh] OR work absen*[tiab] OR work disabilit* OR absenteeism[tiab] OR sick leav*[tiab] OR sick day*[tiab] OR sickness absen*[tiab] OR disability leav*[tiab] OR Illness Day*[tiab] OR absenteeism[tiab] OR absentism[tiab] or return to work[tiab] OR returning to work[tiab] OR absence from work*[tiab] OR away from work[tiab] OR employee performance[tiab] OR job performance[tiab] OR lost work day*[tiab] OR lost work*[tiab] OR missed work*[tiab] OR missing work[tiab] OR presenteeism[tiab] OR work ability[tiab] OR work attend*[tiab] OR work day*[tiab] OR work impairment*[tiab] OR workday*[tiab] OR work performance*[tiab] OR work productivity*[tiab] OR work loss*[tiab])

#6 #3 OR #4 OR #5

#7 #1 AND #2 AND #6

#8 routine diagnostic imaging[tiab] OR Unnecessary scan*[tiab] OR Unnecessary mri*[tiab] OR Unnecessary radiograph*[tiab] OR Unnecessary imag*[tiab] OR Unnecessary x ray* OR acr appropriateness criteria*[tiab] OR choosing wisely[tiab] OR Mri utiliz*[tiab] OR MRI use[tiab] OR MRI usage[tiab] OR CT utiliz*[tiab] OR CT use[tiab] OR CT usage[tiab] OR image utiliz*[tiab] OR image use[tiab] OR scan utiliz*[tiab] OR scan use[tiab] OR scan usage[tiab] OR x ray utiliz*[tiab] OR x ray use[tiab] OR x ray usage[tiab] OR radiography use[tiab] OR radiography utiliz*[tiab] OR Early mri*[tiab] OR early x ray*[tiab] OR early imag*[tiab] OR early radiograph*[tiab]

#9 #1 AND #8

#10 #7 OR #9

Chapter 3

Guideline adherence of physiotherapists in the treatment of patients with low back pain: a qualitative study

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ABSTRACT

Rationale: Adherence rates to guidelines show room for improvement, and increase in adherence to guidelines may potentially lead to better outcomes and reduced costs of treatment. To improve adherence, it is essential to understand the considerations of physiotherapists regarding the assessment and management of low back pain. The purpose of this study is to gain insight in the considerations of Dutch physiotherapists on adherence to the national physiotherapy guideline in the treatment of patients with low back pain.

Methods: This is a qualitative study, using an interpretive approach of semi-structured interviews with 14 physiotherapists who regularly treat patients with low back pain. Thematic analysis was conducted with open coding using an existing framework. This framework distinguishes five components to adherence based on patient factors, provider factors, guideline characteristics, institutional factors, and the implementation process.

Results: Participating physiotherapists mentioned that the guideline should provide more information about psychosocial prognostic factors and psychosocial treatment options. The participants experienced difficulties in addressing patient expectations that conflict with guideline recommendations. The implementation process of the guideline was considered insufficient. Physiotherapists might rely too much on their experience, and knowledge on evidence-based treatment might be improved. In general, the interviewed physiotherapists thought they were mainly non-adherent to the guidelines. However, when comparing their considerations with the actual guideline recommendations they were mainly adherent.

Conclusion: To improve adherence, the guideline should provide more information about addressing psychosocial prognostic factors, and Dutch physiotherapists might be trained in communication skills to better address patient expectations. A more extensive implementation process is warranted for the next guideline to increase the physiotherapists' knowledge on evidence-based treatment.

INTRODUCTION

Low back pain (LBP) poses a major burden on modern healthcare systems. It is the most prevalent musculoskeletal disorder worldwide and the treatment and societal costs are very high and increasing over time, warranting more efficient care.[1,2,3] Fifteen percent of the patients receiving physical therapy in primary care suffer from low back pain.[4] In The Netherlands, a national guideline for low back pain is available for physical therapists to guide clinical decision making.[4] This guideline was recently updated without changes to the main content. The scientific evidence for the recommendations has increased.[5] An increase in adherence to guidelines may lead to better outcomes and may reduce costs of treatment.[6,7,8,9,10,11,12] Yet, in quantitative studies, adherence rates to these guidelines show room for improvement.[6,13,14,15,16,17,18,19] Rutten et al. studied the adherence rates of physical therapists to the Dutch physical therapy guideline for low back pain. They reported percentages of adherence ranging from 2% to 99% for the individual steps of the diagnostic process and from 47% to 88% for the individual steps of the therapeutic process.[6] In the study of Bahns et al., physical therapists in Germany adhered to the guideline recommendations in 38% of the low back pain cases.[20] Qualitative studies evaluating considerations for adhering to guidelines for low back pain are scarce. A qualitative study found that perceived barriers and facilitators of Dutch general practitioners towards using their guidelines were patient-related, suggesting that current guidelines do not always adequately incorporate patient preferences, needs, and abilities. The perceived adherence and perceived barriers varied largely across recommendations and consisted of patient ability and behavior, patient preferences, and lack of applicability of recommendations in general.[21] Côté et al. reported in a qualitative study that it appears that physical therapists' understanding of the guideline for low back pain, the level of compatibility between their practices and the guideline recommendations, the level of guideline relevance as perceived by the physical therapists, and their level of agreement with the guidelines, all affected their use of the guidelines.[22] Poitras et al. conducted a qualitative study and found that physical therapists thought that the guidelines did not provide enough information on the pathophysiological management of LBP, and that management recommendations could conflict with patient expectations.[23] Physical therapists often struggle to adhere to guideline recommendations.[18,20] It has been suggested that this is because they are used to a biomedical approach or because they think the patient is expecting a "hands-on-treatment".[6,20,24,25,26,27,28] The social context of each patient differs and a person centered approach seems to be warranted.[29] A systematic review of quantitative and qualitative studies by Gardner et al. revealed two main considerations of physical therapists in their management of chronic low back pain: a biomedical treatment orientation and patient factors, such as patient beliefs and treatment expectations.[20,28,30]

To improve adherence, it is essential to understand the considerations of physical therapists regarding assessment and management of low back pain.[6,12,31,32,33] The considerations of Dutch physical therapists regarding guideline adherence to the low back pain guideline have not been previously investigated through qualitative research. This qualitative study therefore aims to gain insight in the considerations of Dutch physical therapists on guideline adherence in the treatment of patients with low back pain.

METHODS

Study design and setting

This qualitative study, using an interpretive approach, was conducted to clarify underlying meanings of quantitative data of previous research, and to further understand the considerations of physical therapists on being nonadherent to the guideline.[6,20,34] To design and report the qualitative research the COREQ checklist was used.[35] Ethics approval for this study was obtained from the Radboud University Medical Centre Ethics Committee (registration no. 2020-6675). This study was performed in accordance with the declaration of Helsinki.

This study was performed in The Netherlands, where physical therapy care is part of primary care practice. Patients with low back pain can consult a physical therapist with or without a referral from their general practitioner. The majority of patients are covered for physical therapy services by their health insurer. The amount of reimbursement is limited, and differs between insurance companies and health insurance packages.

The current national guideline for physical therapy on low back pain, published by the Royal Dutch Society for Physical therapy (KNGF) recommends dividing patients with low back pain into three profiles based on duration and the course of low back pain, and psychosocial prognostic factors.[4,5] A summary of recommendations is provided in Table 1. Recommendations are mainly in accordance with international guidelines for low back pain.[36,37]

Table 1. Summary of recommendations of the Royal Dutch Society for Physical therapy guideline on low back pain[4]

Measurement instruments The guideline development team recommends the following measurement instruments for the assessment of limitations of activities and restrictions of participation: · Numeric Rating Scale for Pain (NRS Pain); · Patient-Specific Complaints (PSC); · Quebec Back Pain Disability Scale (QBPDS).
Therapeutic process Management strategy for non-specific low back pain with normal course (profile 1) · Reassure the patient. · Explain that low back pain is not a serious condition, often resolves spontaneously, but may recur. · Preferably do not recommend continuous bed rest. Recommend a maximum of 2 days of bed rest if that is the only way for the patient to sufficiently control the pain; explain that the bed rest should thereafter be gradually phased out. · Avoid recommendations that encourage the patient to remain passive, and recommend a physically active lifestyle. · Explain that increased activity will not damage any structures in the patient's back. · Explain that (moderate and gradually increasing) exercise, gradually increasing activity levels, and continuing or resuming work (if necessary with temporarily adjusted workload) promote recovery. · Limit the number of treatments to 3 sessions.

3

Management strategy for non-specific low back pain with abnormal course, without dominant presence of psychosocial factors impeding recovery (profile 2)
· Avoid recommendations that encourage the patient to remain passive, and recommend a physically active lifestyle.
· Explain that an increase in pain is not associated with damage to structures in the patient's back.
· Encourage the patient to engage in (moderate and gradually increasing) exercise, gradually increase their activity levels, and continue or resume work (if necessary with temporarily adjusted workload).
· Design an exercise program that fits in with the patient's needs and your own expertise and experience as a therapist.
· In case of impaired joint functionality, consider:
  · joint mobilization or manipulation and/or
  · massage or thermal therapy (of limited duration) to reduce the pain. If necessary refer patient to a manual therapist.
  · If the patient has been on sick-leave for more than 4 weeks, ask about any arrangements that have been made with the company doctor, and if necessary discuss the management strategy with the company doctor or company physical therapist.

Note: The guideline development team discourages the use of electrotherapy, TENS, ultra-shortwave, ultrasound and traction, in view of the lack of evidence.

Management strategy for non-specific low back pain with abnormal course, with dominant presence of psychosocial factors impeding recovery (profile 3)
· Advise the patient to keep exercising and explain to them that movements are not harmful and even speed up the recovery process.
· Emphasize that the patient's psychosocial factors (depressive feelings, fear of movement, catastrophizing, etc) may have an adverse influence on their recovery.
  · Recommend contacting the family doctor, company doctor and/or psychologist if serious or persistent psychosocial factors are hampering the recovery, and discuss the management options.
· Discuss the management options with the patient's company doctor, company physical therapist or the occupational health and safety service if the recovery process is being impeded by heavy physical work, prolonged sick leave or a labor dispute, or if collaboration is expected to promote the recovery.
· Encourage the patient to engage in (moderate and gradually increasing) exercise, gradually increase their activity levels, and continue or resume work (if necessary with temporarily adjusted workload).
· Prescribe a graded activities program.
· If the patient is on sick leave, try to match the targets of the exercise program to the targets for work resumption.
· Contact the patient's family doctor if the treatment has had no effect (in the sense of increased activity and participation levels) after 3-6 weeks, and terminate the treatment.

Participants

A purposive sampling method was used to recruit physical therapists for the interviews through recruitment messages on social media accounts of the Radboud university medical centre, and the researchers and their network.[38] Participants were eligible when they had a bachelor's degree in physical therapy and when they treated at least 5 patients with low back pain per week on average. To ensure that all categories of physical therapy (i.e., specialization, years of experience, employer or employee, age) were included, consecutive registrations of physical therapists were included until sufficient participants in one category of physical therapy specialism or type of employment were reached. Thereafter the other categories were filled with consecutive registrations. This strategy was used to ensure a representative sample of physical therapists. All participants were informed about the aim and procedures of the study. If the participants agreed to participate, verbal and written consent was provided for the interview, the recording, and the publication of anonymized data.

Interviews

Both researchers (GL and JB) interviewed the physical therapists. There was no pre-existing relationship between the interviewers and participants. Both researchers were trained and experienced in conducting interviews and had multiple years of experience in the field of low back pain.

For this study, an interview guide was developed using an iterative consensus process involving all participating researchers. The complete interview guide is presented in Appendix A. The participants were asked about their experience with the use of the low back pain guideline of the Royal Dutch Society for Physical therapy and about their considerations for not adhering to the guideline. The main topics were the considerations of the physical therapists in the diagnostic phase, treatment phase, and considerations concerning the use of questionnaires.

Next, this interview guide and the procedure was pilot tested prior to the actual interviews by conducting two test interviews. After the first two interviews, the researchers provided each other with feedback to optimize the interviewing process. These two interviews were not analyzed for this study. The number of interviews depended on the point of saturation, i.e., when no new information could be identified in the interviews.[39] The interviews were performed through a video conference with a mean duration of one hour. Field notes were made during the interviews. The interviews were audio recorded and subsequently transcribed verbatim. The transcripts of the interviews were offered to the participants for corrections and additional comments.[40,41]

Data analysis

Thematic analysis was conducted with open coding within a framework suggested by Cabana in 2010.[33] Coding is the interpretative process in which conceptual labels are given to data.[42] This framework distinguishes five components of adherence to clinical guidelines: based on 1. patient factors, 2. provider factors, 3. guideline characteristics, 4. institutional factors, and 5. the implementation process. Within the use of this framework, this study's approach is considered as partially inductive as well as deductive.

The data were analyzed through thematic analysis, with the unit of analysis being the recorded interviews.[43] In thematic analysis, researchers get familiar with the data by reading and re-reading the data, generate initial 'open' codes, search for overarching themes, and review these themes.[43] After the first two interviews, not the test interviews, the interviewers (GL and JB) each transcribed one interview and coded both transcripts separately. The researchers considered quotes concerning assessment, management as non-adherent to the guideline if they conflicted with the guideline recommendations. Adding something to the guideline recommendations was considered adherent. In this study, the considerations on non-adherence are displayed and discussed. Most of the considerations can also be interpreted as adherence instead of non-adherence. A description of the coding tree is presented in table 3. The researchers have a different background to ensure different reflexive positions (GL= manual therapy, JB= healthcare policy and management, JBS=epidemiology, WL= psychology, GW= medical sociology, PW= allied health sciences). First, transcripts were read, and relevant words, sentences, or paragraphs related to guideline adherence were marked and coded. Qualitative data analysis software program Atlas.ti version 8.4.20 was used to code the interview transcripts. Second, codes concerning the same type of consideration were grouped together into a category. Finally, categories were reviewed for patterns to

create overarching themes. GL and JB discussed each step until consensus was reached between both researchers. A third researcher (PW) was consulted when needed. Categories and themes were formed with the unanimous agreement of the researchers. Relevant quotes were selected from the transcripts to illustrate the categories and themes.

RESULTS

Study population

Fifteen Dutch physical therapists responded to participate in this study. One participant dropped out prior to the interview due to personal circumstances. Therefore, we conducted 14 semi-structured individual interviews. Interviews 10 to 14 revealed only one new theme. Therefore, the researchers concluded that saturation was reached. Participant characteristics are presented in Table 2. Physical therapists of different ages, specializations, types of employment, years of experience, and sex were included. The interviews took between 50 and 70 minutes. No other persons were present during the interview. There were no repeat interviews.

Table 2. Characteristics of Participants

Sex	**Interviews (n=14)**
Female (%)	5 (36)
Male (%)	9 (64)
Age (mean)(range)	**36,57 (22-64)**
22-30 years (%)	5 (36)
31-40 years (%)	4 (29)
41-65 years (%)	5 (36)
Specialization	
Manual Therapy (%)	9 (64)
Psychosomatic (%)	1 (7)
Sport (%)	1 (7)
None (%)	3 (21)
Type of employment	
Employer (%)	4 (29)
Employee (%)	10 (71)
Years of experience (mean)(range)	**13,46 (0-35)**
<8 years (%)	4 (29)
8 – 13 years (%)	5 (36)
>13 years (%)	5 (36)

Considerations for non-adherence

The participants mentioned multiple considerations for being non-adherent to the national physical therapy guideline low back pain (Table 3). In general, the interviewed physical therapists thought they were mainly non-adherent. However, when checking their considerations with the guideline they were mainly adherent. Physical therapists mentioned being non-adherent because of the use of specific questionnaires or treatment modalities but after a comparison with the guideline, these did not seem to conflict with the guideline recommendations.

Table 3. Considerations for non-adherence to the guideline Low Back Pain

Category	**Factor**
Patient Factors	
	Patient preference
	Financial status or health insurance coverage
	Patient is short in time
	High pain intensity
	Not willing to complete questionnaires
Provider factors	
	Experience with the treatment of patients with low back pain
	QBPDS[1] no added value according to physical therapist
	Physical therapist is unfamiliar with and/or does not use the QBPDS[1]
	Knowledge from specific courses or training
	Physical therapist feels short in time
	Laziness of the physical therapist
	Physical therapist only satisfied when at least a part of the treatment consisted of hands-on therapy
	Not using questionnaires at all
Guideline Characteristics	
	Diagnostics and treatment in profile one is too limited
	Aftercare or prevention for recurrence is not described
	Information provided is not detailed enough
	In profile three, physical therapist wants to do more in psychosocial domain than only graded activity
	Too much room for passive therapy modalities
Institutional Factors	
	Financial status of practice and/or average treatment sessions
	Agreements with the healthcare insurers for a specific form of stratified care for low back pain
Implementation Process	
	Implementation process was insufficient

[1]Quebec Back Pain Disability Scale

3

1. Patient factors

The majority of participants mentioned the health insurance coverage or financial situation of the patient as a reason to be non-adherent to the guideline. For example, patients with chronic low back pain with psychosocial factors, and with a bad financial situation often reject the treatment plan because of insufficient funding.

"Patients with no or limited health insurance coverage recover faster than patients with larger coverage. Patients with larger coverage think 'I am paying for it, so let's make use of this'." (participant 6)

Another consideration that was mentioned by a large proportion of participants was the preference of the patient (i.e., for passive therapy modalities like manual therapy, massage, etc.).

"Some patients almost demand you to perform massage or manual therapy while the advice from the guideline consists mainly of advice to stay active and to refrain from hands-on therapy." (participant 1)

A few participants mentioned that patients had a lack of time or were unwilling to complete questionnaires, causing the therapist not being able to be guideline adherent. High pain intensity was also mentioned as a factor to cause non-adherence because the physical therapist was not able to perform the appropriate assessment or was limited to passive therapy modalities in the choice of treatment.

2. Provider factors

The majority of participants mentioned considerations for non-adherence because of experience with successful treatments that were not recommended in the Low Back Pain guideline.

"I look at results from previous cases. If a not-recommended type of therapy was successful in a similar case I often apply that therapy again. I know that is not a guarantee, but that is how I work." (participant 10)

The Quebec Backpain Disability Scale[44] is recommended by the guideline for the assessment of limitations of activities and restrictions of participation (table 1). The participants mentioned not experiencing added value when using this questionnaire and therefore often being non-adherent on this item. Some participants mentioned being unfamiliar with the Quebec Backpain Disability Scale or just not using it. This led to non-adherence in multiple cases.

"The Quebec Backpain Disability Scale has no added value for me in the assessment or management of a patient with low back pain." (participant 12)

Other possible reasons for non-adherence were specific courses or training (i.e., passive therapy modalities, which are not recommended for more than three sessions in the guideline), financial considerations for the provider, and lack of time or laziness of the physical therapist.

"Sometimes just laziness is the reason to be non-adherent, I think. Sometimes I work on the autopilot." (participant 8)

A few physical therapists mentioned that they were only satisfied with the treatment when at least a part of the treatment consisted of hands-on therapy.

"I have 20 years of experience in physical therapy and in treating patients with low back pain. When I see a patient, I know from my experience that I can fix this problem in 1 or 2 sessions of hands-on treatment, despite the guideline advice to refrain from hands-on therapy." (Participant 14)

3. Guideline characteristics

In general, physical therapists are satisfied that there is a guideline on low back pain although they have some remarks on the content of it. The majority of participants mentioned that the guideline is too limited in prognostic factors and diagnostics, especially in cases of acute low back pain.

"When a patient with acute low back pain shows a lot of psychosocial prognostic factors it is hard for me to just reassure and give the advice to stay active." (Participant 2)

A fair number of participants mentioned that the guideline lacks recommendations for aftercare and prevention of recurrence for patients who had multiple episodes of low back pain.

"I struggle the most with patients with recurrent low back pain. The don't seem to fit in one of the profiles." (participant 3)

A small number of participants mentioned that the guideline recommendations for the treatment of people with chronic low back pain with psychosocial prognostic factors (profile 3) are limited to mainly graded activity. In graded activity, a behaviorally-oriented treatment, the aim is to restore functionality by decreasing patient disability and to achieve this target by positively reinforcing patient activity levels in a time contingent manner despite existing pain levels.[45] Based on current evidence, therapists would like to add treatments based on psychosocial prognostic factors such as other forms of cognitive behavioral therapy, motivational interviewing, acceptance and commitment therapy, pain neuroscience education, etc.

"I think it is beneficial for the patient to pay more attention to stress management and relaxation instead of limiting the treatment to graded activity or even before starting with graded activity." (participant 7)

Another reason mentioned for non-adherence was the guideline lacking detail in general, and lacking guidance on referral to other healthcare professionals. The guideline recommendations also leave too much room for passive therapy forms, like massage, ultrasound, etc.

"If the guideline provided more detailed direction, it would be easier for me to be more adherent to it." (participant 9)

4. Institutional characteristics

A fair number of participants mentioned that their private practice had agreements with the healthcare insurers for a specific form of stratified care for low back pain. In the most of these forms of stratified care, the outcome of the STarT Back Screening Tool was the only factor to determine which

treatment protocol was to be followed. This might conflict with the guideline recommendations.

"We work with a stratified form of care based on low, medium, and high risk for future disability derived from the STarT Back Screening Tool. There are some similarities with the guideline, but in our company, the guideline recommendations are secondary to what we do, based on the STarT Back Screening Tool." (participant 12)

The average treatment sessions and the turnover of the institution were also mentioned as reasons for non-adherence.

"I can imagine the consideration of a colleague to schedule 1 or 2 extra treatment sessions while there is no medical need for it." (Participant 11)

5. Implementation process

A minority of the participants reported that a reason for being non-adherent was the unsuccessful implementation process of the guideline. Physical therapists are therefore not familiar enough with the content of the guideline.

"How can we reach physical therapists who are unwilling to adopt to a new guideline? What does the actual implementation process look like? Does everybody have to get familiar with the new guideline by email? Or would an actual training be better?" (participant 7)

DISCUSSION

Main findings and related literature

Understanding the considerations of physical therapists of being non-adherent to the guideline might help in updating the guideline, and therefore, possibly contribute to an increase of adherence rates, to reduce costs, and to improve treatment outcomes.[6,7,8,9,10,11,12] In this study, 22 considerations related to patient factors, provider factors, guideline characteristics, institutional factors, and the implementation process were found for being non-adherent to the low back pain guideline.

In summary, the participants mentioned that the guideline should provide more information about psychosocial prognostic factors and psychosocial treatment options. The physical therapists experience difficulties in addressing patient expectations that conflict with guideline recommendations. The implementation process of the guideline was insufficient. Physical therapists might rely too much on experience, and their knowledge on evidence-based treatment might be improved.

In general, the interviewed physical therapists thought they were mainly non-adherent. However, when checking their considerations with the guideline they were mainly adherent. On the other hand, no participant was completely adherent in the diagnostic phase, treatment phase, and in the use of questionnaires. These findings are in concordance with the study of Bahns et al.[20], Kiel et al.[19], and Rutten et al.[6]

Patient factors

The preference of the patient (i.e., for passive therapy modalities like manual therapy, massage, etc.) seems to be an important factor in guideline adherence. Physical therapists think that patients often prefer passive therapy modalities while the guideline recommendations consist mainly of advice to stay active, reassurance, and physical exercises. The physical therapists sometimes struggle with communication and shared decision-making in this context. Bekkering et al., 2003 and Kiel et al., 2020 conducted surveys among 100 physical therapy practices and among 977 patients of general practices to identify barriers for implementation of the low back pain guideline. Similar results concerning patient preference were found. In these studies, physical therapy practices reported discrepancies between the current treatment and the recommendations in the guidelines because they received negative responses from the patients, stating that patients were very focused on pain and expected "real" (hands-on) treatment instead of (hands-off) exercise therapy and education.[24] "Patient views are strongly influenced by previous treatment experiences and education level".[19] In addition to these results, Poitras et al. reported in a qualitative study that physical therapists thought that management recommendations could conflict with patient expectations.[23]

In the present study, the majority of participating physical therapists mentioned the health insurance coverage or financial situation of the patient as a reason to be non-adherent to the guideline. For example, when patients have no health insurance coverage and are not able to pay for physical therapy while the guideline recommendations consist of an extensive graded activity program, the physical therapist is unable to be adherent to the guideline. To date, no other studies are known to compare this finding with.

Provider factors

Experience with successful treatments not recommended in the guideline for patients with low back pain seems to play a role in non-adherence. Guideline adherence of physical therapists and general practitioners was previously researched by Bahns et al.[20], Bekkering et al.[24], and Lugtenberg et al.[32] In these studies, 38-67% of the physical therapists and general practitioners reported discrepancies between current practice and the guideline recommendations due to a lack of knowledge or skills. These findings support a lack of knowledge about the content of the guideline being a significant factor in guideline non-adherence, although these findings cannot be adequately compared, due to the differences between the studies. Bahns et al.[20] and Bekkering et al.[24] performed a survey amongst physical therapists to explore adherence to, amongst others, the low back pain guideline. Lugtenberg et al.[32] held focus group interviews with general practitioners for guideline adherence to multiple guidelines.

Guideline characteristics

The present study reveals that according to the participants the guideline offers too little guidance on prognostic factors and diagnostics, especially in acute low back pain. Based on the research of the last decade, physical therapists prefer to put more emphasis on psychosocial factors.[46] In the study of Lugtenberg et al.[32], the most frequently perceived barriers were lack of agreement with the recommendations due to lack of applicability or lack of evidence (68% of key recommendations), and guideline factors such as unclear or ambiguous guideline recommendations (43%). This lack might be partially compensated by adding a screening tool like the STarT Back Screening Tool. Current research supports the need for screening on prognostic factors, especially psychosocial factors.[46,47,48] A fair part of physical therapists already incorporated the STarT Back Screening Tool in their working method.

Institutional factors

The average number of offered treatment sessions and the income of the institution were mentioned as reasons for non-adherence. The physical therapists in this study mentioned feeling the need to ensure a low average of treatment sessions towards healthcare insurers. Sometimes, this conflicted with the guideline recommendations. For example, when a more comprehensive treatment program is recommended by the guideline. Besides, some physical therapists mentioned scheduling one or two extra treatments sometimes to fill gaps in their agenda. This might conflict with the recommendations of the guideline to restrict treatment to a maximum of 3 sessions for patients with profile 1 low back pain. The negative influence of organisational aspects was reported by 32% of the physical therapists concerning the diagnostic process in the study of Bekkering et al.[24] Lugtenberg et al. reported that one of the most perceived barriers was lack of agreement with the recommendations due to environmental factors such as organisational constraints (52%).[32]

Implementation process

A minority of the participants reported that a consideration for being non-adherent was the unsuccessful implementation process of the guideline. Therefore, physical therapists are not familiar enough with the content of the guideline. This is in concordance with the studies of Bahns et al.[20], Stander et al.[49], and Schröder et al.[28] Bahns et al. studied the overall guideline adherence to the national guideline on low back pain in Germany.[20] In the study of Stander et al. the guideline uptake of physical therapists in South Africa was explored. Schröder et al. reported a short-term increase in guideline adherence of physical therapists after a new implementation program. This increase in adherence diminished after 12 months.[28] Because of insufficient funding the guideline was only disseminated through the website of the Royal Dutch Society for Physical therapy and by a notification to the regional departments of this organisation. No training courses for physical therapists were provided. The guideline was recently updated. As no major changes in recommendations were made in comparison to the version of 2013, the results of this study are still relevant for the implementation of the updated version of the guideline.[4,5] A more extensive implementation process might be helpful to increase adherence to this new guideline.

Strengths and limitations

This is the first qualitative study that describes the considerations of Dutch physical therapists concerning adherence to the guideline for low back pain. Previous studies on this subject used quantitative designs or researched a different type of healthcare professionals.[6,20,24,32] Another strength of this study is that there was no pre-existing relationship between the interviewers and the physical therapists. The participants were assured that all the data would be processed anonymously. Hence, the physical therapists were able to speak freely about their considerations. The threshold for participation was rather low because the video interviews were scheduled at the convenience of the participants. Semi-structured video interviews with mainly open questions were used to explore considerations in-depth.[40,41] Interviews were scheduled until no new codes could be retrieved and saturation was reached. The study population consisted of a varied sample in terms of age, experience, specialization, type of employment, and sex.

A recommendation for future research is to further explore the considerations of patients concerning health insurance coverage and financial barriers in general when the physical therapist suggests a specific treatment plan.

Implications for practice

An increase in adherence to guidelines may lead to more evidence-based treatment decisions, better outcomes, and may reduce costs of treatment.[6,7,8,9,10,11,12] The researchers of this study provided recommendations to the Royal Dutch Society for Physical therapy for the development of the recent update of the guideline. There seems to be a need for guidance for the physical therapists in communication with the patient and shared decision making. Physical therapists prefer to acquire more details about psychosocial prognostic factors in the assessment of low back pain and like to address them more thoroughly in the management of low back pain. More guidance on these factors and a more extensive implementation process of the guideline might improve adherence. More effort should be made to educate physical therapists about evidence-based assessment and management of low back pain to increase adherence to the guideline recommendations.

CONCLUSION

To improve adherence, the guideline should provide more information about psychosocial prognostic factors, and more details about psychosocial treatment options. Guideline adherence might be improved by training Dutch physical therapists in communication skills to better address patient expectations that conflict with guideline recommendations. A more extensive implementation process is warranted for the next guideline to reach more physical therapists and to increase the physical therapists' knowledge on evidence-based treatment.

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3

APPENDIX 1

Interview guide

3 main questions that we want answers to. Considerations for:
- the diagnostic process
- the therapeutic process
- the use of questionnaires

Introduction:

Hello mr./ms.…….

Thank you for taking the time to participate in this study.

This research aims to improve physical therapy care for low back pain. The purpose of this interview is to explore your considerations concerning the use of the Royal Dutch Physical therapy Association guideline for low back pain. This will partly be done based on several patient cases.

In this interview of maximum one hour, I will ask questions regarding the purpose just described. Please try to answer as comprehensively as possible. Do you agree with the conversation being recorded? This recording will only be used for this study. All data is processed anonymously and confidentially, so feel free to be honest about your experiences and considerations.

General:
- Can you tell us something about your background? (i.e., the practice, work experience, specialization, etc.)

The Royal Dutch Physical Therapy Association (RDPA) guideline for low back pain:
- How do you apply the guideline in your daily practice?
- Do you know the different profiles of the RDPA guideline low back pain?
- How would you describe these profiles in your own words? (explain if necessary, see appendix)
- How do you use this profile classification when drawing up the treatment plan?
- Can you indicate whether the guideline is useful for you in practice?
- What do you think of the guideline? (manageability)
    - What are weaknesses of the guideline?
        - How do you deal with these?
    - What are strengths of the guideline?
- How much difficulty do you have in following the advice formulated in the guideline?
- What do you miss in the guideline?

"To stay close to the practice, we discuss a number of patient cases with you. We use this to determine the further direction of the interview."

- Patient case profile 2 (without the interviewee knowing the profile)
    - What are your considerations in the diagnostic process?
    - What are your considerations in the therapeutic process?
    - What are your considerations regarding questionnaires?
- Patient case profile 3 (without the interviewee knowing the profile)
    - What are your considerations in the diagnostic process?
    - What are your considerations in the therapeutic process?
    - What are your considerations regarding questionnaires?
- Patient case profile 1 (without the interviewee knowing the profile)
    - What are your considerations in the diagnostic process?
    - What are your considerations in the therapeutic process?
    - What are your considerations regarding questionnaires?

Diagnostic Process:
- Which diagnostic procedures do you often use for patients with low back pain?
    - For what reason do you use these?
- Which factors/items outside the guideline help determine the diagnostic process? (For example previous experience with low back pain research, time, pain intensity, degree of disability, convenience, reimbursement, money, duration of complaints, questionnaires, clinical reasoning, guideline implementation process, etc.)
- In approximately how many out of 10 cases does your diagnostic process match that of the guideline?

Therapeutic Process:
- Which therapeutic procedures do you often use for patients with low back pain?
    - For what reason do you use them?

- Which factors/items, which are not stated in the guideline, also determine the treatment process to be followed? (For example previous experience with low back pain treatment, time, pain intensity, degree of disability, convenience, reimbursement, money, duration of complaints, questionnaires, clinical reasoning, guideline implementation process, etc.)
- In approximately how many out of 10 cases does your therapeutic process match that of the guideline?
- In a discussion round with physical therapists during the yearly, national physical therapist's day, it was established that financial considerations influence the chosen care process for a patient. Do you have any idea what these therapists might mean by that? (If necessary, give the interviewer the examples: compensation, client's financial situation, and therapist's income)

Questionnaires:

- Which questionnaires do you use during the first contact with a patient with low back pain?
  - For what reason do you use these?
- In approximately how many of the 10 cases does your use of questionnaires match the recommendations of the guideline?

Always make a note of the following at the end of the interview: (if not mentioned at the intro/start)

- age
- sex
- amount of experience
- relevant courses
- specialization
- type of employment

Appendix:

Profile 1: non-specific low back pain with normal course

Profile 2: non-specific low back pain with abnormal course, without dominant presence of psychosocial factors impeding recovery

Profile 3: non-specific low back pain with abnormal course, with dominant presence of psychosocial factors impeding recovery

Chapter 4

The association of physical activity and sedentary behavior with low back pain disability trajectories: a prospective cohort study

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Submitted

ABSTRACT

Objective: To investigate whether habitual physical activity and sedentary behavior measured at the onset of physical therapy treatment in adults with low back pain are associated with disability trajectories.

Methods: Prospective cohort study in 347 patients with low back pain who sought physical therapy care at three primary care practices in the Netherlands. Linear mixed models were estimated to describe the association of habitual physical activity levels (Short Questionnaire to Assess Health-enhancing physical activity) and sedentary behavior (average sedentary hours per day) measured at the start of physical therapy treatment with disability (Oswestry Disability Index) trajectories at one and a half, three, six, and twelve months follow-up.

Results: Habitual sedentary behavior measured at the onset of physical therapy treatments in adults with low back pain were not associated with low back pain disability trajectories. For physical activity measured at the onset of physical therapy treatments, participants with one MET hour per day above average recovered 0.04 [95% CI 0.004 to 0.076] points on the ODI per month faster than participants with an average amount of MET hours per day.

Conclusion: Habitual sedentary behavior was not associated with low back pain disability trajectories. High levels of habitual physical activity before starting treatment of low back pain seems to be associated with improved recovery in low back pain disability trajectory, but the finding is not clinically relevant.

INTRODUCTION

Low back pain is a worldwide problem and it is the leading cause of disability and absence from work.[1,2,3] Fifteen percent of the patients receiving physical therapy in primary care suffer from low back pain.[4] Low back pain is a multifaceted problem and multiple prognostic factors can be of influence on the recovery process. The course of low back pain differs substantially between patients.[5]

The identification and increased knowledge of prognostic factors, such as habitual physical activity and sedentary behavior, may contribute to a better understanding of the course of low back pain and it may aid healthcare professionals and patients with low back pain to facilitate recovery.[6,7,8,9] Recommendations for people with low back pain in guidelines include the advice to remain physically active, because a prolonged time of inactivity will adversely affect recovery.[10,11] Furthermore, physical activity might speed up the recovery of low back pain.[4,12] On the other hand, strenuous levels of physical activity may also impede recovery.[13,14,15] This provides some evidence for a U-shaped relationship between physical activity and the prognosis of low back pain.[13,14] Contrary to this, multiple systematic reviews reported no evidence supporting physical activity as a factor positively influencing the course of low back pain.[16,17,18,19] For sedentary behavior several studies reported worse outcomes of low back pain recovery in people with more sedentary behavior compared to people with less sedentary behavior.[17,20,21,22,23] However, in the systematic review of cohort studies by Chen et al. no evidence was reported supporting less sedentary behavior as a factor positively influencing the course of low back pain.[24]

Understanding the role of physical activity and sedentary behavior in the recovery of people with low back pain is important for the treatment and the education of people with low back pain.[8,10,25] Other studies have reported separately about sedentary behavior or physical activity, but never simultaneously about physical activity and sedentary behavior.[22,26,27,28] As more sitting does not automatically mean less physical activity and vice versa, it is important to consider both factors in parallel. Other studies reported mainly about leisure time physical activity or other specific domains of physical activity while physical activity that results from work or household activities has a major influence on people's habitual physical activity levels.[13,15,17,21,22] Other studies that reported on the association of physical activity or sedentary behavior with low back pain recovery/disability showed results on one or two timepoints or had low follow-up percentages.[16,22,26,27,29,30,31]

In conclusion, there is conflicting and limited evidence on the role of physical activity and sedentary behavior in relation to the recovery of low back pain. Therefore, the aim of this cohort study is to investigate whether habitual physical activity levels and sedentary behavior measured at the start of physical therapy treatment in adults with low back pain are associated with disability trajectories. We aim to explore the entire trajectory of disability up to one year.

METHODS

Design

This prospective cohort study was conducted at three Dutch primary care physical therapy practices specialized in spine-related complaints, located in the cities Arnhem, Winterswijk, and Nijmegen. Initially, this project started off with six practices but three of them withdrew their participation in the starting phase of the project due to staffing problems. Participants were enrolled by 20 physical therapists employed in the three practices. Data collection took place between June 2020 and June 2021, with follow-up data collected through June 2022. This coincides with the COVID-19 pandemic. Participants were followed for up to twelve months. The study was performed in compliance with the Declaration of Helsinki and was approved by the Central Committee on Research Involving Human Subjects (Radboud CMO file number: 2020-6295). This study was registered in Clinicaltrials.gov (109643). The STROBE reporting guidelines for observational studies were used.[32]

Participants

Physical therapists enrolled consecutive low back pain patients at their first appointment. All patients who were eligible were asked to participate. Patients were eligible if they dealt with an episode of low back pain and were at least eighteen years old, including those with non-radicular leg pain, radicular leg pain and nonspecific low back pain. Individuals were excluded if they were unable to complete questionnaires and in case of pregnancy. All participants signed a

written informed consent before enrolment. The physical therapists also signed a written informed consent before participating in this study. All participants received usual physical therapy care according to the recommendations of the national guideline for physical therapy on low back pain. The guideline recommends dividing patients with LBP into three profiles based on LBP duration, the course of LBP, and psychosocial prognostic factors.[4] The number of treatment sessions and type of treatment were based on individual needs, ranging from manual therapy to exercise therapy to education whether or not in parallel. No other healthcare professionals were involved in the treatment.

Baseline measures

At baseline, participants' age, gender, educational level, number of previous episodes of low back pain, and duration of low back pain were collected digitally in the electronic health record system. Previous research revealed that these factors might affect the course of low back pain.[57] For example, people with a high number of previous episodes of low back pain often recover slower and less complete, probably due to the presence of multiple prognostic factors.[23] In addition, four questionnaires were completed, yielding data on habitual physical activity levels, habitual sedentary behavior, pain intensity, and disability.

The Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) was used to measure participants' habitual physical activity levels. The SQUASH gives an indication of habitual physical activity levels with respect to leisure time, occupation, household, and transportation over the past three months. The SQUASH has been validated with accelerometry.[33] All weekly physical activities were linked to the corresponding metabolic equivalent of task (MET) according to the compendium of physical activity used by the study by Bakker et al.[34] and Ainsworth et al.[35] The MET values of each activity were multiplied by the activity duration to obtain MET hours per day. Continuous values were used for analysis. Furthermore, six extra questions concerning sitting, standing, and lying down were added to the questionnaire to assess sedentary behavior. These questions were adopted from a report on sedentary behavior by the Dutch Organization of Applied Scientific Research (TNO).[36]

Outcome measures

The primary outcome was the score of the Oswestry Disability Index (ODI). The ODI was used to assess pain-related disability in people with low back pain. The total score of the ODI ranges from 0 (no limitation) to 100 (bed-bound or dramatic limitation).[38,39] The Minimal Clinically Important Change (MCIC) has been reported to be six points or a 30% improvement from baseline.[39,40,41]

Follow-up

Follow-up questionnaires at one and a half, three, six, and twelve months included mean pain intensity in the previous week (NPRS) and disability (ODI). Participants were requested to complete the questionnaire digitally. If the participants did not complete the questionnaires, they were contacted by their physical therapist via email or telephone to ask if they wanted to complete the questionnaires. In case of no response, they were contacted again within 48 hours by the coordinating researcher. In case of loss to follow-up, the reason for drop-out was registered by the physical therapist. All missing data are presented in figure 1.

Data analysis

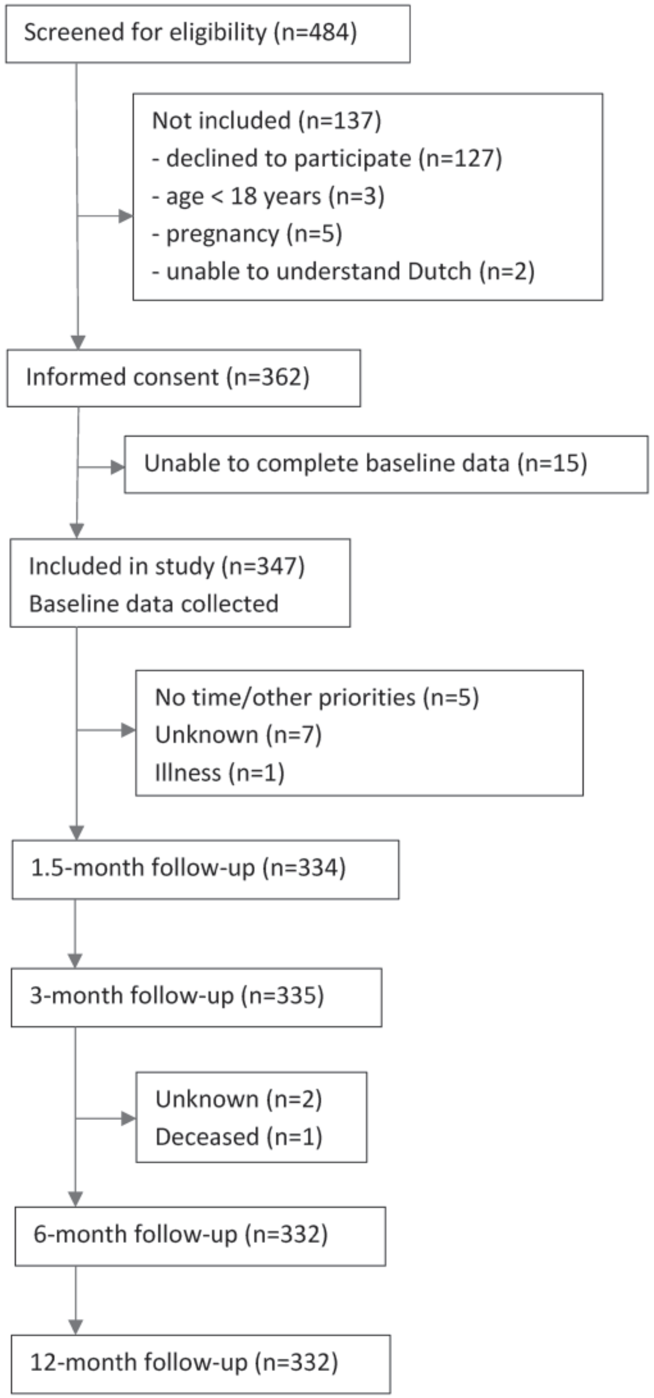
Descriptive statistics were applied to all variables included. General linear mixed models were used to describe the association of habitual physical activity levels and sedentary behavior measured at the start of physical therapy with disability (ODI) trajectories over follow-up at one and a half, three, six, and twelve months. Predictors were baseline levels of physical activity, gender, education level, sedentary behavior, age, pain, and disability, number of previous episodes of low back pain, and duration of low back pain. Individual growth modeling within the multilevel modeling framework was used.[42] R-statistics version 4.1.2 was used for descriptive statistics and the general linear mixed models. When data on one of the predictors sedentary behavior (n=57) and physical activity level (n=0) was missing, cases were left out of the analysis. Missing on ODI score at one of the follow-up timepoints was handled by the linear mixed models. Therefore, available ODI data was used in the analysis. In a second analysis, categories were created by dividing both physical activity and sedentary behavior into tertiles of low, medium, and high based on the data. Combining these categories resulted in nine categories with low, medium, and high physical activity, and low, medium, and high sedentary behavior. General linear mixed models were applied to compare eight categories with the reference category medium physical activity and low sedentary behavior. This category was chosen as the reference category, as previous studies pointed in the direction of low sedentary behavior and medium physical activity as most beneficial for the recovery of low back pain.[13,17,22]

RESULTS

The flow of participants through the study

In total, 484 consecutive potential participants were screened for eligibility. Of the 484 potential participants, 362 met the inclusion criteria (Figure 1). Fifteen participants were unable to complete the baseline data. A total of 347 participants were enrolled in the study, while 332 participants (95.7%) were successfully followed until the 12-month follow-up (15 participants were lost to follow-up). Some participants missed out on one follow-up measurement because of circumstances but continued to participate in the following measurements.

Figure 1. Flowchart of participants



Characteristics of participants

The mean age of the participants was 43 years (table 1). Of the 347 participants, 175 were male and 172 were female. Back pain duration at baseline was very different between participants. At baseline, the ODI had a median outcome of 18 and the NPRS a mean outcome of 5.3. Participants had a mean physical activity of 11.67 MET hours per day and a mean of 8.1 sitting hours per day. The group of participants showed a large heterogeneity on most of the baseline characteristics, resulting in large standard deviations. Table 1 contains the complete characteristics of the participants.

Table 1. Characteristics of Participants (n=347)

Gender (n)		**Questionnaires**	
Female (%)	172 (49.6)	ODI baseline (median)(IQR)	20 (10-32)
Male (%)	175 (50.4)	ODI 1.5 months (median)(IQR)	8 (2-20)
Age in years (mean)(SD)	43.41 (14.6)	ODI 3 months (median)(IQR)	6 (0-14)
Back pain duration at baseline (n) (%)		ODI 6 months (median)(IQR)	4 (0-14)
0-2 weeks	25 (7.2)	ODI 12 months (median)(IQR)	4 (0-10)
3-12 weeks	47 (13.5)	NPRS baseline (mean)(SD)	5.32 (2.3)
3-6 months	21 (6.1)	**Physical activity in MET hours per day (mean)(SD)**	
7-12 months	30 (8.6)	Total MET hours	11.67 (13.68)
1-4 years	91 (26.2)	**Sedentary behavior in hours per day (mean)(SD)**	
5-9 years	60 (17.3)	Sitting at work	4.77 (3.1)
10-20 years	43 (12.4)	Sitting or lying after work	3.77 (2.2)
>20 years	29 (8.4)	Total sedentary time	8.1 (3.8)

n= number, SD= Standard Deviation, ODI= Oswestry Disability Index, IQR=Inter Quartile Range NPRS=Numeric Pain Rating Scale, MET= Metabolic Equivalent of Task

Growth models

Building from the unconditional means model, the best fitting unconditional growth model for ODI over the follow-up included a linear and a quadratic fixed slope to allow the average patient to follow a recovery trajectory that initially improved with -3.35 ODI points per follow-up time point which gradually slowed down over time when minimal ODI scores were approached (table 2). A random intercept and random linear slope were added to allow individual participants to deviate from the population mean trajectory as the differences in baseline and slopes in ODI were considerable. E.g., given an average slope of -3.35 ODI per follow-up time point, recovery slopes of individual patients could be as large as -4.35 points ODI per follow-up time point, but they could be -2.35 as well, based on the 95% confidence interval in the random linear slope of -4.35 to -2.35 for the unconditional model (model 1). The random effects were negatively correlated (r=-0.79), implying that persons with higher baseline ODI scores had higher negative slopes over time (i.e., faster recovery in ODI) (model 1).

Baseline (time-invariant) predictors of differences in baseline and slope in ODI scores

After fitting the unconditional quadratic growth model (model 1), we added baseline physical activity and sedentary behavior measures as predictors of heterogeneity in baseline values and slopes in ODI (model 2). In the final multivariable model (model 3) we added several covariables alongside physical activity and sedentary behavior. Sedentary behavior in sitting hours per day showed no significant association with ODI scores at baseline or at the follow-up measurements (table 2). Physical activity in MET hours per day showed a statistically significant association with the linear rate of change on the ODI in the unadjusted (model 2) and in the adjusted model (model 3). Participants with one MET hour per day above average recovered 0.03 point [95% CI -0.002 to 0.062] (model 2) or 0.04 point [95% CI 0.004 to 0.076] (model 3) on the ODI per month faster than participants with an average amount of MET hours per day. The quadratic rate of change for physical activity was statistically significant in model 3. This means that participants with one MET hour per day above average recovered 0.003 points on the ODI per quadratic month slower compared to the linear rate of change.

Table 2. The Results of Fitting Different Individual Growth Models in Disability Trajectory Outcome Oswestry Disability Index

Parameter	**Model 1: Unconditional quadratic growth model (n=347)** Estimate (CI[b])	**Model 2: Effects of Physical Activity and Sedentary Behavior, unadjusted (n=290)** Estimate (CI)	**Model 3: Effects of Physical Activity and Sedentary Behavior, adjusted[a] (n=290)** Estimate (CI)	**Categorical Analysis. Categories compared to reference category SB[c] low PA[d] med (n=290)** Estimate (CI)
FIXED EFFECTS				
Intercept	19.76 [-0.80, 40.32]	18.99 [0.05, 37.93]	18.88 [3.80, 33.96]	21.43 [3.07, 39.79]
Physical Activity		0.04 [-0.066, 0.146]	0.03 [-0.07, 0.13]	
Sedentary Behavior		- 0.04 [-0.43, 0.35]	0.21 [-0.17, 0.59]	
SB low PA low				0.89 [-6.29, 8.07]
SB low PA high				- 3.75 [-10.39, 2.03]
SB med PA low				- 0.99 [-7.57, 5.59]
SB med PA med				- 3.82 [-10.1, 2.46]
SB med PA high				- 4.09 [-10.51, 2.33]
SB high PA low				- 5.85 [-12.47, 0.77]
SB high PA med				- 1.15 [-7.39, 5.09]
SB high PA high				1.15 [-6.61, 8.91]
Linear rate of change	- 3.35 [-4.35, -2.35]	- 3.16 [-3.72, -2.60]	- 2.97 [-3.444, -2.496]	- 3.99 [-4.55, -3.43]
Physical Activity		- 0.03[e] [-0.062, 0.002]	- 0.04[e] [-0.076, -0.004]	

Table 2. Continued

Parameter	Model 1: Unconditional quadratic growth model (n=347) Estimate (CI[b])	Model 2: Effects of Physical Activity and Sedentary Behavior, unadjusted (n=290) Estimate (CI)	Model 3: Effects of Physical Activity and Sedentary Behavior, adjusted[a] (n=290) Estimate (CI)	Categorical Analysis. Categories compared to reference category SB[c] low PA[d] med (n=290) Estimate (CI)
Sedentary Behavior		- 0.04 [-0.158, 0.078]	- 0.10 [-0.228, -0.028]	
SB low PA low				2.11 [-0.11, 4.33]
SB low PA high				0.63 [-1.15, 2.41]
SB med PA low				1.89 [-0.15, 3.93]
SB med PA med				0.32 [-1.64, 2.28]
SB med PA high				1.14 [-0.84, 3.12]
SB high PA low				1.34 [-0.74, 3.42]
SB high PA med				- 0.08 [-2.00, 1.84]
SB high PA high				- 0.31 [-2.73, 2.11]
Quadratic rate of change	0.20 [0.168, 0.232]	0.19 [0.156, 0.224]	0.17 [0.134, 0.206]	0.22 [0.10, 0.34]
Physical Activity		0.002 [0.000, 0.004]	0.003[e] [0.001, 0.005]	
Sedentary Behavior		0.003 [-0.007, 0.013]	0.006 [-0.004, 0.016]	

Table 2. Continued

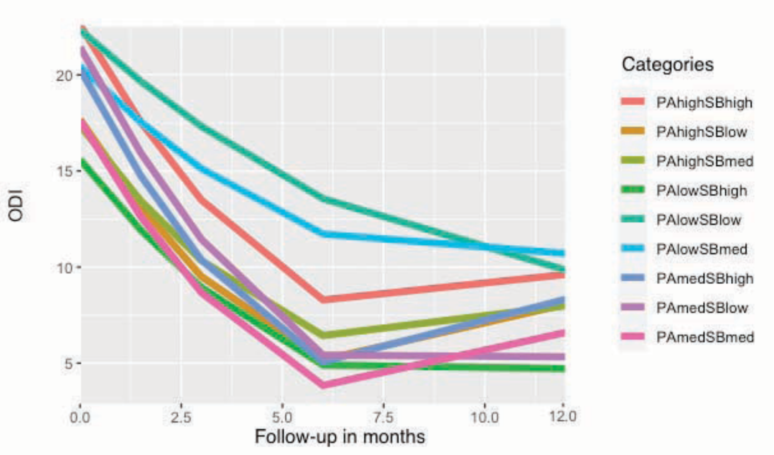
Parameter	Model 1: Unconditional quadratic growth model (n=347) Estimate (CI[b])	Model 2: Effects of Physical Activity and Sedentary Behavior, unadjusted (n=290) Estimate (CI)	Model 3: Effects of Physical Activity and Sedentary Behavior, adjusted[a] (n=290) Estimate (CI)	Categorical Analysis. Categories compared to reference category SB[c] low PA[d] med (n=290) Estimate (CI)
RANDOM EFFECTS				
SD in random intercept	10.28	9.47	7.54	9.18
SD in random linear slope	0.50	0.28	0.25	0.28
correlation between random effects	- 0.79	- 1.00	- 0.85	- 1.00
Residual SD	9.54	9.25	8.77	9.20

a Adjusted for baseline pain, back pain duration, gender, age, number of low back pain episodes, and education level
b 95% Confidence Interval
c Sedentary Behavior (low: <=6 hours per day, med: >6 and <= 10 hours per day, high: >10 hours per day)
d Physical Activity (low: <=3.77 MET hours per day, med: 3.78-11.5 MET hours per day, high: >11.5 MET hours per day)
e P-value < 0.05

Categorical analysis

After the linear mixed models with physical activity and sedentary behavior as continuous variables, the variables physical activity and sedentary behavior were both divided into three categories based on the number of hours sitting per day and the number of MET hours per day and added as predictor to the growth model. Combining these categories resulted in nine categories with low, medium, and high physical activity, and low, medium, and high sedentary behavior (figure 2). 47 participants did not fill out the questions regarding sitting at work and sitting/lying after work because they were unemployed, mostly due to retirement or college. Ten participants were excluded from this analysis because they reported more than 24 hours of sedentary behavior per day.

Figure 2. The disability trajectory of nine categories of physical activity and sedentary behavior based on model 3



ODI= Oswestry Disability Index
PA= Physical Activity
SB= Sedentary Behavior
The purple line (PAmedSBlow) is the reference category

No differences in baseline ODI or disability trajectory (ODI) were found between the reference category physical activity medium, sedentary behavior low and the other categories (table 2). The categories physical activity high, sedentary behavior high, and physical activity low, sedentary behavior low showed higher baseline ODI scores, although not statistically significant. The categories physical activity high, sedentary behavior high, and physical activity medium, sedentary behavior high showed a steeper decline on the ODI scores, although not statistically significant.

DISCUSSION

The results of this prospective cohort study showed that levels of sedentary behavior measured at the start of physical therapy treatments in adults with low back pain were not associated with low back pain disability trajectories. Our data showed that higher levels of habitual physical activity measured at the start of physical therapy treatments in adults with low back pain were associated with improved low back pain disability trajectories. Yet, this association seems not clinically relevant. The mean disability trajectory for the low back pain

patients showed an improvement that slowed down over the follow-up time. The heterogeneity in the baseline values age, back pain duration, habitual physical activity levels, sedentary behavior, and in the disability trajectory of the Oswestry Disability Index was large.

There remains a lot to be discovered about the course of low back pain. Some factors are known that influence the trajectory of low back pain, such as depression, anxiety, fear, stress, hard labour, and sleep hygiene.[4,7,13] Nevertheless, the precise influence of contributing factors on the course of low back pain is still largely unknown. A benefit of etiological knowledge is the identification of potential targets for effective treatment strategies. As physical activity and sedentary behavior are modifiable factors, the prescription of these factors has been considered as important components of prevention and multifactorial treatments for low back pain.[5,10] In this study, the association found for physical activity levels and the disability trajectory is not clinically relevant as the minimal clinical detectable change on the Oswestry Disability Index is six points or 30%.[40,41] Large variations in physical activity and sedentary behavior were found in the study population of the current study, which may partially explain the lack of associations identified. The large variations may be because physical activity at work was included in the total physical activity values. Physical activity at work generally reflects a large part of a person's habitual physical activity levels and can vary greatly between individuals. The study of Bakker et al. on physical activity levels and morbidity also showed relatively large variations in physical activity levels but the study population was much larger.[34]

Other follow-up studies[16,27,31] and systematic reviews[11,16,19] reported no evidence supporting physical activity as a prognostic factor of low back pain. On the other hand, multiple studies reported that high levels of physical activity during work seem to impede recovery.[43,44,45,46] These studies all researched different populations and used different variables compared to the present study. Multiple cohort studies showed similar results as the present study and reported positive associations of people's physical activity levels with the recovery of low back pain.[17,21,26,47] However, Holm et al. and Holterman et al. did not report on occupational physical activity, while this might contribute to habitual physical activity levels.[13,26,47] Furthermore, several studies[17,21,26] used categorical measures of physical activity instead of MET values. These measures, with few details about frequency and intensity, might have resulted in different outcomes.

The results of this prospective cohort study showed that levels of sedentary behavior at the start of physical therapy treatments in adults with low back pain were not associated with low back pain disability trajectories. Several other studies reported less favourable outcomes of low back pain recovery in people with sedentary behavior compared to people with less sedentary behavior at baseline.[17,20,21,22,23] On the contrary, Korshøj et al. reported that a longer duration of total and temporal sitting periods at work were significantly associated with a favourable recovery of low back pain.[29] The participants of the study by Korshøj et al. were mainly blue-collar workers. As hard labour might be detrimental to the recovery of low back pain, these workers might benefit from more sitting instead of doing strenuous work. The study populations used in previous studies on factors related to recovery were mostly narrowed to subtypes of low back pain such as chronic or acute low back pain, while a more generalized population would give a more generalizable view of the prognostic role.[10,17,18,19,20,21,22,23,24,25,48] The daily sitting time of the population in the present study is concordant with other studies.[49,50,51,52]

To our knowledge, this is the first quantitative study that describes the association of low back pain disability trajectory with both sedentary behavior and physical activity. Other cohort studies only investigated either physical activity levels or sedentary behavior in people with low back pain.[21,22,27,28,29,30,31] Measuring both household and work-related physical activity besides sedentary behavior can be considered a strength since it reflects a better overview of all physical activity and sedentary behavior in daily life. Another strength was the heterogeneous patient population. Every person aged 18 years or older who consulted a physical therapist with an episode of low back pain was eligible and asked to join the study. This makes the patient population a good representation of people with low back pain in a primary care practice, which strengthens the external validity. Furthermore, the study has a relatively large sample size[53], frequent follow-up timepoints, and less than 5% loss to follow-up over twelve months. Also, many potential confounders were assessed, which strengthens the internal validity. However, psychosocial factors were not included in the analysis. As these factors are supposed to impede recovery, this may have

had consequences for the data analyzes and the results.[4,7,54] Data analysis was performed by a team of researchers who were not involved with the treatment of patients with low back pain. The type of statistical analysis over multiple time points can be considered as a strength.

What can be considered both a strength and a weakness of this study is that it was performed during the COVID pandemic. It might be valuable to report on physical activity levels for possible comparisons with physical activity levels before the COVID pandemic. In this study the habitual physical activity level (11.67 MET hours per day) was higher than the physical activity level in the study of Bakker et al. (8,73 MET hours per day).[34] The measurement method used in this study might have led to an overestimation of physical activity because people tend to overestimate their own physical activity level.[55] Levels of habitual physical activity and sedentary behavior were only measured before the start of physical therapy. Participants were asked for their habitual physical activity level but in some cases the estimated levels might be influenced by the low back pain. These levels might have changed throughout the study due to the advice of the physical therapist or otherwise. To analyze the association with disability, we chose not to analyze the Numeric Pain Rating Scale (NPRS) as main outcome variable of interest. For the purpose of generalizability, the Oswestry Disability Index (ODI) was preferred over the Patients Specific Functional Scale (PSFC). Future research will report more specifically on baseline measures Start Back Screening Tool and the type of leg pain (radicular vs. non-radicular). In this study, data on type of occupation was not available. All physical therapists in this study provided usual physical therapy care according to the national guideline recommendations but physical therapist preferences will have caused individual differences in the treatment program. In this study, 26% of the participants started treatment while they had low back pain for 1-4 years. This means they already had chronic low back pain. This might be due to the spine-specialized character of the physical therapy practices in this study.

CONCLUSION

Levels of sedentary behavior were not associated with the low back pain disability trajectory. High levels of habitual physical activity before starting treatment of low back pain seems to be associated with improved recovery in the low back pain disability trajectory, but the finding is not clinically relevant.

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Chapter 5

The association of the STarT Back Screening Tool and type of leg pain with low back pain disability trajectories: a prospective cohort study

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ABSTRACT

Introduction: Multiple factors influence the recovery process of low back pain (LBP). The identification and increased knowledge of prognostic factors might contribute to a better understanding of the course of LBP. The purpose of this study is to investigate the association of the STarT Back Screening Tool risk score and the type of leg pain (non-radiating LBP, referred non-radicular, and radicular radiating leg pain) with the disability trajectory (at baseline, the slope, and recovery at one year) in adults with low back pain.

Methods: This is a prospective cohort study in 347 patients with low back pain who sought physical therapy care at three primary care practices in the Netherlands. Linear mixed models were estimated to describe the association of the STarT Back Screening Tool risk score and the type of leg pain with disability at baseline, the slope in the disability trajectory, and at twelve months follow-up.

Results: A higher risk score on the STarT Back Screening Tool is associated with higher baseline disability scores on the ODI, faster initial recovery, and still a higher disability ODI score at 12 months follow-up. Non-radicular referred and radicular radiating leg pain were associated with worse baseline disability ODI scores in LBP. This association was not present for the initial recovery or at the 12 months follow-up.

Conclusion: The STarT Back Screening Tool is a useful tool to predict the disability trajectory in a heterogeneous group of people with low back pain in primary care and might, therefore, be recommended in future clinical practice guidelines.

INTRODUCTION

Low back pain is costly and the disease burden is huge worldwide.[1,2] When encountering low back pain, self-management and physical therapy are recommended in clinical practice guidelines.[3,4] People with low back pain consist of a heterogeneous population with substantial variability in prognosis where psychosocial and physical prognostic factors are explicitly mentioned in low back pain guidelines.[5] Another prognostic factor is the presence of leg pain which can be of radicular or non-radicular origin.[3,4] Remarkably, some recent guidelines no longer distinguish between low back pain with or without leg pain as there is conflicting evidence on the course of low back pain with or without leg pain.[3,4] The STarT Back Screening Tool (SBST) is a prognostic tool measuring five psychosocial items and four physical items that may support prognosis and clinical decision making.[6] More clarity about the association of the SBST risk score and the distinction of the type of leg pain with the course of low back pain might contribute to an increase of knowledge on the course of the low back pain, adjustment of treatment, and to inform future guidelines.

The SBST risk score is used to assign patients' risk of long-term low back pain-related disability to a low, intermediate, or high-risk category.[6] Several randomized controlled trials[7,8,9] separated people with back pain into distinct categories of risk for persistent disabling back pain. Multiple cohort studies[10,11,12,13,14,15,16,17] reported associations of SBST subgroups with a higher risk for poorer clinical outcomes. However, a recent meta-analysis reported that for patient-reported pain intensity and disability, there is insufficient evidence supporting the use of classification systems above generalized interventions when managing low back pain.[18]

Several systematic reviews and cohort studies reported less favorable outcomes for people with low back pain including radicular complaints in the leg versus people with low back pain.[19,20,21,22,23,24] However, other systematic reviews reported no differences or an unclear association in the recovery trajectory between people with and people without radicular complaints in the leg.[25,26,27] Classification systems used in these studies vary a lot, and few of them focus on distinguishing different types of leg pain, showing the need for further research into type of leg pain-subgroups based on non-radiating low back pain, non-radicular referred low back pain, and radicular radiating low back pain.[25,28]

In conclusion, there is uncertainty about the long-term low back pain trajectory according to the SBST risk score and the type of leg pain. The purpose of this study was to investigate the association of the SBST risk score and the type of leg pain, with the disability trajectory (at baseline, the recovery slope, and recovery at one year) in adults with low back pain seeking primary care. We hypothesized that participants with a higher risk score on the SBST or radiating leg pain show a higher baseline disability score on the ODI, a slower recovery, and a worse disability score on the ODI at 12 months follow-up compared to participants with a lower risk on the SBT or to participants with non-radiating low back pain.

METHODS

Design

In this prospective cohort study, participants were enrolled by twenty physical therapists who were employed at three primary care physical therapy practices specialized in back and neck complaints, located in three cities in the Netherlands. The inclusion of participants occurred between June 2020 and June 2021. Follow-up data were collected at one and a half, three, six, and twelve months. The Central Committee on Research Involving Human Subjects (RadboudUMC 2020-6295) approved this study. For the reporting in this study, the STROBE guidelines were applied.[29] This study was performed in concordance with the Declaration of Helsinki.

Participants

Consecutive patients with low back pain of at least eighteen years old who applied for physical therapy were invited to participate. People with various types of low back pain, e.g., radiculopathy, previous surgery, were included. Individuals were not enrolled if they were unable to complete questionnaires and in case of pregnancy. Before enrolment, written informed consent was signed by all participants. Usual physical therapy care based on the recommendations of the national physical therapy guideline for low back pain was applied to all

participants.[4] The number of treatment sessions and type of treatment were based on individual needs, ranging from manual therapy to exercise therapy to education whether or not in parallel. No other healthcare professionals were involved in the treatment.

Measurements

The baseline measurements for each participant included educational level, age, gender, duration of low back pain, and the number of previous episodes of low back pain. These data were collected digitally in the electronic health record system. In addition, three questionnaires regarding pain (NPRS), disability (ODI), and psychosocial prognostic factors (SBST) were completed.

The main independent variables of interest were prognostic factors measured with the SBST and the type of leg pain. The Dutch Version of the SBST was used for an impression of the risk of developing long-term disability.[30] The SBST is a valid and reliable risk stratification tool, which categorizes people based on the total score of nine questions. Questions one to four address physical factors, and questions five to nine address psychosocial factors. The risk score is categorized into a low, medium, or high risk of developing persistent disabling low back pain.[31] At the first appointment with the physical therapist, the type of leg pain of the participant was assessed by the physical therapist. The three pain subgroups based on non-radiating low back pain (LBP between 12th rib and pelvic rim), non-radicular referred leg pain (LBP lower than pelvic rim but not below the knee and Straight Leg Raise negative), and radicular radiating leg pain (LBP with radicular complaints below the knee and Straight Leg Raise positive) were pre-defined by the researchers and the physical tests were performed by the physical therapists.[32,33]

Perceived disability measured with the Oswestry Disability Index (ODI) was the dependent variable and the main outcome of interest. The ODI was used to assess pain-related disability in people with low back pain. The total score of the ODI ranges from 0 (no limitation) to 100 (bed-bound or dramatic limitation).[34,35] The Minimal Clinically Important Change (MCIC) has been reported to be six points or 30% improvement from baseline.[34,35] The ODI was measured at one and a half, three, six, and twelve months follow-up. In case of an incomplete measurement, the participants were contacted by their physical therapist via telephone or email with a request to complete the questionnaires. When after 48 hours the questionnaires were not completed, they were contacted by the coordinating researcher. The reason for loss to follow-up was registered by the physical therapist. All missing data are presented in figure 1.

Data analysis

General linear mixed models were used to describe the association of the risk for long-term disability (SBST) and the type of leg pain at the start of physical therapy, with disability (ODI) trajectories over follow-up at one and a half, three, six, and twelve months. Predictors at baseline were the type of leg pain and the SBST risk score. Gender, education level, age, pain, number of previous episodes of low back pain, and duration of low back pain were analyzed as additional predictors in the regression analyses.[5,36] Within the multilevel modelling framework, individual growth modelling was applied to the data.[37,38] R version 5.12.10 was used for descriptive statistics and the general linear mixed models (lme4). Unconditional growth models with random effects were composed including unstructured variance-covariance matrices. The fit of the model was compared using likelihood ratio testing for nested models. Based on the observed trajectories and fit statistics for an unconditional quadratic growth model across the full 12 months follow up, we additionally explored a spline growth model, that allowed the trajectory between 6 and 12 months to deviate from the trajectory over the first 6 months. Our predictors of interest and the covariates were added to the best unconditional growth model in a second step. Differences on baseline (intercept) and the slope (linear and quadratic rate), and the difference in ODI scores at 12 months follow-up were researched. Full maximum likelihood was used for building the models and restricted maximum likelihood was used in the final model that investigated the influence of our predictors on the average growth parameters. When data on one of the predictors SBST (n=4) and leg pain (n=2) was missing, cases were left out of the analysis. Missing on ODI score at one of the follow-up timepoints was handled by the linear mixed models. Therefore, available ODI data were used in the analysis.

In a secondary analysis, the participants were divided into a group with ODI scores of 22 and below and a group of ODI scores above 22 at baseline. In previous research the average ODI score of people with low back pain-related

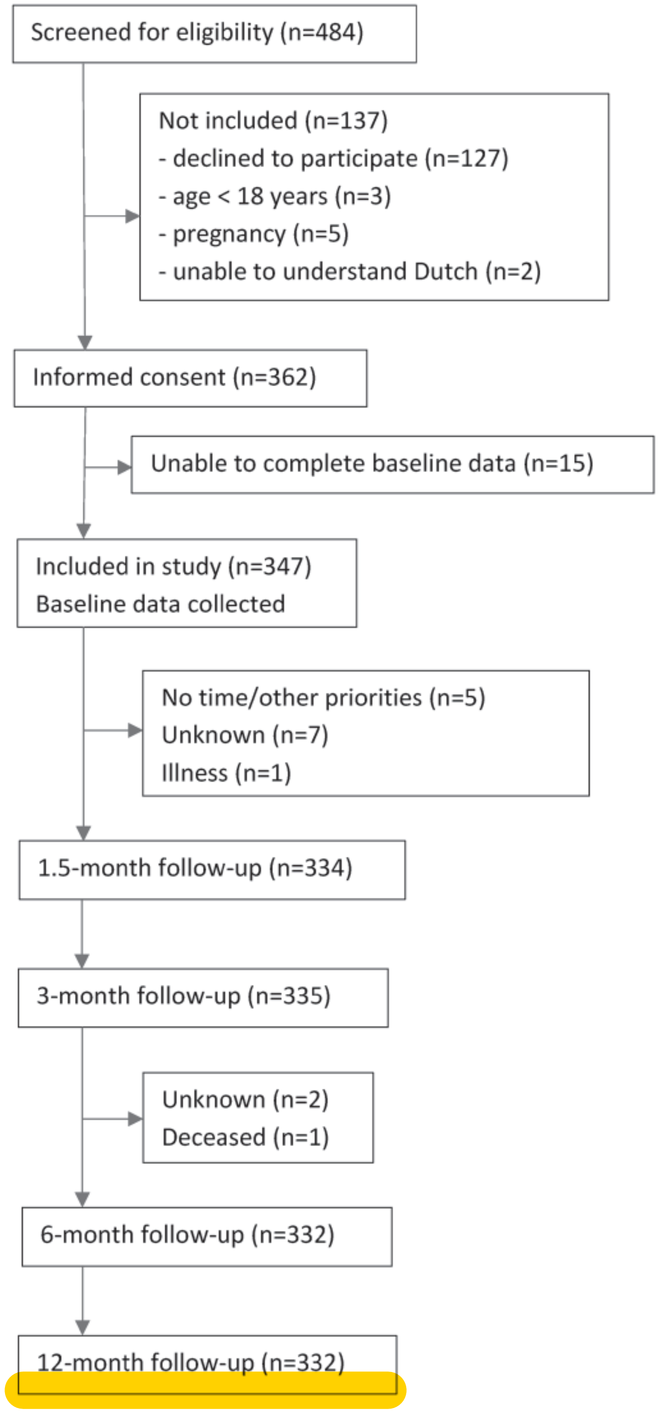
disability was 22.08 points.[35] This analysis was performed because we expected faster initial recovery in the group with worse baseline ODI scores, because these patients also need to improve more to return to the preclinical situation. As we also expected a correlation between baseline ODI and SBST scores, this would result in higher SBST risk scores being related to better rather than worse recovery rates in the whole group. The number of participants with high-risk SBST scores and radicular radiating type of leg pain were low. To improve the statistical power of this analysis the three risk score groups low, medium, and high risk of the SBST were divided into two groups of low risk and medium/ high risk. The type of leg pain groups were divided into non-radiating low back pain and non-radicular referred/radicular radiating leg pain. A general linear hypotheses test (glht) was applied to check the significance of the difference between low and medium/high risk SBST groups, and the difference between non radiating low back pain and non-radicular referred/radicular radiating leg pain at 12 months follow-up.

RESULTS

The flow of participants through the study

Eligibility screening was performed for 484 consecutive potential participants. 362 of the potential participants were eligible and willing to participate (Figure 1). Baseline data were not completed by 15 participants. A total of 347 participants completed the baseline data and were enrolled in the study. 332 participants (95.7%) completed the questionnaires until the 12-month follow-up (15 participants lost to follow-up).

Figure 1. Flowchart of participants



Characteristics of participants

The participants had a mean age of 43(SD 14.6) years (table 1). The 347 participants consisted of 50% men and 50% women. The participants showed large differences in back pain duration at baseline. The ODI had a median (IQR) outcome of 20 (10-32) at baseline. 48% of the participants had a low-risk SBST score for long-term disability, 41% had a medium risk for long-term disability, and 10% had a high-risk for long-term disability. Concerning type of leg pain, 40% had non-radiating LBP, 54% had non-radicular referred leg pain, and 6% had radicular radiating leg pain. There was substantial heterogeneity amongst the participants on the majority of the baseline characteristics, resulting in large standard deviations. Table 1 summarizes the characteristics of the participants.

Table 1. Characteristics of Participants (n=347)

Gender (n)		**Questionnaires**	
Female (%)	172 (50)	ODI baseline (median)(IQR)	20 (10-32)
Male (%)	175 (50)	ODI 1.5 months (median)(IQR)	8 (2-20)
Age in years (mean)(SD)	**43 (15)**	ODI 3 months median)(IQR)	6 (0-14)
Back pain duration at baseline (n) (%)		ODI 6 months (median)(IQR)	4 (0-14)
0-2 weeks	25 (7)	ODI 12 months (median)(IQR)	4 (0-10)
3-12 weeks	47 (14)	NPRS baseline (mean)(SD)	5.3 (2.3)
3-6 months	21 (6)	**Outcome StarT Back Screening Tool (n) (%)**	
7-12 months	30 (9)	Low risk	166 (48)
1-4 years	91 (26)	Medium risk	143 (41)
5-9 years	60 (17)	High risk	34 (10)
10-20 years	43 (12)	**Type of leg pain (n) (%)**	
>20 years	29 (8)	Non-radiating low back pain	137 (40)
		Non-radicular referred leg pain	186 (54)
		Radicular radiating leg pain	22 (6)

n= number, SD= Standard Deviation, ODI= Oswestry Disability Index, IQR=Inter Quartile Range
NPRS=Numeric Pain Rating Scale

Growth models

The best fitting unconditional growth model for the Oswestry Disability Index (ODI) over the follow-up time points included a linear and a quadratic fixed

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slope across the first 6 months of follow up and a spline to model the difference in ODI scores between 6 and 12 month follow up. As such, the average patient presented with a ODI score of 22 (95% CI) at baseline and followed a disability trajectory that initially improved with -6.3 points (95% CI) on the ODI per month in the first six months. The average improvement gradually slowed down over time with 0.7 ODI point per month. For the average patient this resulted in a ODI score of 9 at six months, that further decreased 1.5 ODI points from six to twelve months (model 1, table 2). To allow individual participants to deviate from the population mean trajectory a random intercept and random linear slope were added as the differences in baseline and slopes in ODI were considerable (model 1). Negatively correlated (-0.72) random effects were found, meaning that participants with higher baseline ODI scores had higher negative linear slopes over the follow-up time points (i.e., faster recovery in ODI disability scores) (model 1).

Table 2. The Results on baseline and slope for Fitting Different Individual Growth Models in Disability Trajectory Outcome Oswestry Disability Index

	Model 1: Unconditional growth model (n=347)			**Model 2: Effects of Type of leg pain[a] and SBST[b] outcome UNadjusted (n=347)**			**Model 3: Effects of Type of leg pain and SBST outcome adjusted[c](n=347)**		
Characteristic	**Beta**	**95% CI[d]**	**p-value**	**Beta**	**95% CI[d]**	**p-value**	**Beta**	**95% CI[d]**	**p-value**
ODI at BL	22	20, 23	<0.001	12	9.9, 15	<0.001	12	9.4, 15	<0.001
SBST category									
Low				—	—		—	—	
Medium[e]				12	8.9, 15	<0.001	11	7.8, 14	<0.001
High				23	18, 27	<0.001	22	17, 27	<0.001
Type leg pain									
LBP				—	—		—	—	
Referred[f]				2.7	-0.13, 5.6	0.061	2.5	-0.64, 5.7	0.12
Radicular				12	6.4, 18	<0.001	15	9.0, 22	<0.001
linear change during first 6 months	-6.3	-7.1, -5.6	<0.001	-3.6	-5.0, -2.2	<0.001	-2.2	-3.7, -0.67	0.005
SBST category * linear change during first 6 months									
Medium * linear change during first 6 months				-5.0	-6.6, -3.3	<0.001	-6.2	-8.0, -4.4	<0.001
High * linear change during first 6 months				-7.0	-9.7, -4.3	<0.001	-9.2	-12, -6.3	<0.001

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Table 2. Continued

	Model 1: Unconditional growth model (n=347)			Model 2: Effects of Type of leg pain[a] and SBST[b] outcome UNadjusted (n=347)			Model 3: Effects of Type of leg pain and SBST outcome adjusted[c](n=347)		
Type leg pain * linear change during first 6 months									
Referred * linear change during first 6 months				-0.05	-1.7, 1.6	>0.9	-0.34	-2.1, 1.4	0.7
Radicular * linear change during first 6 months				0.03	-3.3, 3.4	>0.9	-1.3	-4.9, 2.3	0.5
quadratic change during first 6 months	0.72	0.60, 0.83	<0.001	0.41	0.20, 0.62	<0.001	0.23	0.00, 0.45	0.053
SBST category * quadratic change during first 6 months									
Medium * quadratic change during first 6 months				0.64	0.39, 0.89	<0.001	0.80	0.52, 1.1	<0.001
High * quadratic change during first 6 months				0.75	0.34, 1.2	<0.001	1.1	0.62, 1.5	<0.001
Type leg pain * quadratic change during first 6 months									
Referred * quadratic change during first 6 months				-0.02	-0.27, 0.23	0.9	0.01	-0.26, 0.28	>0.9
Radicular * quadratic change during first 6 months				-0.16	-0.67, 0.35	0.5	-0.04	-0.59, 0.51	0.9
difference between ODI at 6 and 12 months	-1.5	-2.9, -0.22	0.023	-1.9	-4.2, 0.44	0.11	-2.5	-5.1, 0.08	0.058
SBST category * difference between ODI at 6 and 12 months									
Medium * difference between ODI at 6 and 12 months				0.38	-2.5, 3.2	0.8	1.1	-2.1, 4.3	0.5
High * difference between ODI at 6 and 12 months				3.8	-0.93, 8.5	0.12	5.7	0.64, 11	0.027

Table 2. Continued

	Model 1: Unconditional growth model (n=347)			Model 2: Effects of Type of leg pain[a] and SBST[b] outcome UNadjusted (n=347)			Model 3: Effects of Type of leg pain and SBST outcome adjusted[c](n=347)		
Type leg pain * difference between ODI at 6 and 12 months									
Referred * difference between ODI at 6 and 12 months				-0.18	-3.0, 2.6	0.9	0.03	-3.0, 3.1	>0.9
Radicular * difference between ODI at 6 and 12 months				-1.5	-7.6, 4.7	0.6	-1.9	-8.6, 4.7	0.6
random intercept (sd)	12			9.5			9.4		
correlation random effects	-0.72			-0.64			-0.67		
random linear slope (sd)	1.5			1.4			1.4		
residuals (sd)	8.7			8.6			8.4		
AIC	12,82			12,47			10,39		
BIC	12,86			12,60			10,64		

a Non-radiating low back pain (reference category), non-radicular referred leg pain, or radicular radiating leg pain
b StarT Back Screening Tool, Low risk (reference category), Medium risk, or High risk
c Adjusted for baseline pain, back pain duration, gender, age, number of low back pain episodes, and education level
d 95% Confidence Interval
e e.g., value of 12 indicates participants with a Medium risk on the SBST score 12 points higher on the ODI compared to the Low risk-participants
f e.g., value of 2.7 indicates participants with non-radicular referred leg pain score 2.7 points higher on the ODI compared to the non-radiating low back pain participants

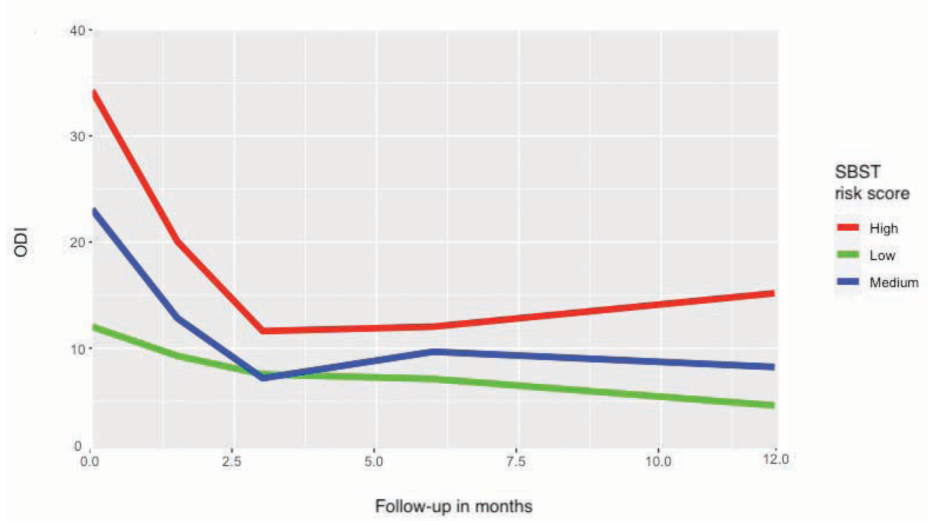
Baseline (time-invariant) predictors of differences in baseline and slope in ODI scores

After fitting the unconditional growth model, we added the baseline score on the StarT Back Screening Tool and the baseline type of leg pain to test the hypotheses. We added the baseline score on the StarT Back Screening Tool and the baseline type of leg pain simultaneously as predictors of heterogeneity in the growth parameters in ODI (model 2). We added the covariables gender, education level, risk for long-term disability, age, pain, and disability, number of previous episodes of low back pain, and duration of low back pain to build an adjusted model which is the final model (model 3). At the baseline, significant differences between low, medium, and high-risk groups of the SBST were present in models two and three (table 2). The baseline SBST risk score showed a statistically significant association with the linear and quadratic rate of change on the ODI (models 2 and 3). In model 3, average participants with non-radiating low back pain and with a low-risk score on the SBST initially recovered 2.2 [95% CI 0.67 to 3.7] points on the ODI (minus the quadratic effect) per month. The participants with a medium-risk score on the SBST initially recovered with 6.2 [95% CI 4.4 to 8.0] points per month faster on the ODI (minus the quadratic effect) compared to the low risk-participants. Participants with a high-risk score on the SBST initially recovered 9.2 [95% CI 6.3 to 12.0] points faster on the ODI per month compared to the participants with a low-risk score on the SBST. The quadratic rate of change for the SBST was statistically significant in models 2 and 3. This suggests that participants with a medium or high-risk score on the SBST show more slowing down of the improvement through time in comparison with participants with a low-risk score in the SBST. The patients with low-risk SBST scores at baseline further improved from 6 to 12 months FU (-2.5 (95CI)), although this effect was not significantly different from zero. Particularly patients with high-risk SBST scores did no longer improve from 6 to 12 months and some even worsened again: the change from six to twelve months follow-up show a difference of 5.7 [95% CI 0.64 to 11] ODI points between the high-risk and the low-risk group (table 2, model 3, figure 2). At 12 months follow-up, participants with a high-risk baseline score on the SBST have a higher disability level with 10.6 [95% CI 5.9 to 15.2] points higher on the ODI in comparison with the participants with a low-risk score on the SBST (Table 3, contrasts as derived from model 3). Participants with a medium-risk SBST score have a 3.6 [95% CI 0.6 to 6.6] points worse 12-month ODI than the low-risk group. At 12 months follow-up, participants with a high-risk baseline score on the SBST have a higher disability level with 7.0 [95% CI 2.3 to 11.6] points higher on the ODI in comparison with the participants with a medium risk on the SBST.

In the adjusted model (model 3) participants with radicular radiating leg pain show a 15 [95% CI 9.0 to 22.0] points higher score on the baseline ODI compared to the participants with non-radiating low back pain. Concerning the type of leg pain categories, there were no significant associations for the initial slope, the slope from 6 to 12 months follow-up, nor for the difference at 12 months follow-up between the type of leg pain-groups (table 2 model 3, table 3 model 3, figure 3).

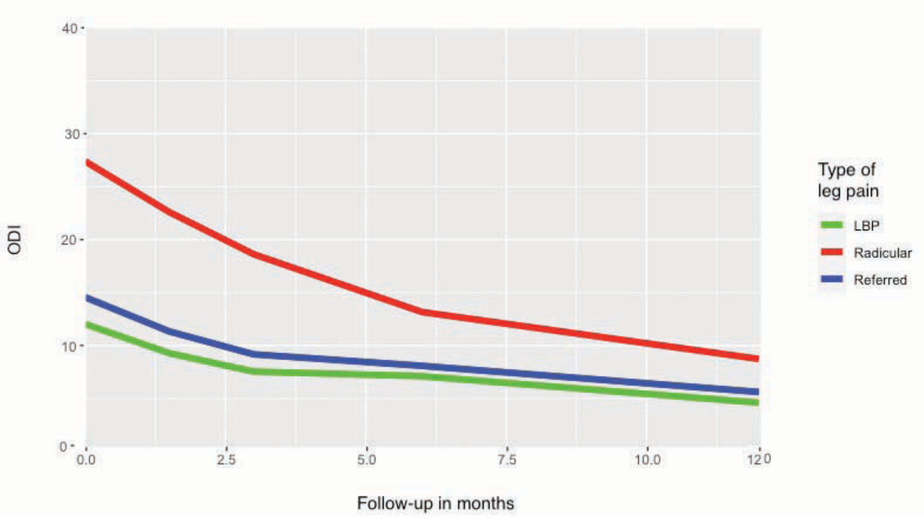
There was no collinearity between the variables SBST and type of leg pain as the Pearson correlation was -0.316. Figures two and three show the disability trajectories of the three categories of STarT Back Screening Tool risk score and the three types of leg pain.

Figure 2. The disability trajectory of three categories of StarT Back Screening Tool (SBST) risk score for type of leg pain=non-radiating low back pain (model 3)



ODI= Oswestry Disability Index
Low, Medium, High = Low, Medium or High risk for long-term disability (Low=reference category)

Figure 3. The disability trajectory of three types of leg pain for category SBST=low risk (model 3)



ODI= Oswestry Disability Index.
LBP= non-radiating low back pain (Reference category)
Referred= radiating, non-radicular low back pain
Radicular= radicular radiating low back pain

Table 3. The Scores and Differences at 12 months follow-up in the Disability Trajectory Outcome Oswestry Disability Index

	Model 3: Effects of Type of leg pain[a] and SBST[b] outcome adjusted[c] (n=347)			**Model 4: Secondary Analysis with high and low ODI strata (n=347)**			
Characteristic	**Beta**	**95% CI[d]**	**p-value**	**LOW ODI STRATA[e]**	**Beta**	**95% CI[d]**	**p-value**
SBST Low[f]	4.6			SBST Low	4.22		
SBST Medium	8.2			SBST Medium/ High	5.45		
SBST High	15.2			SBST Low vs. SBST Medium/High	1.22	-4.2, 6.6	0.659
SBST Low vs. SBST Medium	3.6	0.6, 6.6	0.017	Type LBP	4.23		
SBST Low vs. SBST High	10.6	5.9, 15.2	<0.001	Type Referred/ Radicular	5.82		
SBST Medium vs. SBST High	7.0	2.3, 11.6	0.003	Type LBP vs. Referred/Radicular	1.59	-3.0, 6.2	0.494

Table 3. Continued

	Model 3: Effects of Type of leg pain[a] and SBST[b] outcome adjusted[c] (n=347)			**Model 4: Secondary Analysis with high and low ODI strata (n=347)**			
Characteristic	**Beta**	**95% CI[d]**	**p-value**	**HIGH ODI STRATA[e]**	**Beta**	**95% CI[d]**	**p-value**
Type of leg pain LBP	4.6			SBST Low	5.44		
Type of leg pain Referred	5.6			SBST Medium/ High	10.49		
Type of leg pain Radicular	8.7			SBST Low vs. SBST Medium/High	5.05	1.24, 8.85	<0.001
Type LBP vs. Referred	1.0	-1.8, 3.9	0.488	Type LBP	5.44		
Type LBP vs. Radicular	4.1	-1.9, 10.2	0.182	Type Referred/ Radicular	6.45		
Type Referred vs. Radicular	3.1	-2.8, 9.0	0.301	Type LBP vs. Referred/Radicular	1.01	-2.6, 4.6	0.579

a Non-radiating low back pain (reference category), non-radicular referred leg pain, or radicular radiating leg pain
b StarT Back Screening Tool, Low risk (reference category), Medium risk, or High risk
c Adjusted for baseline pain, back pain duration, gender, age, number of low back pain episodes, and education level
d 95% Confidence Interval
e Low: ODI ≤ 22, High: ODI > 22, differences at 12 months follow-up
f e.g., value of 4.6 indicates participants' score on the ODI at 12 months follow-up

5

The association of SBST and type of leg pain with ODI trajectories stratified for groups of high and low baseline ODI scores

After dividing the participants into groups for low (≤22) and high (>22) baseline ODI scores we analyzed the disability trajectories for groups with low and medium/high risk scores on the SBST (table 4, figure 4), and for groups of low back pain and referred/radicular leg pain (table 4, figure 5). We did so to evaluate whether SBST and type of pain could differentiate between better and worse ODI outcome (trajectories) for patients with at baseline comparable pain-related disability severity as rated using ODI. The group with a medium/ high risk score on the SBST within the high baseline ODI stratum showed a 9.1 [95% CI 2.7 to 16] points higher score on the ODI at baseline, a steeper decline in the first 6 months of -7.1 [95% CI -11 to -3.2] ODI points, and a higher ODI score of 5.05 [95% CI 1.24 to 8.85] (table 3) at 12 months follow-up compared to the low risk score group (figure 4). The group with a medium/high risk score on the SBST within the low ODI strata shows a similar baseline score, a non-significant increase in ODI score in the first 3 months (1.5 [-1.8, 4.7], P=0.4, figure 4), and a non-significant higher ODI score of 1.22 [95% CI -4.2 to 6.6] at 12 months follow-up compared to the low-risk score group (table 3, table 4).

Differences between type of leg pain groups non-radiating LBP and non-radicular referred/radicular radiating leg pain were not statistically significant. The group with non-radicular referred/radicular radiating leg pain within the high ODI strata shows a higher baseline ODI score, lesser decline in the first 3 months (figure 5), and a higher ODI score of 1.01 [95% CI -2.6 to 4.6] (table 3) at 12 months follow-up compared to the non-radiating LBP group (figure 5). The group with non-radicular referred/radicular radiating leg pain within the low ODI stratum shows a similar baseline ODI score, lesser decline in the first 3 months (figure 5), and a higher ODI score of 1.59 [95% CI -3.0 to 6.2] (table 3) at 12 months follow-up compared to the non-radiating LBP group.

Table 4: Secondary Analysis of high and low ODI[a] strata (n=347)

Characteristic	Beta	95% CI[c]	p-value
ODI at BL[b]	6.3	3.1, 9.5	<0.001
ODI at BL in two groups: Low (=<12) & High (>12)			
Low	—	—	
High	16	11, 21	<0.001
SBT category: Low vs Medium/High			
Low	—	—	
Medium/High	-1.0	-6.4, 4.3	0.7
Type back pain: LBP vs Referred/Radicular			
LBP	—	—	
Referred/Radicular	0.62	-3.9, 5.1	0.8
Linear change during first 6 months	0.24	-1.7, 2.2	0.8

Table 4: Continued

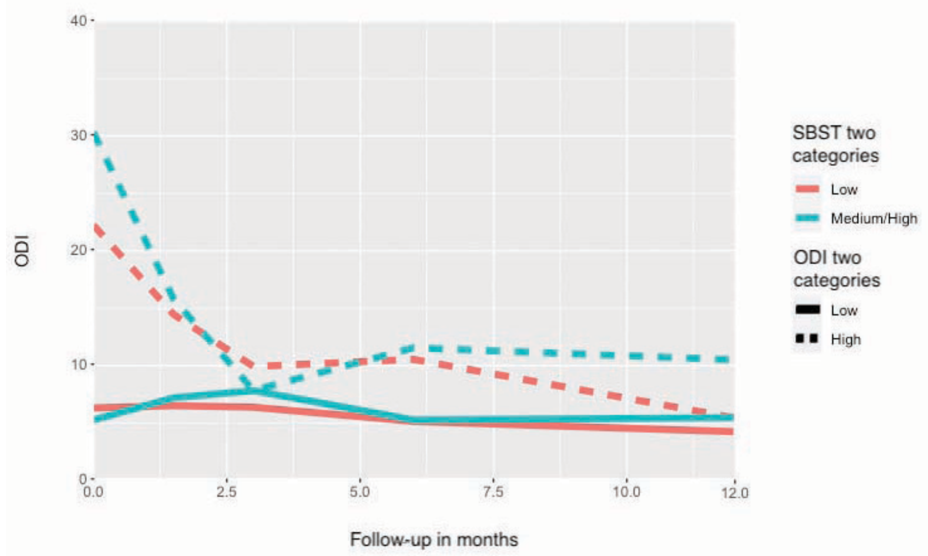
Characteristic	Beta	95% CI[c]	p-value
ODI at BL in two groups: Low (=<12) & High (>12) * Linear change during first 6 months			
High * Linear change during first 6 months	-6.5	-9.4, -3.6	<0.001
SBT category: Low vs Medium/High * Linear change during first 6 months			
Medium/High * Linear change during first 6 months	1.5	-1.8, 4.7	0.4
Type back pain: LBP vs Referred/Radicular * Linear change during first 6 months			
Referred/Radicular * Linear change during first 6 months	-0.26	-3.0, 2.5	0.9
SBT category: Low vs Medium/High * ODI at BL in two groups: Low (=<12) & High (>12) * Linear change during first 6 months			
Medium/High * High * Linear change during first 6 months	-7.1	-11, -3.2	<0.001
ODI at BL in two groups: Low (=<12) & High (>12) * Type back pain: LBP vs Referred/Radicular * Linear change during first 6 months			
High * Referred/Radicular * Linear change during first 6 months	1.2	-2.3, 4.6	0.5
Quadratic change during first 6 months	-0.07	-0.37, 0.22	0.6
ODI at BL in two groups: Low (=<12) & High (>12) * Quadratic change during first 6 months			
High * Quadratic change during first 6 months	0.79	0.36, 1.2	<0.001
SBT category: Low vs Medium/High * Quadratic change during first 6 months			
Medium/High * Quadratic change during first 6 months	-0.21	-0.71, 0.28	0.4
Type back pain: LBP vs Referred/Radicular * Quadratic change during first 6 months			
Referred/Radicular * Quadratic change during first 6 months	0.03	-0.39, 0.44	>0.9
SBT category: Low vs Medium/High * ODI at BL in two groups: Low (=<12) & High (>12) * Quadratic change during first 6 months			
Medium/High * High * Quadratic change during first 6 months	0.95	0.35, 1.5	0.002
ODI at BL in two groups: Low (=<12) & High (>12) * Type back pain: LBP vs Referred/Radicular * Quadratic change during first 6 months			
High * Referred/Radicular * Quadratic change during first 6 months	-0.22	-0.74, 0.31	0.4
Difference between ODI at 6 and 12 months	-0.89	-4.3, 2.5	0.6

Table 4: Continued

Characteristic	Beta	95% CI[c]	p-value
ODI at BL in two groups: Low (=<12) & High (>12) * Difference between ODI at 6 and 12 months			
High * Difference between ODI at 6 and 12 months	-4.2	-9.1, 0.77	0.10
SBT category: Low vs Medium/High * Difference between ODI at 6 and 12 months			
Medium/High * Difference between ODI at 6 and 12 months	1.1	-4.6, 6.8	0.7
Type back pain: LBP vs Referred/Radicular * Difference between ODI at 6 and 12 months			
Referred/Radicular * Difference between ODI at 6 and 12 months	1.6	-3.2, 6.3	0.5
SBT category: Low vs Medium/High * ODI at BL in two groups: Low (=<12) & High (>12) * Difference between ODI at 6 and 12 months			
Medium/High * High * Difference between ODI at 6 and 12 months	2.9	-3.8, 9.7	0.4
ODI at BL in two groups: Low (=<12) & High (>12) * Type back pain: LBP vs Referred/Radicular * Difference between ODI at 6 and 12 months			
High * Referred/Radicular * Difference between ODI at 6 and 12 months	-1.6	-7.6, 4.4	0.6
SBT category: Low vs Medium/High * ODI at BL in two groups: Low (=<12) & High (>12)			
Medium/High * High	9.1	2.7, 16	0.006
ODI at BL in two groups: Low (=<12) & High (>12) * Type back pain: LBP vs Referred/Radicular			
High * Referred/Radicular	1.6	-4.0, 7.3	0.6
random intercept (sd)	7.8		
correlation random effects	-0.50		
random linear slope (sd)	1.2		
residuals (sd)	8.1		
AIC	10,189		
BIC	10,46		

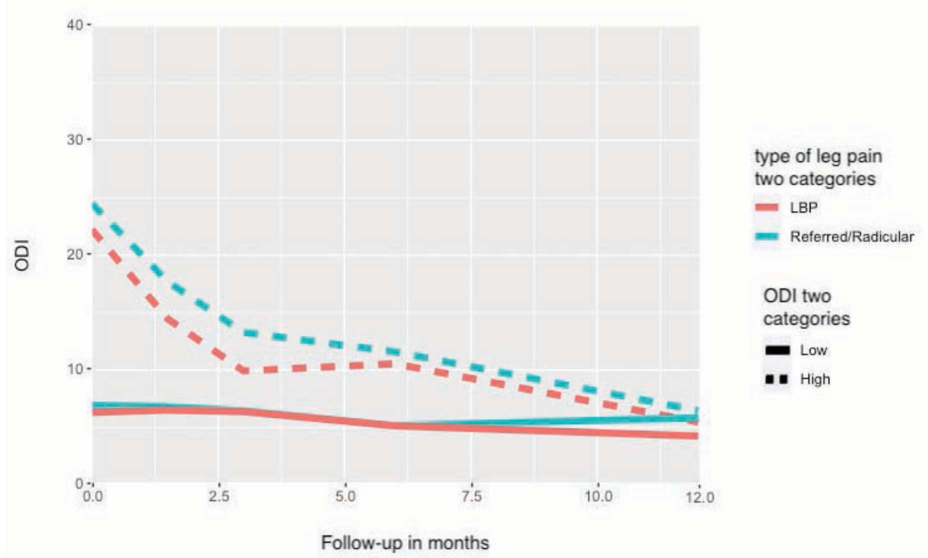
a Oswestry Disability Index
b Baseline
c Confidence Interval

Figure 4. The disability trajectory of two categories of STarT Back Screening Tool risk score for two groups of low and high ODI scores



ODI= Oswestry Disability Index.
SBST two categories= strata of low risk (n=166) and medium/high risk (n=177) score on the SBST
ODI two categories= strata of low (≤22) ODI scores and high (>22) scores

Figure 5. The disability trajectory of two categories of type of leg pain for two groups of low and high ODI scores



ODI= Oswestry Disability Index.
Type of leg pain two categories= strata of non-radiating low back pain (n=137) and radiating (radicular and non-radicular, n=208) leg pain
ODI two categories= strata of low (≤22) ODI scores and high (>22) scores

5

DISCUSSION

Main findings and related literature

The results of this study showed that a medium or high-risk score on the STarT Back Screening Tool (SBST) was associated with a higher baseline disability score on the ODI, faster initial recovery, and still a higher disability ODI score at 12 months follow-up, compared to a low-risk score on the SBST. The outcomes at baseline and 12 months follow-up supported our hypothesis. The change in disability in the first 3 months of the high risk-group showed a steeper improvement than the medium and low risk group. This outcome conflicted with our hypothesis. The change in disability from 6 to 12 months was significantly worse in the high-risk compared to the low-risk group, which supported our hypothesis.

In the secondary analyses of high and low ODI strata we concluded that a part of the association of the SBST risk score with the LBP trajectory can be explained by the fact that participants with a high-risk score on the SBST mostly reported a high ODI disability score and thus also had more room to recover. However, within the high ODI stratum (i.e., within a group of patients that is more homogeneous in terms of ODI scores at baseline) still the medium/high risk SBST group showed a steeper disability decline in the first 6 months. Yet, the high ODI stratum also showed a higher score at 12 months follow-up compared to the low-risk group.

Radicular radiating leg pain was associated with a higher baseline score on the ODI and there is a trend for a steeper decline in the disability trajectory. These associations were not present for non-radicular referred leg pain and non-radiating low back pain. No associations of type of leg pain with ODI scores at 12 months follow-up were present. This partially supported our hypothesis of participants with radiating leg pain (referred and radicular) showing a higher baseline disability score on the ODI, showing a slower recovery, and a worse disability score on the ODI at 12 months follow-up compared to the participants with non-radiating low back pain without referred or radicular leg pain. We found substantial heterogeneity in the baseline values of back pain duration, age, and the disability trajectory of the Oswestry Disability Index. The mean disability trajectory for the low back pain patients showed an improvement that slowed down over the follow-up time.

The course of low back pain is a common topic in scientific research, still, a lot remains unknown. Stress, fear, depression, anxiety, sleep hygiene, and hard labor are factors that seem to influence the disability trajectory in low back pain.[4,5,39] There remains uncertainty about which factors contribute how much to what types of low back pain.

Multiple studies showed similar results on the general course of low back pain.[40,41,42] Regarding the associations of the SBST with the disability of patients with LBP, multiple studies reported similar results as in our study.[10,16,17] Contrary to our findings, the systematic reviews of Tagliaferri et al. and Karran et al. reported a lack of evidence supporting the classification systems as the SBST for the management of low back pain. Our study had a small group at high risk compared to medium and low risk, which is similar to other studies.[9,43,44] The association between the score of the SBST and the disability trajectory found in our study seems clinically relevant as the minimal clinical detectable change of the ODI of >6 points is present for low vs high and for medium vs high risk groups at 12 months follow-up.[45] At twelve months follow-up, the low (4.6) and medium-risk (8.2) groups were below the functional limitations cut-off value of 12 points on the ODI, whereas the high-risk (15.2) group was above this cut-off value.[35] This implies that the people in the high-risk group, on average, still had functional limitations at twelve months follow-up and might be considered as not recovered.

No associations of type leg of pain and ODI disability scores at 12 months follow-up were present. This is in concordance with the systematic reviews of Vroomen et al., Chou et al., and Verwoerd et al.[26,27,46] In a cohort study, Spijker-Huiges et al. reported that the association of radicular complaints in the leg is unclear for the recovery trajectory in low back pain.[25]

In contrast, the systematic reviews of Shaw et al. and Konstantinou et al. reported less favorable risk scores for people with low back pain including radicular complaints in the leg versus people with low back pain after a similar follow-up period.[22,24] Shaw et al. showed that radicular pain was one of many factors to delay recovery in low back pain disability without explaining the exact size of the effect.[24] A systematic review[22] and two cohort studies[21,23] showed that LBP patients with leg pain scored higher for measures of pain and disability at baseline and at follow-up in comparison with patients with LBP without leg pain. Perhaps in our study, the relatively small sample of people (22 participants, 6.3%) with radicular radiating leg pain played a role in the absence of an association for slopes and at 12 months follow-up score for type of leg pain, although this percentage of 6% is already somewhat high for a primary care practice.

Strengths and limitations

This is the first quantitative study that describes associations of the low back pain disability trajectory with the score of the StarT Back Screening Tool (SBST) and with the well-defined type of leg pain. Other cohort studies investigated only either the predictive ability of the SBST or the type of leg pain in people with low back pain, never in one study.[7,8,9,10,11,12,13,14,15,16,17,19,20,21,22,23,24] To investigate possible confounding effects between the type of leg pain and the SBST score it might be useful to analyze both in parallel. An important strength of our study is the growth modelling over multiple follow-up measurements with a very high follow-up percentage of 95.7% up to twelve months. The heterogeneous patient population is a strength considering generalizability. Internal validity is strengthened by the potential confounders that were assessed and adjusted for. However, psychosocial factors like anxiety and catastrophizing were not separately assessed, although these constructs were to some extent covered by single items of the SBST. This may have had consequences for the data analyses and the results as these factors are supposed to impede recovery in low back pain.[4,5,47] The researchers that performed the data analysis were not involved in the treatment of participants with low back pain.

In this study, around a quarter of the people with low back pain started physical therapy when they had complaints for one to four years. The majority of the people in this study already had chronic low back pain at the onset of physical therapy. The participating physical therapy practices in this study were all specialized in spinal disorders. This is a possible explanation for the long low back pain duration at the onset of physical therapy and the relatively high prevalence of radicular radiating leg pain.[4,27,48,49] Participants in this study received usual physical therapy care according to the Dutch national guidelines

of physical therapy for low back pain.[4] The preference of physical therapists and patients might have led to differences in the content of the physical therapy treatments. In the SBST is one question about complaints in the leg that might have caused some collinearity with the type of leg pain in the analysis. Another limitation is the small sample size (n=22) of the participants with radicular radiating leg pain within the type of leg pain.

Implications for practice and future research

The SBST was associated with the disability trajectory of low back pain. An implication for practice is that the outcome of the SBST provides a better understanding of the disability trajectories within the heterogeneous low back pain population in primary care. Patients with low back pain might benefit from tailored treatment based on the SBST outcome. For example, addressing modifiable psychosocial factors immediately might prevent people from non-recovery.

Future research might focus on researching the distinction between non-radiating low back pain, non-radicular referred leg pain, and radicular radiating leg pain in a larger cohort study.

CONCLUSION

A higher risk-score for long-term disability using the StarT Back Screening Tool is associated with higher ODI disability scores at baseline, a different recovery slope in the recovery trajectory, and an impeded recovery at 12 months follow-up in patients with low back pain. The type of leg pain was associated with the baseline ODI disability scores, while the type of leg pain was not associated with the slope in the disability trajectory or the ODI scores at 12 months follow-up. The StarT Back Screening Tool is a useful tool to predict the disability trajectory in a heterogeneous group of people with low back pain in primary care and might, therefore, be recommended in future clinical practice guidelines.

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Chapter 6

Low back pain and disability trajectories in primary care: a growth mixture modeling analysis

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Submitted

ABSTRACT

BACKGROUND: People with low back pain are a heterogeneous group in terms of symptom presentation and resolution. To aid personalized treatment we need a better understanding of their different pain and disability trajectories. Growth Mixture Modeling (GMM) approaches are useful to identify clustering of pain and disability trajectories and predictors thereof in adults seeking physical therapy care for low back pain.

METHODS: Patients (n=347) were followed for 12 months in a prospective cohort. Pain intensity (Numeric Pain Rating Scale) and disability (Oswestry Disability Index) were assessed at baseline and at 1.5, 3, 6, and 12 months follow-up. Growth classes were identified using GMM separately for pain and disability. Next, we studied whether class membership for pain coincided with class membership for disability and predictors of class membership using multinomial logistic regression analysis.

RESULTS: The best fitting GMM identified two growth classes in both the pain and disability courses. For pain, one trajectory was assigned to 254 patients typically exhibiting moderate pain at first visit that recovered and a second trajectory was assigned to 93 patients who had moderate pain at first visit that however did not recover. For disability, 299 patients were assigned to a trajectory of moderate disability at start that recovered well and 48 patients to a trajectory with moderate disability at first that did not recover. Patients in the worst class for disability had a higher odds of being the worst class for pain as well (OR 6.8, 95% CI 1.69-9.28). Predictors of class membership for the worst classes in pain and disability were longer duration of complaints (OR 1.24, 95% CI 1.02-1.46) for pain and higher NPRS score (OR 1.31, 95% CI 1.09-1.52) and higher STarT Back Screening Tool (SBST) score (OR 5.49, 95% CI 1.69-9.28) for disability.

CONCLUSION: Two typical trajectories were identified for the course of pain and disability in adults with low back pain in primary care. The odds are high for people in the non- recovery class for disability to also be in the worst recovery class for pain. Longer duration of complaints, higher pain scores and more presence of psychosocial factors were identified as predictors to the slower recovery trajectories.

INTRODUCTION

Low back pain (LBP) is the most common of all long-lasting health problems, and the prevalence of low back pain has increased in recent decades.[1,2,3] People with low back pain represent a heterogeneous group where there is a need for a better understanding of the different trajectories towards either speedy symptom resolution or tendency towards chronicity with persisting disease burden.[4,5] An increase in knowledge of these trajectories and contributing prognostic factors such as high baseline pain, high baseline disability, sleep hygiene, physically demanding labor, sedentary behavior, stress, fear, depression, and anxiety might assist healthcare professionals in better identifying and predicting patient-specific needs and performing tailored treatment.[6,7,8]

Latent Class Growth Analysis (LCGA) or Growth Mixture Modeling (GMM) approaches have been increasingly recognized for their usefulness in identifying homogeneous subpopulations within heterogeneous populations.[9] So far, the majority of studies on LBP assessed on pain trajectories primarily.[10,11,12,13,14,15,16,17] However, assessment of disability trajectories was very limited. Secondly, most studies to identify meaningful growth classes in LBP used LCGA rather than GMM. The biggest difference between LCGA and GMM is that GMM does allow for within- and between class random variation in terms of heterogeneity in starting levels and slopes, while LCGA assumes that all members assigned to that class follow the same (class specific) trajectory. The latter is the result of the fact that LCGA does not involve the inclusion of random effects. Therefore, GMM is a more flexible technique compared to LCGA in determining which parameters can vary both within and across classes.[18] Finally, most of the studies on typical growth curve have been conducted in specialist or community settings.[17,19,20,21,22,23,24,25] However, the majority of patients are being cared for in primary care and there are good reasons to expect that recovery trajectories may differ between primary care and secondary settings. To the extent that the clustering of pain recovery has been studied in primary care, typically three to four typical trajectories are identified, characterized by either being recovered or improved with variations in recovery speed, or fluctuating, or even persistent pain.[10,12,14,15, 26,27] Factors such as high pain intensity at baseline, higher scores for distress, anxiety, and depression, longer pain duration, and low educational level are reported predictors of worse recovery in these pain trajectories.[10,12,14,15,23,26,27] Only one study reported on

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disability trajectories in primary care. In this study an older adult population with acute low back pain was studied.[27] Four disability trajectories were identified, i.e. (1) Disability recovery, (2) Incomplete disability recovery, (3) Persistent moderate-severe disability, and (4) Persistent severe disability. In secondary care, several studies investigated disability trajectories.[21,24,25] In specialist settings, also, some studies investigated both pain and disability trajectories in people with LBP.[19,20,22] Since only one study[27] assessed disability trajectories in people with LBP in a primary care setting, this is an area where more evidence is needed. Of course, patients with LBP are impacted both in terms of pain, disability as well as other outcomes. These symptoms do not exist in isolation. However, whether recovery trajectories for different outcomes coincide has not been researched before, although this seems likely. Wrapping it all up, we have investigated with GMM both pain and disability recovery trajectories and their concordance as well as predictors of recovery class in an adult population in primary care.

The present study aims to identify 1) Pain and disability recovery trajectories in adults who presented with a new episode of low back pain in primary care, 2) Predictors of class membership, and 3) To study to which extent pain and disability trajectories in adults with low back pain in primary care coincide.

METHODS

Participants

Data from a prospective patient cohort study were used. Participants were recruited at three Dutch primary physical therapy care practices specialized in back and neck pain and followed from the first presentation by the physical therapist for a new episode of LBP. Participants were included between June 2020 and June 2021. All consecutive patients of at least eighteen years old with low back pain were invited to participate. Exclusion criteria were pregnancy and inability to complete questionnaires in Dutch. Informed consent was signed by all participants before enrolment. All participants received usual physical therapy care based on the recommendations of the national physical therapy guideline for low back pain.[28] Data collection occurred at baseline, and at one and a half, three, six, and twelve months. The Study was ethically approved by the institutional review board (RadboudUMC 2020-6295) of the Radboud

University Medical Centre, Nijmegen, the Netherlands. This study was executed in concordance with the Declaration of Helsinki. The STROBE guidelines for reporting of observational studies were followed in this study.[29]

Outcome measures

Pain intensity was measured with the Numeric Pain Rating Scale (NPRS), ranging from 0 (no pain) to 10 (most imaginable pain) indicating the average level of pain over the past seven days as rated by the participant.[30] LBP-related disability in people with low back pain was measured with the Oswestry Disability Index (ODI). The total score of the ODI ranges from 0 (no limitation) to 100 (bed-bound or dramatic limitation).[31,32]

Independent variables

The following variables were included based on existing literature: age (years); sex (male/female); educational level (less than primary, primary, lower secondary, upper secondary, post-secondary non-tertiary, university entrance level, intermediate vocational education, bachelor or equivalent, master, doctoral or equivalent); duration of LBP (0-2 weeks, 3-12 weeks, 3-6 months, 7-12 months, 1-4 years, 5-9 years, 10-20 years, > 20 years), previous episodes of LBP (number), risk of developing long-term disability as measured with SBST (low (0-3)/medium (≥ 4, psychosocial sub-score ≤ 3)/high(≥ 4, psychosocial sub-score ≥ 4),[33] baseline pain (NPRS 0-10), and baseline disability (ODI 0-100).[7,34]

Statistical analyses

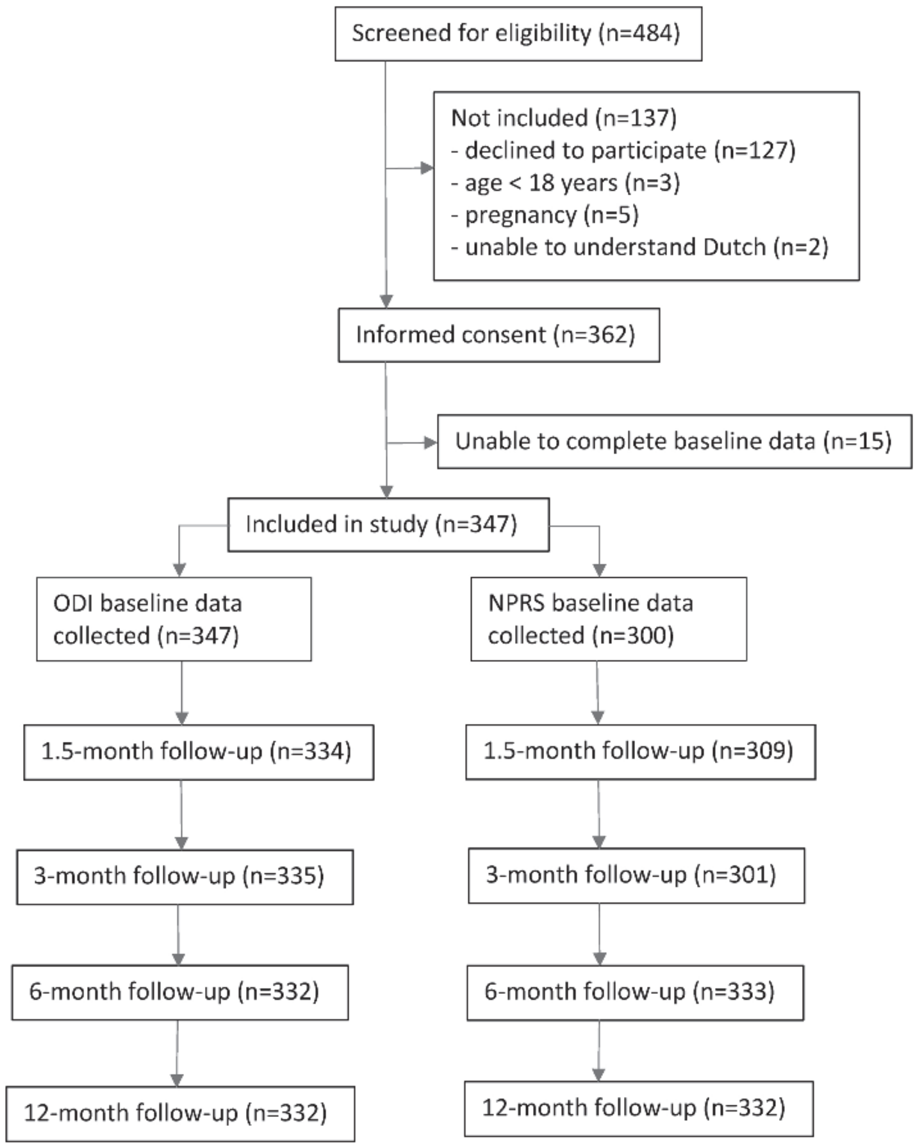
Growth mixture models (GMMs) were used to model trajectories of pain (NPRS) and disability (ODI) separately over time. Growth mixture modeling (GMM) is a method for identifying multiple unobserved sub-populations, describing longitudinal change within each unobserved sub-population, and examining differences in change among unobserved sub-populations.[35] GMM allocates participants into latent classes, based on similarities in their outcome (i.e. pain and disability in this study) trajectories over time (baseline, one and a half, three, six, and twelve months). An increasing number of growth classes is fit until an optimal balance between model simplicity and model fit is reached. The approach was to build a growth mixture model for the NPRS and ODI by successively determining (1) the optimal shape of the trajectories, (2) optimal number of latent classes, (3) the (class specific) fixed and random effects that are needed to optimally describe the growth in the outcomes of interest.[9] The final unconditional growth mixture model (without covariables) was chosen on the Bayesian information criterion (BIC), Lo-Mendell-Rubin likelihood ratio test (LMR), Bootstrap likelihood ratio test (BLRT), and class size. The BIC indicates the model fit. The better the fit of the model, the lower the value is. The LMR test is used to compare model fit between 2 nested models. A significant LMR test indicates that the model with *k* classes has a better fit than the same model with *k – 1* classes. Experts' advice a class should have at least 1% of the sample population to be included.[9] The parameter estimates were obtained using maximum likelihood estimation. Allowing random variances around the quadratic slope resulted in non-convergence. Therefore, the random variances around the quadratic slope were fixed to zero throughout our analyses. We fitted models with and without constrained residuals to time points (baseline, one and a half, three, six, and twelve months) and found that the increase in model fit justified the more complex model with unconstrained residuals. Participants were assigned to the latent class based on their posterior class membership probabilities. The factors that predicted class membership were identified using multinomial logistic regression analysis.[36,37] Odds ratios ORs) and 95% confidence intervals (CI) were calculated for this multivariable analysis. Finally, we used a pseudo class method to calculate ORs between the assigned growth class for pain and assigned the growth class for disability. In this approach, to account for the uncertainty in class membership assignment, the latent growth class for both outcomes was treated as missing and imputed based on the most likely posterior probability class membership with 20 imputations. Next, logistic regressions are performed for each imputation and combined using Rubin's rule to compute a mean OR of the imputed data sets. The (pre)processing of the data and inputfiles for and the results of the analyses in Mplus were performed with RStudio v. 5.12.10 using the Mplusautomation package.[38]

RESULTS

Flow of participants through the study

A total of 484 participants were screened for eligibility. Following, a total of 347 participants matched the inclusion criteria and agreed to participate. The data of the NPRS scores included more missing values compared to the ODI on the first three timepoints. The study flowchart is presented in Figure 1.

Figure 1. Flowchart of participants



Baseline characteristics

Baseline characteristics of all participants are shown in Table 1 (second column). Gender was with 49.6% female almost equally distributed over the total population and the mean (SD) age of all participants was 43 (15) years. At baseline, the median (Q1-Q3) ODI score was 20 (10-32) and the mean (SD) NPRS score was 5.3 (2.3).

Table 1. Characteristics of participants (n=347)

	All participants (n=347)	ODI Class 1: Moderate disability non-recovery (n=48)	ODI Class 2: Moderate disability recovery (n=299)	NPRS Class 1: moderate pain recovery (n=254)	NPRS Class 2: moderate pain non-recovery (n=93)
Age, mean (SD)	43.4 (14.6)	44.8(2.1)	43.2 (2.3)	43.7(0.9)	42.7(1.8)
Gender (female), % (n)	49.6 (172)	62.5 (30)	47.7 (142)	48.4(123)	52.7(49)
Recurrences of low back pain, mean (SD)	5.5 (11.4)	5.5 (1.7)	5.5 (1.8)	5.6(0.7)	5.3(1.4)
NPRS, mean (SD)	5.3 (2.3)	5.5 (0.4)	5.2 (0.4)	4.7 (0.2)	5.3 (0.3)
ODI, mean (SD)	20 (10-32)	29.9 (2.9)	16.0 (1.0)	20.5 (1.0)	25.8 (1.9)
Education, % (n)					
less than primary	0.3 (1)	0.0 (0)	0.3 (1)	0.0 (1)	0.0 (0)
primary	0.6 (2)	4.2 (2)	0.0 (0)	0.0 (1)	0.01 (1)
lower secondary	5.5 (19)	6.3 (3)	5.4 (16)	6.0 (15)	4.3 (4)
upper secondary	7.0 (24)	8.3 (4)	6.7 (20)	6.0 (16)	8.6 (8)
post-secondary non-tertiary	8.4 (29)	14.6 (7)	7.4 (22)	8.7 (22)	7.5 (7)
University entrance level	2.3 (8)	0.0 (0)	2.7 (8)	2.8 (7)	0.01 (1)
Intermediate vocational education	33.0 (114)	37.5 (18)	32.3 (96)	29.4 (74)	43.0 (40)
bachelor or equivalent	28.7 (99)	18.8 (9)	30.3 (90)	32.1 (81)	19.4 (18)
master. doctoral or equivalent	14.2 (49)	10.4 (5)	14.8 (44)	13.9 (35)	15.1 (14)

Table 1. Continued

	All participants (n=347)	ODI Class 1: Moderate disability non-recovery (n=48)	ODI Class 2: Moderate disability recovery (n=299)	NPRS Class 1: moderate pain recovery (n=254)	NPRS Class 2: moderate pain non-recovery (n=93)
Duration of complaints, % (n)					
0-2 weeks	7.2 (25)	4.2 (2)	7.7 (23)	7.9 (20)	5.4 (5)
3-12 weeks	13.6 (47)	8.3 (4)	14.4 (43)	15.4 (39)	8.6 (8)
3-6 months	6.1 (21)	4.2 (2)	6.4 (19)	7.1 (18)	3.2 (3)
7-12 months	8.7 (30)	12.5 (6)	8.1 (24)	9.5 (24)	6.5 (6)
1-4 years	26.3 (91)	31.3 (15)	25.5 (76)	24.5 (62)	31.2 (29)
5-9 years	17.3 (60)	16.7 (8)	17.4 (52)	17.4 (44)	17.2 (16)
10-20 years	12.4 (43)	10.4 (5)	12.8 (38)	11.9 (30)	14.0 (13)
> 20 years	8.4 (29)	12.5 (6)	7.7 (23)	6.3 (16)	14.0 (13)
SBST, % (n)					
Low	48 (166)	10.4 (5)	54.6 (161)	54.0 (135)	33.3 (31)
Medium	41 (143)	60.4 (29)	38.6 (114)	37.6 (94)	52.7 (49)
High	10 (34)	29.2 (14)	6.8 (20)	8.4 (21)	14.0 (13)

SD= standard deviation
SBST= Start Back Screening Tool
NPRS= Numeric Pain Rating Scale. range 0-10; 0=no pain
ODI= Oswestry Disability Index. range 0-100; 0=no disability

Latent classes of progression

Pain trajectories

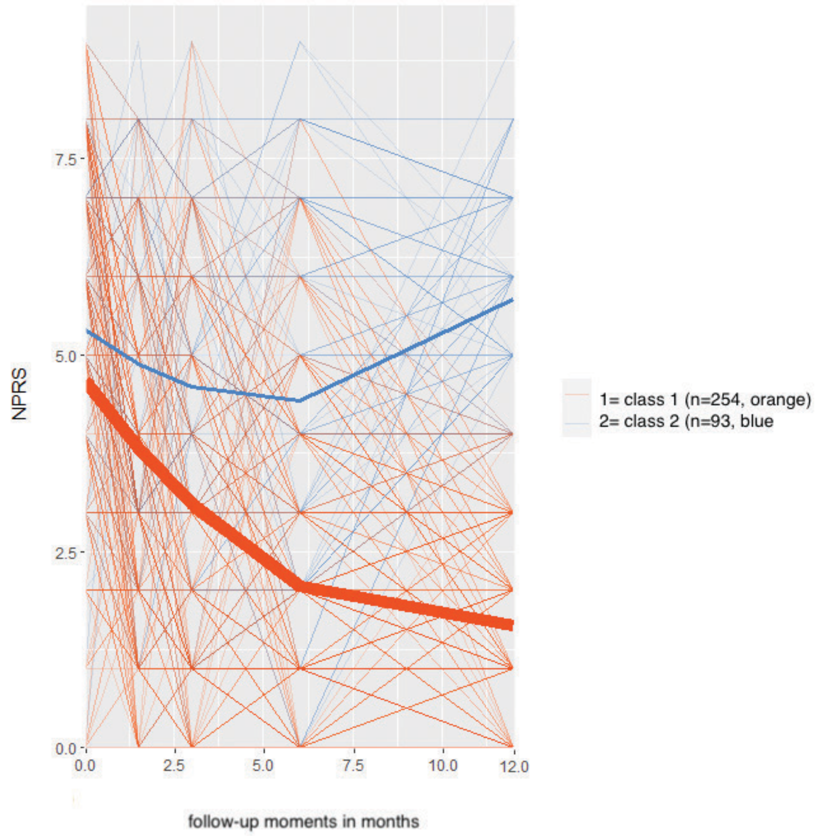
The best fit growth mixture model for pain trajectories measured with the NPRS included two classes based on class proportions and clinical interpretation of the trajectory classes identified and the statistical indices for model fit: LMR, BLRT and entropy score. An overall random intercept and linear slope were added. However, class-specific random effects did not benefit the model fit. The high posterior probabilities of class 1 (0.97) and class 2 (0.85) indicated a good model fit. Class 1 contained the most participants (n=254, 73%) compared to class 2 (n=93, 27%). For the majority, both classes showed similar proportions of baseline characteristics, there were some small differences in education level, SBST profile and duration of pain (table 1, column 5 and 6). Class 1 (moderate pain at presentation which recovered in time) started with a lower baseline mean pain score (4.7 points) and showed a steeper linear improvement over time (mean= -0.62 points which slowed down with 0.03 points per month of follow up) compared to class 2 (moderate pain at presentation that persisted) mean pain score (5.3 points) and a slower linear decline over time (mean= -0.34 points which slowed down with 0.03 points per month of follow up). In contrast, class 1 showed a continuous decrease in complaints over the 12-month period, while class 2 showed a slight increase in pain from 6 months. The parameter estimates are shown in Table 2 and the trajectories of both classes are depicted in Figure 2.

Table 2. Parameter estimates for the ODI and NPRS trajectories by latent class

Parameter	ODI Class 1 (n=48) Mean (SE)	ODI Class 2 (n=299) Mean (SE)	NPRS Class 1 (n=254) Mean (SE)	NPRS Class 2 (n=93) Mean (SE)
Fixed effects, mean (SE)				
Intercept	29.92 (2.94)	16.00 (0.97)	4.68 (0.17)	5.32 (0.29)
Linear rate of decline	-2.11 (0.91)	-2.84 (0.24)	-0.62 (0.06)	-0.34 (0.12)
Quadratic rate of decl	0.18 (0.08)	0.16 (0.02)	0.03 (0.01)	0.03 (0.01)
Random effects, mean (SE)				
Intercept variance	8.92 (4.86)	8.92 (4.86)	1.56 (0.57)	1.56 (0.57)
Slope variance	0.70 (0.49)	0.70 (0.49)	0.09 (0.08)	0.09 (0.08)
Residual variances				
T0	13.71 (4.72)	13.71 (4.72)	2.16 (0.72)	2.16 (0.72)
T1	8.78 (3.29)	8.78 (3.29)	1.60 (0.74)	1.60 (0.74)
T2	7.55 (3.11)	7.55 (3.11)	1.74 (0.60)	1.74 (0.60)
T3	8.55 (3.22)	8.55 (3.22)	1.83 (0.59)	1.83 (0.59)
T4	5.08 (4.70)	5.08 (4.70)	1.01 (0.70)	1.01 (0.70)

SE= standard error
NPRS= Numeric Pain Rating Scale. range 0-10; 0=no pain
ODI= Oswestry Disability Index. range 0-100; 0=no disability

Figure 2. Trajectories of pain measured with the NPRS (Numeric Pain Rating Scale)

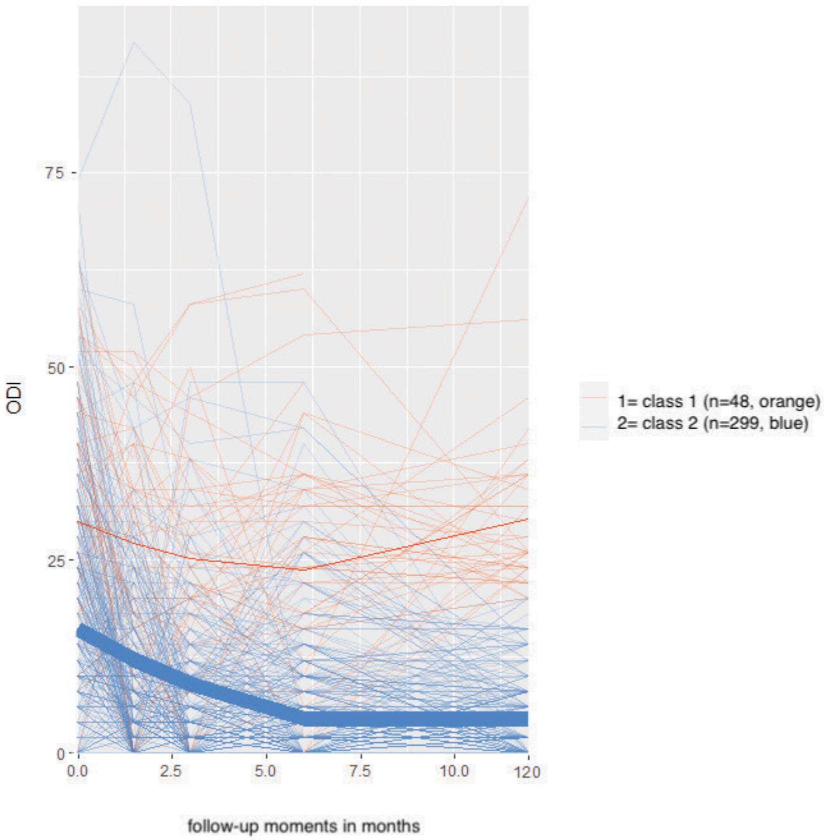


The mean trajectories of both classes are shown with a bold line. The thin lines indicate the trajectories of individual patients assigned to the respective classes based on highest class probability. Thickness of the line indicates class size

Disability trajectories

The best fit growth mixture model for pain trajectories measured with the ODI included two classes based on class proportions and clinical interpretation of the trajectory classes identified and the statistical indices for model fit: LMR, BLRT and entropy score (Supplement A). The high posterior probabilities of the class 1 (0.93) and class 2 (0.99) indicated a good model fit. In contrast to pain trajectories, a class-specific intercept and slope were added to both classes to create the best fitting model. ODI growth class 1 included the least number of participants (n=48,14%) compared to class 2 (n=299, 86%). The baseline characteristics were mostly similar for both classes with some distinct differences in the SBST scores specifically (Table 1, column 3 and 4): patients assigned to the worst ODI recovery group had a considerably higher likelihood of being the medium or high class for SBST. This association between class membership and SBST was more prominent for ODI than for pain. Class 1 (moderate disability non-recovery) showed the highest mean disability ODI score at baseline (29.9 points) with a slower linear decline over time (mean= -2.1 points which slowed down with 0.18 points per month of follow up) compared to class 2 (moderate disability recovery) and showed a lower baseline mean disability ODI score (16.0 points) with a steeper decline over time (mean= -2.8 points which slowed down with 0.16 points per month of follow up). In contrast, class 1 showed a slight increase in complaints from 6 months onwards, while class 2 seems to remain stable. The parameter estimates are shown in Table 2 and the trajectories of both classes are depicted in Figure 3.

Figure 3. Trajectories of disability measured with the ODI (Oswestry Disability Index)



The mean trajectories of both classes are shown with a bold line. The thin lines indicate the trajectories of individual patients assigned to the respective classes based on highest class probability. Thickness of the line indicates class size

Predictors of class membership

Pain trajectories

Class 1 (moderate pain recovery) with the lowest pain score at baseline was used as the reference class to identify the predictors for being a member of class with high pain score trajectory. The ORs and 95% CI for membership in class 1 are shown in table 3. In the multivariable model, an increase in duration of complaints increased the odds of being part of class 1 with a slower recovery (OR 1.24, 95% CI 1.02-1.46) relative to odds of being assigned to class 2, based on posterior class membership probability. Patients with a higher SBST at baseline had a higher odds for being in the worse recovery class as well, but the OR for pain was not statistically significant and lower than for disability.

Table 3. Odds ratios and 95% confidence intervals for membership

	Disability		Pain	
	Reference is class 2		Reference is class 1	
Characteristic	Multivariable	p-value	Multivariable	p-value
Age	1.00 (0.98-1.03)	0.919	0.99 (0.97-1.01)	0.208
Gender	2.59 (0.10-5.08)	0.211	1.13 (0.44-1.81)	0.722
Education	0.90 (0.68-1.13)	0.402	0.98 (0.81-1.16)	0.844
Duration of complaints	0.93 (0.70-1.16)	0.550	1.24 (1.02-1.46)	0.030*
Recurrences of low back pain	1.00 (0.97-1.03)	0.829	0.99 (0.95-1.02)	0.501
SBST at baseline	5.49 (1.69-9.29)	0.020*	1.75 (0.83-2.68)	0.108
NPRS at baseline	1.31 (1.09-1.52)	0.005*		
ODI at baseline			1.01 (0.99-1.03)	0.301

SBST, Start Back Screening Tool; NPRS, Numeric Pain Rating Scale
ODI, Oswestry Disability Index
*Significant at $p<0.05$

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Disability trajectories

Class 2 (moderate disability recovery), with the lowest disability score at baseline, was used as the reference class. The odds ratios (ORs) and 95% confidence intervals (CIs) for membership in class 2 are shown in table 3.

The NPRS and SBST at baseline showed significant estimation effects on the probability of membership in class 2. This means that an increase of one point on the NPRS (OR 1.31, 95% CI 1.09-1.52) and every category higher on the SBST (OR 5.49, 95% CI 1.69-9.28) increased the odds of being part of class 1 with a slower recovery progression. Duration of complaints was not associated with class membership for disability.

Cohesion of pain and disability trajectories

The odds are high (OR 6.8, 95% CI 1.69-9.28) for people in the moderate disability non-recovered class to be also in the moderate pain non-recovered class.

DISCUSSION

Main results

In this study, two disability trajectories and two pain trajectories were identified in adults with low back pain in primary care. Initially all pain and disability trajectories show improvements in pain and disability scores. But the non-recovery groups tend to increase in pain and disability after the 6 months follow up for both pain and disability trajectories. The steepest decline in pain or disability occurred in the first 6 weeks. Subsequently, a gradual decline in pain or disability over time was shown until a plateau was reached and both recovered groups of the pain and disability trajectories did not improve anymore. Patients belonging to one pain and disability trajectory recovered at twelve months, while those in the other trajectory did not recover. At baseline the non-recovery groups for the pain and disability trajectories have notably higher percentage more people in the medium and high-risk categories of the SBST. Moreover, as an interesting new finding, pain and disability trajectories in primary care appear to be related. There is a likelihood that people in the moderate disability non-recovered class also belong to the moderate pain non-recovered class.

Comparison with other literature

Most other studies reporting pain or disability trajectories have been conducted in a specialist setting.[17,19,20,21,22,23,24,25] Other studies reporting pain trajectories in primary care found at least three pain trajectories. Similar to our study, trajectories with moderate baseline pain were found in other studies performed in primary care. In the study of Chen et al. the pain intensity and disability scores of the moderate baseline pain group were lower than in our study and the scores were more comparable with the fluctuating group and severe group of the pain trajectories. One of the three pain trajectories in the study of Da Silva et al. had similarities with our recovered pain trajectory starting with moderate pain at baseline that slowly and gradually decreases over time.[27] In contrast, another pain trajectory these authors found was highly different from our pain trajectories, as this was characterized by severe pain at the baseline and for 94% of the participants also had severe pain in all follow-up measurements. Da Silva et al. also identified a small class with very fast complete recovery. In their study their population of older adults had higher pain intensity scores at baseline compared to our study, but disability scores were comparable to our study.[27] However, other studies rather showed trajectories of persisting moderate pain than recovery trajectories with moderate pain.[10,14,15,26] This could be due to the presence of more psychological factors to hinder recovery compared to our study. For example, Stynes et al. reported that 58% of their people in moderate pain trajectory had a medium risk profile on the SBST and 33% had a high-risk profile of psychological factors to hinder recovery.[26] Ogollah et al. reported that people in their moderate pain trajectory had a possible anxiety disorder.[15] The group with a persisting moderate pain trajectory in the study of Dunn et al. reported a relatively long duration of complaints.[26] Furthermore, the study of Stynes et al. reported most participants in the medium- and high-risk group of the SBST, while our study population fits more in the low-risk group.[26] This is a possible explanation for not finding a trajectory with severe pain as reported in other studies.[10,12,14,15,27] Most other studies used LCGA for analysis, while in this study GMM is applied in which random effects for intercept and slope were added leading to greater variation within classes. This may have led to fewer classes. Besides, the study of Chen et al.[14] used a class-restricted model based on four pre-established clusters (no or occasional mild, persistent mild, persistent severe, and fluctuating between mild and severe pain), which is the reason they reported more than two classes.

We found that longer duration of complaints (pain trajectories) and higher scores on psychological factors (disability trajectories) were predictors of class membership for a slower recovery, which is in concordance with other studies.[10,12,27] The only study reporting disability trajectories in a low back pain population in a primary care setting was Da Silva et al.[27] However, they focused on an older adult population. Two of the four disability trajectories reported by

Da Silva et al. showed similarities to the two disability trajectories found in this study. Da Silva et al. also found one trajectory with a higher baseline disability score accompanied by a slower recovery rate compared to the other trajectory with a lower baseline disability score accompanied by a more rapid recovery rate.[27] In the current study, we found that the group with the highest pain and disability scores at baseline also had the poorest chance of recovery. This is in concordance with the study of Da Silva et al.

Strengths and limitations

To our knowledge, this is the first study identifying both pain and disability trajectories within the adult population with low back pain in primary care. Other studies representing an adult population either reported pain trajectories or disability trajectories, never in parallel. With our findings, we provided new knowledge on the different pain and disability trajectories of low back pain in primary care. This is the first study to report on cohesion between pain and disability trajectories in low back pain in primary care.

The heterogeneous patient population used in this study strengthens the external validity of the study. Every individual equal to or over eighteen years of age who consulted a physical therapist was considered eligible, regardless of the location of low back pain or the extent of radiation. This is a representative representation of people with low back pain in primary care. Another strength of this study is the use of the sophisticated analysis technique of growth mixture modeling to identify homogeneous subpopulations within heterogeneous populations. This technique allows individuals to differ in growth trajectory within classes, in which membership is established using a step-wise approach.[9,39] The high follow-up percentage of 96% up to twelve months within the disability trajectories also strengthens the validity of this study. A limitation of the current study is missing data of about 14% for the NPRS measurements at baseline and missing data to a lesser extent at the follow-up moments. Another limitation of our study is the use of self-reported measures, which could have provoked recall and measurement bias but this could also be a strength because it is the interpretation of the participant.[40]

Implications for practice and future research

We showed that information on the initial presentation of low back pain patients in primary care could help classify patients into distinct groups. The implication for practice is that grouping patients gives a better understanding of the different pain and disability trajectories within the heterogeneous low back pain population in primary care. Patients might benefit from tailored treatment on prognostic factors. For example, addressing modifiable prognostic factors like psychosocial factors immediately, might prevent people from non-recovery.

Future research should focus on optimal management approaches for the more homogeneous groups within the heterogeneous low back pain population, perhaps in a randomized trial. Other future research should focus on people's quality of life in different pain and disability trajectories.

CONCLUSION

Two different trajectories were identified for the course of pain (moderate pain recovered and moderate pain non-recovered) and disability (moderate disability non-recovered and moderate disability recovered) in adults with low back pain in primary care. The odds are high for people in the moderate disability non-recovered class to also be in the moderate pain non-recovered class. Higher pain scores, more presence of psychosocial factors, and longer duration of complaints were identified as factors to be assigned to the slower recovery trajectories.

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Chapter 7

General discussion

"As a physical therapist, I often experience the gap between guideline recommendations and the individual needs and preferences of people with low back pain."

The main objective of this thesis is to provide further substantiation for aspects of guideline-informed care for low back pain. We have evaluated the consequences of medical imaging, reviewed considerations relating to non-adherence to the guideline for low back pain, and explored associations between various prognostic factors and the disability trajectories of people with low back pain. We did this with the aim of aiding healthcare professionals by providing additional support for guideline recommendations and more detailed information that could allow them to customize treatment strategies to the individual needs and values of people with low back pain. The thesis examines five research questions: 1) How is imaging in patients with low back pain associated with increased costs, healthcare utilization, and absence from work?; 2) What reasons do Dutch physical therapists have for deviating from guideline recommendations in the treatment of patients with low back pain?; 3) How are habitual physical activity levels and sedentary behavior measured at the start of physical therapy treatment associated with disability trajectories in patients with low back pain?; 4) How are a psychosocial risk score and the type of leg pain associated with disability trajectories in patients with low back pain seeking primary care?; 5) Is it possible to identify and describe different pain and disability trajectories in patients with low back pain in primary care?

This general discussion begins with a reflection on low back pain within the broader perspective of musculoskeletal disorders in general, followed by implications for research, policy, and practice. We end this general discussion with our conclusions.

THE BROADER PERSPECTIVE: LOW BACK PAIN IN LIGHT OF MUSCULOSKELETAL DISORDERS IN GENERAL.

The problem of low back pain remains the leading cause of years lived with disability globally. In 2020, more than half a billion prevalent cases of low back pain were reported worldwide.[1] For musculoskeletal disorders in general,

1.3 billion prevalent cases were reported globally in 2017, with 138.7 million disability-adjusted life years.[2] Overall, there is a high level of consistency in recommendations across clinical practice guidelines for low back pain[3,4,5,6] and musculoskeletal disorders.[7,8,9] We elaborate on this point in greater detail below.

Medical imaging

Eight musculoskeletal clinical practice guidelines and a synthesis article of guidelines discourage the routine use of radiological imaging.[3,4,8,9,10,11,12,13,14] In the case of low back pain, routine imaging is discouraged unless serious pathology is suspected (i.e., red flag conditions), findings are likely to change management (e.g., if an epidural or spinal surgery is under consideration), or if there has been only a limited response to conservative care.[3,6,7,11,13] Three clinical practice guidelines for low back pain recommend explaining to patients that imaging may not be needed.[3,4,13] One clinical practice guideline and a synthesis article of guidelines on musculoskeletal disorders recommends caution when ordering imaging and providing patients with relevant and appropriate information.[8,9] In contrast, one chiropractic clinical practice guideline recommends considering imaging if there is 'suspicion of an underlying anatomical anomaly, such as spondylolisthesis, moderate to severe spondylosis' or 'mechanical instability'.[11] A guideline on diagnostic imaging in musculoskeletal disorders states that diagnostic imaging should not be routinely requested in primary or intermediate care for non-traumatic low back pain, knee, or shoulder pain, and that clinical practice guidelines do not justify the increasing rate of imaging for musculoskeletal disorders in the United Kingdom.[15] The recommendations of clinical practice guidelines for musculoskeletal disorders are concordant with those of clinical practice guidelines for low back pain with regard to medical imaging.[7] In addition to the fact that routine imaging provides no health benefits, our systematic review of **Chapter 2** adds high-level evidence that routine imaging in the case of low back pain might lead to increases in costs, healthcare utilization, and absence from work. We recommend refraining from medical imaging unless serious pathology is suspected or when the findings of such imaging are likely to change management.

Patient-centered healthcare

Clinical practice guidelines recommend patient-centered healthcare for low back pain[3,4,5,6] and musculoskeletal[7,8,9] disorders in general. Despite these recommendations, guideline recommendations often consist of general advice that is not adjusted to the individual needs of patients with low back pain.[5] Clinical practice guidelines typically lack recommendations for the actual delivery of patient-centered healthcare. The Institute of Medicine defines patient-centered care as "care that is respectful of and responsive to individual patient preferences, needs, and values."[16] Patient-centered healthcare includes care that responds to the individual biopsychosocial context of the patient, employs appropriate communication, and uses shared decision-making processes.[16] It can consist of 1) individualized healthcare based on biopsychosocial context and patient values, 2) shared decision-making, 3) the use of appropriate communication, and/or 4) conversation on patient-centered healthcare.[3,4,5,6,7,8,9]

Although the division of low back pain into subgroups appears to offer a promising direction for guiding treatment, it is unlikely to capture the full complexity of low back pain.[17,18] We recommend that guideline developers should provide more precise recommendations for specific subgroups. For example, if Factor A is present, apply Therapy X. Although it would be impossible to develop guideline recommendations for each individual patient with low back pain, guidelines that help to identify subgroups and that mention specific recommendations that could be adjusted to individual patients might contribute to the availability of more patient-centered care. Guidelines should include recommendations for delivering and discussing the recommended therapy with the patient.

One important element of patient-centered care that is recommended in most clinical practice guidelines is shared decision-making.[7] This is a collaborative process that involves patients and clinicians working together to make health-related decisions after discussing the available options, as well as the benefits and harms of each option, while also considering the values, preferences, and personal circumstances of the patient.[19] It allows clinicians to apply evidence-based information while placing the patient (and family members, when appropriate) at the center of clinical decisions.[20,21] When applied in practice, shared decision-making has been found to improve patient-clinician communication, in addition to improving the accuracy of patient expectations concerning the benefits and harms of specific interventions, while increasing

their involvement in decision-making and sense of being informed. It has also been shown to increase satisfaction with care for both patients and clinicians.[21] Despite the increasing importance of shared decision-making in all health-related professions, it has rarely been studied within the context of physical therapy.[22] Shared decision-making has been identified as one of the most accurate indicators of satisfaction and likelihood to recommend in patients attending musculoskeletal physical therapy in private practice.[23] The uptake of shared decision-making in musculoskeletal practice seems to be slow. Multi-directional strategies and behavior change are needed in order to enhance the incorporation of shared decision-making into musculoskeletal practice.[21] Research on the effects of shared decision-making is scarce. Within the context of low back pain, there are indications that shared decision-making does not improve recovery.[24,25] One randomized clinical trial did not detect any improvement in the clinical outcomes or healthcare consumption of patients with non-chronic low back pain after their general practitioners had been trained in shared decision-making.[25] To achieve decisions that are truly shared by care professionals and patients, the pre-consultation expectations of patients should be better incorporated into models of and education in shared decision-making.[26] Decision aids such as those used in primary care are effective at reducing decisional conflict and improving knowledge of diseases and treatment options, awareness of risk, and satisfaction with the decisions made.[27] Although shared decision-making does seem to be a promising method for delivering patient-centered healthcare, additional research is needed to assess its impact in primary care practice.[27]

Despite the lower costs and better patient outcomes associated with increasing the adherence of healthcare professionals to clinical practice guidelines, healthcare professionals have trouble adjusting guideline recommendations to the needs of individual patients.[7,28,29,30,31] They tend to perceive guidelines as voluminous documents that are not user-friendly and that lack transparency about their development.[32,33] These shortcomings have also been attributed to the clinical practice guidelines for both low back pain and musculoskeletal disorders.[4,5,7,8,33] Interventions aimed at increasing adherence to guideline recommendations for low back pain and musculoskeletal disorders have yielded limited results.[34] According to one study, however, musculoskeletal therapists are likely to choose treatment strategies that correspond to recommendations from international guidelines.[35]

The struggles encountered in the delivery of patient-centered healthcare are taken into account in the qualitative study described in **Chapter 3**. Effective patient-centered healthcare calls for a trustworthy therapeutic alliance, which consists of agreement on goals and tasks, along with the development of a personal bond.[36] We recommend that healthcare professionals should develop mutual trust with their patients, in addition to utilizing two-way communication and sharing power with patients.[37] Clinicians and educators should focus on developing these skills to encourage an effective therapeutic alliance, thereby enhancing patient satisfaction and increasing adherence to guideline recommendations.[23]

Physical activity and sedentary behavior

Physical activity is advocated in the clinical practice guidelines for low back pain, as well as for musculoskeletal disorders in general.[3,4,5,6,8,9] Precise recommendations concerning the type and intensity of physical activity vary across different clinical practice guidelines, if they are present at all.[4,5,7,8] Recommendations range from maintenance of normal activity level to aerobic exercise, strength training, mobility exercise, neuromuscular education, or supervised exercise.[3,10,11,12,13,14,38,39] Current evidence suggests that physical activity has a modest positive effect on short-term recovery after musculoskeletal interventions, but not at longer-term follow-up. It is important to note, however, that the quality of such evidence is quite low.[40] There is some evidence that advising patients with chronic low back pain to remain active in addition to participating in exercise therapy could improve disability outcomes in the long term, although advice alone is insufficient for resolving chronic low back pain.[8] In the study presented in **Chapter 4** concerning the association between baseline physical activity levels and disability trajectories, we conclude that higher levels of habitual physical activity before starting treatment for low back pain seem to be associated with improved recovery in terms of disability trajectory, although the association is too small to be clinically relevant. In contrast to these findings, multiple systematic reviews have reported no evidence that physical activity has a positive influence on the course of low back pain.[41,42,43,44] These differences in findings can be explained in part by the combination of types of physical activity.

People with physically demanding jobs might be too active, while people with sedentary jobs might benefit from additional physical activity.[45,46,47] This provides some evidence for a bandwidth of optimal physical activity levels, with a less favorable prognosis for low back pain when physical activity levels are above or below the optimal bandwidth.[45,46] In our study, we did not find such associations between levels of physical activity and sedentary behavior.

Although high levels of sedentary behavior seem to be associated with cardiovascular diseases,[48] the association between low back pain and sedentary behavior is unclear. In recovery from low back pain, worse outcomes have been reported for people with more sedentary behavior, as compared to those with less sedentary behavior.[42,49,50,51,52] A systematic review nevertheless reveals no evidence to support less sedentary behavior as having a positive influence on the course of low back pain.[53] The results of the study presented in **Chapter 4** provide no evidence of an association between sedentary behavior and the disability trajectory of low back pain. No associations between the number of hours spent sitting per day and the disability trajectory were found in either the analyses with growth models or the categorical analyses. In the categorical analyses, the variables physical activity and sedentary behavior were both divided into three categories based on the number of hours spent sitting per day and the physical activity levels, and they were then added as predictors to the growth model. For musculoskeletal disorders in general, a systematic review and meta-analysis report that reducing sitting time in the workplace has been associated with a reduction in musculoskeletal disorders, thereby prompting the recommendation that future studies should focus on prospective analyses and examining potential interactions with chronic diseases.[54] Existing evidence of prognostic associations between sedentary behavior and neck/shoulder pain or general musculoskeletal pain is inconclusive.[54] Future research on sedentary behavior within the context of low back pain or musculoskeletal disorders in general should focus on a broad spectrum of prognostic factors.

Psychosocial factors

In recent decades, the emphasis on psychosocial factors in the treatment of low back pain and musculoskeletal disorders has increased.[3,4,5,6,8,9] There is agreement that the assessment of psychosocial factors is good practice for these conditions.[5,7] Nine clinical practice guidelines—including four for low back pain,[3,11,13,14] two for neck pain,[38,39] two for osteoarthritis,[10,55] and one for rotator cuff disorders[12]—recommend assessing psychosocial factors. These factors include depression, anxiety, fear, kinesiophobia, and patient expectations. Some low back pain guidelines include recommendations for the use of the Subgroups for Targeted Treatment (STarT) Back Screening Tool (SBST)[56] or the Orebro Musculoskeletal Screening Tool[57] to identify psychosocial risk factors and, possibly, to customize treatment strategies.[3,13,58] In the quantitative studies presented in **Chapter 5 and 6**, we identify high risk scores on the SBST as a predictor of poorer recovery in low back pain in primary care physical therapy practice. Separate psychosocial predictors were not measured in this cohort.

Cognitive functional therapy seems to be a very promising and effective treatment strategy for addressing psychosocial factors in chronic low back pain, as indicated in a recent randomized controlled trial.[59] Such therapeutic approaches have yet to be incorporated into recommendations in musculoskeletal guidelines. Psychosocial interventions may facilitate post-injury recovery of musculoskeletal disorders in athletes, but further research is necessary to determine the most effective psychosocial interventions for specific psychological factors, the ideal duration of interventions, and the best method of implementation.[60] Psychosocial factors appear to be incorporated into more clinical practice guidelines for low back pain than in those for musculoskeletal disorders in general. This difference might be due to the limited availability of psychosocial screening tools for such disorders. Future studies could focus on the identification of separate psychosocial predictors and what the most efficient, customized treatment would look like, especially for musculoskeletal disorders in general. Care for low back pain might be more effective if the collaboration between physical therapists and psychologists were to be intensified.

Pain and disability trajectories

Further knowledge of different pain and disability trajectories in low back pain and musculoskeletal disorders could be helpful for adjusting treatment to the needs of individual patients. In the past decade, scientific studies have increasingly used latent class growth analysis and growth mixture models to describe trajectories of pain and disability in both low back pain and musculoskeletal disorders.[61]

Recent studies have identified multiple recovery trajectories for low back pain. In these trajectories, various factors have been reported as predictors of worse recovery class, including high pain intensity at baseline, higher scores on distress, anxiety, and depression, longer pain duration, and low educational level.[62,63,64,65,66,67,68] Various recovery trajectories have also been identified for musculoskeletal disorders.[69,70,71,72,73] Factors that predict poorer recovery trajectories in musculoskeletal disorders include psychological problems, mild multi-site pain, common mental disorders, mental health, and poor metabolic health.[69,70,71,73] Similarities in the trajectories of low back pain and musculoskeletal disorders consist mainly of psychosocial factors.[62,63,64,65,66,67,68,69,70,71,73] These results are concordant with those of the analysis of growth mixture models reported in **Chapter 6**, which identify higher risk score on the SBST, high pain intensity at baseline, and longer duration of low back pain as predictors of poorer recovery class. To our knowledge, our study is the first to examine both pain and disability trajectories in adults in primary low back pain care. According to our results, people in the high disability non-recovery class are quite likely to be in the high pain non-recovery class as well. Trajectories of pain and disability for both classes showed an initial decrease in pain and disability in the first six months. The classes with higher pain/disability showed an increase in pain/disability after six months, whereas the lower pain/disability classes continued to decrease in pain/disability from six months to one year. Given the differences in class sizes for pain and disability trajectories, researchers and clinicians should monitor both pain and disability in the recovery trajectories of low back pain.

IMPLICATIONS FOR RESEARCH, POLICY, AND PRACTICE

Research

As clarified in the systematic review presented in **Chapter 2**—which includes studies on individuals with low back pain and which compares those with and without medical imaging—future costs, healthcare consumption, and work absenteeism are associated with medical imaging for low back pain. This finding is in line with recommendations for the broader musculoskeletal domain.[7] Future research could focus on why imaging rates continue to increase. Answers to this question could potentially help to identify why imaging is performed and how to reverse this trend. Another suggestion is to develop standardized guidelines for reporting about costs, healthcare utilization, and absence from work and to include them in all RCTs and observational studies on the effects of imaging. These effects are often not described, and they have received little attention in previous research, especially in studies on low back pain and imaging.[74]

To date, little has been known about the considerations that physical therapists have for deviating from the low back pain guideline. The qualitative study described in **Chapter 3** provides an exploration of these considerations, which are driven primarily by the values of patients and healthcare providers. Examples of these values include patient requests for certain types of treatment and a tendency of physical therapists use certain types of treatment based on their own experience instead of on the guideline recommendations. Remarkably, the physical therapists who were interviewed perceived themselves as largely non-adherent to the guidelines, although a comparison of their considerations with the actual guideline recommendations indicated that they were largely adherent. The exploration of these considerations adds to the existing body of knowledge on adherence.

In scientific research, increasing attention is being devoted to prognostic factors, including lifestyle factors.[7,75] The results from the cohort study described in **Chapter 4** contribute to existing understanding of the association between physical activity, sedentary behavior, and the course of low back pain in primary healthcare. Promoting physical activity appears to contribute to more favorable recovery, as has also been observed within the broader musculoskeletal domain.[7]

The increasing attention that recent guidelines have devoted to psychosocial factors during the recovery of low back pain is supported by the results of the studies presented in **Chapters 5 and 6**, which are based on the same cohort as **Chapter 4**. These results reveal associations between scores on a primarily psychosocial screening tool and the disability trajectories of people with low back pain. More research with a specific focus on psychosocial predictors (e.g., fear, distress, and depression) is warranted as, in these two studies, these factors were investigated only according to a broader screening tool for low back pain.

Recent clinical practice guidelines have placed less emphasis on the presence or absence of leg symptoms during the intake phase of low back pain. This

observation is supported by the results reported in **Chapter 5**, which do not indicate any association between type of leg pain and the disability trajectory of low back pain. In future research, baseline measurements should also be repeated throughout the study to monitor developments and adjust treatments accordingly. For example, physical activity, sedentary behavior, and psychosocial factors may have changed between follow-up measurements. The design of the current study was not able to capture such changes. The timely identification of individuals with low back pain who exhibit slow recovery could certainly help to prevent chronic low back pain.

As demonstrated in our last study, described in **Chapter 6**, recovery trajectories differ in terms of both pain and disability as outcome measures. Further studies using growth mixture modeling techniques could contribute significantly to identifying baseline characteristics of individuals with low back pain who experience delayed recovery. It would be beneficial to repeat studies using these techniques in a larger cohort.

Observational research is well-suited to studying the course of and associations between certain characteristics at baseline. The statistical power in our studies could have been greater if the cohort had included a larger number of individuals. Large-scale routine data collection by healthcare professionals and patients at baseline and follow-up measurements would be of great value to future observational research.

Policymakers

Arriving at the appropriate use of imaging seems difficult for multiple reasons, resulting in both overuse and underuse of imaging for low back pain.[76] Although it is possible to decrease imaging rates, the results of implementation programs on changing guidelines vary. For example, imaging rates did not decrease after the Choosing Wisely campaign in the United Kingdom.[77] One of the main targets of this campaign, which reached more than 30 countries worldwide, was to reduce the number of unnecessary tests and procedures performed within the healthcare system. Despite the somewhat disappointing effects of the campaign, policymaking could have a positive effect on costs and healthcare utilization. Our review helps to raise awareness concerning the possible negative implications of unnecessary imaging in low back pain, including costs and absence from work. The results of this thesis could be useful for policymakers. For example, significant societal savings could be achieved if the government were to incorporate financial incentives to limit medical imaging. The amount of medical imaging could also be decreased substantially by allowing general practitioners and medical specialists to request medical imaging only when there is suspicion of serious pathology or a potential indication for surgery. Such changes in policy are likely to encounter resistance among healthcare providers, given the decrease in autonomy that such measures would entail. Policymakers should enter discussion with healthcare providers concerning possible ways to reduce the amount of medical imaging.

As highlighted in **Chapter 3**, adherence to treatment advice can be challenging for physical therapists. The resolution of some issues that have emerged in the Dutch healthcare system could potentially help to increase adherence. Examples could include policies that encourage the thorough implementation of the guideline or that provide education for patients and healthcare professionals to raise awareness of evidence-based treatment of low back pain.

Based on the results of the studies included in this thesis, it would seem worthwhile to encourage individuals with musculoskeletal complaints to engage in more physical activity, in order to expedite recovery. In the future, health policy could provide for a discount on healthcare insurance fees for individuals who can demonstrate that they engage in sufficient physical activity (e.g., through telemetry). Additional possibilities may arise in the future for addressing other lifestyle domains within this field. Such possibilities may also raise ethical issues, however, and they should also be discussed at the various policymaking tables.

The results reported in this thesis suggest that psychosocial factors play a prominent role in the development of musculoskeletal complaints and delayed or incomplete recovery. Policymakers could try to allocate more financial resources to conduct more extensive research in this regard. The results of the studies in this thesis could prompt policymakers to implement more training programs (possibly mandatory) to improve the ability of healthcare providers in primary and secondary care to recognize and address psychosocial factors, as well as to refer patients to appropriate healthcare professionals in a timely

manner. The provision of good patient education and the incorporation of recommendations for the implementation of shared decision-making might help to ensure that patients have a general awareness of the current state of science and guideline recommendations. This could help to bridge the gap between healthcare providers and patients.

Guideline developers

The results reported in **Chapter 2** provide evidence to indicate that guideline developers in the musculoskeletal domain should be even stronger in advising against medical imaging when there is no evidence of serious pathology or a potential indication for surgery. Guideline developers could utilize the qualitative results on guideline adherence (**Chapter 3**) to structure guidelines according to concrete tools and recommendations, thereby assisting healthcare providers in the effective implementation of guideline recommendations, as well as in conducting conversations with patients. This could potentially increase adherence and result in more effective and cost-efficient care.[78,79] Such efforts could be enhanced by expanding the process for the implementation of low back pain guidelines to include additional training for healthcare providers. In light of the results reported in **Chapter 4**, which indicate that increased physical activity is associated with improved (albeit not clinically relevant) recovery in low back pain, guideline developers should not alter existing recommendations to remain physically active despite low back pain. The results reported in **Chapters 5 and 6** suggest that it would be worthwhile for guideline developers in the musculoskeletal domain to pay more attention to capturing and addressing psychosocial factors. This is particularly important in light of the finding that outcomes of the Subgroups for Targeted Treatment (STarT) Back Screening Tool (SBST) are apparently associated with the disability and pain trajectories of people suffering from low back pain.

Practice

One possible explanation for the association between medical imaging and increased costs, healthcare consumption, and work absenteeism is that some patients might feel less healthy after imaging that reveals disc degeneration. Such outcomes might decrease the confidence that patients have in the resilience of the lower back, despite imaging findings that are only vaguely correlated with symptoms of back pain and that are not associated with low back pain in the future.[80,81] Reducing in the number of referrals for medical imaging could result in cost savings in both primary and secondary care. Imaging without a clinical indication is often ordered for multiple reasons. Such referrals could be 1) prompted by the physician's need for reassurance of diagnosis, 2) intended to specify an anatomical defect, 3) intended to meet the expectations of patients, 4) for financial incentives, or 5) because of a lack of time for a conversation with the patient concerning the need to exercise restraint with regard to imaging.[82,83,84,85]

Healthcare providers could benefit from additional education, communication techniques, and knowledge of evidence-based diagnostics and treatments to bridge the gap with patient values, thereby enhancing guideline adherence. Whereas the recommendations contained in current guidelines are largely generic, individualized care could be more effective and better suited to the needs of patients.

In practice, it could be beneficial to multiple individuals with musculoskeletal complaints if both healthcare providers and healthcare recipients were to pay more attention to psychosocial and lifestyle factors. Despite inconclusive results in scientific research, physical activity seems to be one factor that could prevent musculoskeletal complaints or expedite recovery among various target groups.[3,4,5,6,8,9,41,42,43,44] In addition, studies in the musculoskeletal domain are increasingly indicating that psychosocial factors have a significant influence on recovery.[3,4,5,6,7,8,9,10,11,12,13,14,38,39,55] A broader understanding and timely identification of psychosocial factors by healthcare providers could contribute to more targeted treatment and, consequently, faster or more complete recovery.

What would I do with €1 million in research funding?

With €1 million in research funding, I would closely follow a large cohort of individuals with various types of back pain, including accurate documentation of care received, with the objective of making a significant contribution to the identification of factors that are associated with recovery. This study would require the uniform and specific registration of comorbidities, as well as psychological and social factors. Many previous studies have focused on selections of factors from specific subfields, and they have been conducted in small cohorts. Research funding could be used to increase routine data collection in healthcare, which would result in a body of data for large-scale observational research on prognostic factors for low back pain.

CONCLUSION

The results reported throughout this thesis support guideline recommendations for exercising restraint in using medical imaging when there is no expectation of a severe condition or need for surgery. More insight was gained on the considerations of physical therapists in the treatment of people with low back pain. The results identify variations in recovery trajectories for low back pain, and they suggest that these trajectories are influenced by psychosocial factors and physical activity. These findings provide greater insight into the gap between patient values and guideline recommendations, thus potentially helping to narrow this gap.

"As a physical therapist, I now feel more confident adjusting treatment and closing some of the gap between guideline recommendations and the preferences of people with low back pain."

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Appendices

SUMMARY

The main aim of this thesis was to further substantiate aspects of guideline-informed low back pain care. The consequences of medical imaging, considerations for non-adherence to the low back pain guideline, and the association of prognostic factors with the disability trajectory of people with low back pain were evaluated. The results might aid healthcare professionals with more supported guideline recommendations and more detailed information to allow them to tailor treatment strategies to individual people with low back pain and their values.

In **chapter 2**, a systematic review describes if medical imaging for low back pain leads to increased costs, healthcare utilization, or absence from work. PubMed, CINAHL, EMBASE, Cochrane Library and Web of Science were searched for randomized controlled trials and observational studies, comparing imaging versus no imaging on targeted outcomes. After determining the quality of the body of evidence using the GRADE methodology, the conclusions were that imaging in low back pain may be associated with higher medical costs, increased healthcare utilization and more absence from work.

Chapter 3 describes the reasons of physical therapists to deviate from the guideline recommendations in the treatment of people with low back pain. To gather this information, a qualitative study with 14 interviewed physical therapists that regularly treated people with low back pain was conducted. Thematic analysis was conducted with open coding using an existing framework. This framework distinguishes five components to adherence based on patient factors, provider factors, guideline characteristics, institutional factors, and the implementation process. The participating physical therapists mentioned that the guideline should provide more information about psychosocial prognostic factors and psychosocial treatment options. The physical therapists experienced difficulties in addressing patient expectations that conflict with guideline recommendations. The implementation process of the guideline was considered insufficient. Physical therapists might rely too much on their experience, and knowledge of evidence-based treatment can be improved. In general, the interviewed physical therapists thought they were mainly non-adherent to the guidelines. However, when comparing their considerations with the actual guideline recommendations they were mainly adherent.

For the development of **chapters 4, 5, and 6**, a prospective cohort study in 347 adults with low back pain who sought physical therapy care at three primary care practices in the Netherlands was conducted. The participants completed disability and pain questionnaires at one and a half, three, six, and twelve months. Baseline predictors were gender, education level, age, pain, disability, number of previous episodes of low back pain, and duration of low back pain.

In **chapter 4** describes the association between habitual physical activity (Short Questionnaire to Assess Health-enhancing physical activity) and sedentary behavior (average sedentary hours per day) measured at the onset of physical therapy treatment in adults with low back pain disability trajectories. Linear mixed models were estimated to describe the association of habitual physical activity levels and sedentary behavior measured at the start of physical therapy treatment with disability trajectories. Other predictors were gender, education level, age, pain, number of previous episodes of low back pain, and duration of low back pain. Habitual sedentary behavior measured at the onset of physical therapy treatments in adults with low back pain was not associated with low back pain disability trajectories. High levels of habitual physical activity before starting treatment of low back pain seemed to be associated with improved recovery in low back pain disability trajectory.

Chapter 5 describes the association of the STarT Back Screening Tool risk score and the type of leg pain (non-radiating low back pain, referred non-radicular, and radicular radiating leg pain) with the disability trajectory (at baseline, the slope, and recovery at one year) in adults with low back pain. Linear mixed models were estimated to describe the association of the STarT Back Screening Tool risk score and the type of leg pain with disability at baseline, the slope in the disability trajectory, and at twelve months follow-up. A higher risk score on the StarT Back Screening Tool was associated with higher baseline disability scores, faster recovery in the first 6 weeks, and still a higher disability score at 12 months follow-up. Non-radicular referred and radicular radiating leg pain

were associated with worse baseline disability scores in LBP. This association was not present for the recovery in the first 6 weeks or at 12 months follow-up.

Chapter 6 describes recovery trajectories of pain and disability, and predictors of class membership in adults with low back pain in primary care. Growth Mixture Models were used to model pain and disability scores over time. The growth mixture models analysis identified two trajectories for both the pain and the disability courses: trajectory one with high baseline disability and pain, and incomplete recovery at twelve months follow-up, trajectory two with medium/low baseline disability and pain with a complete recovery at twelve months follow-up. For the disability trajectories, baseline pain and the STarT Back Screening Tool risk score were identified as predictors for class membership. For the pain trajectories, back pain duration and the STarT Back Screening Tool risk score were identified as predictors for class membership.

SAMENVATTING

Het hoofddoel van dit proefschrift was het verder onderbouwen van aspecten van zorg voor lage rugklachten. De mogelijke gevolgen van medische beeldvorming, overwegingen voor het niet naleven van de lage-rugpijnrichtlijn en de associatie van prognostische factoren met het hersteltraject van mensen met lage rugklachten werd geëvalueerd. De resultaten kunnen zorgprofessionals helpen met meer duiding van richtlijnaanbevelingen en meer gedetailleerde informatie om hen in staat te stellen behandelstrategieën af te stemmen op individuele mensen met lage rugklachten en hun voorkeuren.

Hoofdstuk 2 beschrijft een systematisch literatuuronderzoek naar medische beeldvorming voor lage rugpijn leidt tot hogere kosten, meer zorggebruik, of werkverzuim. PubMed, CINAHL, EMBASE, Cochrane Library en Web of Science zijn doorzocht naar gerandomiseerde gecontroleerde onderzoeken en observationele studies waarin beeldvorming werd vergeleken met geen beeldvorming op specifieke uitkomsten. Na de kwaliteit van het bewijs te hebben beoordeeld met behulp van de GRADE-methodologie, is geconcludeerd dat beeldvorming bij lage rugpijn mogelijk gepaard gaat met hogere medische kosten, meer zorggebruik en meer werkverzuim.

In **hoofdstuk 3** worden de redenen waarom fysiotherapeuten afwijken van de richtlijnaanbevelingen bij de behandeling van mensen met lage rugpijn beschreven. Om deze informatie te verzamelen, is een kwalitatieve studie uitgevoerd waarbij 14 fysiotherapeuten zijn geïnterviewd die regelmatig mensen met lage rugpijn behandelen. Er werd een thematische analyse uitgevoerd met open codering aan de hand van een bestaand kader. Dit kader onderscheidt vijf componenten van naleving op basis van patiëntfactoren, zorgverlenerfactoren, richtlijnkenmerken, institutionele factoren en het implementatieproces. De deelnemende fysiotherapeuten gaven aan dat de richtlijn meer informatie zou moeten bevatten over psychosociale prognostische factoren en psychosociale behandelopties. De deelnemers hadden moeite met het omgaan met de verwachtingen van de patiënt die in strijd zijn met de richtlijnaanbevelingen. Het implementatieproces van de richtlijn werd als ontoereikend beschouwd. Fysiotherapeuten vertrouwen mogelijk te veel op hun ervaring, en de kennis van wetenschappelijk onderbouwde behandeling kan worden verbeterd. Over het algemeen dachten de geïnterviewde fysiotherapeuten dat ze richtlijnadviezen slecht opvolgden. Echter, bij het vergelijken van hun overwegingen met de daadwerkelijke richtlijnaanbevelingen volgden ze de aanbevelingen eigenlijk goed op.

Voor de ontwikkeling van **hoofdstukken 4, 5 en 6** is een prospectieve cohortstudie uitgevoerd bij 347 volwassenen die zich met lage rugpijn meldden bij drie Nederlandse fysiotherapiepraktijken in Nederland. De deelnemers vulden vragenlijsten in om pijn en beperkingen in activiteiten in kaart te brengen op anderhalf, drie, zes en twaalf maanden. Voorspellende factoren bij aanvang waren geslacht, opleidingsniveau, leeftijd, pijn, beperkingen in activiteiten, aantal eerdere episoden van lage rugpijn en de duur van de rugklachten.

Hoofdstuk 4 beschrijft de associatie tussen gebruikelijke fysieke activiteit (Korte Vragenlijst voor het Beoordelen van Gezondheidsbevorderende Fysieke Activiteit) en sedentair gedrag (gemiddeld aantal uren per dag zittend doorgebracht) gemeten bij aanvang van fysiotherapiebehandeling bij volwassenen met lage rugpijn en het beloop van de beperkingen in activiteiten. Lineaire gemengde modellen zijn gebruikt om de associatie tussen gebruikelijke fysieke activiteit en sedentair gedrag bij aanvang van fysiotherapiebehandeling met het beloop in beperkingen te beschrijven. Andere gebruikte voorspellers waren geslacht, opleidingsniveau, leeftijd, pijn, aantal eerdere episoden van lage rugpijn, en de duur van lage rugpijn. Sedentair gedrag gemeten bij aanvang van fysiotherapiebehandeling bij volwassenen met lage rugpijn is niet geassocieerd met het beloop in beperkingen van lage rugpijn. Hoge niveaus van gebruikelijke fysieke activiteit voorafgaand aan de behandeling van lage rugpijn leken geassocieerd te zijn met een beter herstel in het beloop van beperkingen in activiteiten.

In **hoofdstuk 5** wordt de associatie tussen de risicoscore van de STarT Back Screening Tool en het type beenpijn (niet-uitstralende lage rugpijn, beenpijn zonder zenuwwortelprikkeling, en uitstralende beenpijn met zenuwwortelprikkeling) met het beloop in beperkingen in activiteiten (bij aanvang, de snelheid van afname en het herstel na één jaar) bij volwassenen met lage rugpijn beschreven. Lineaire gemengde modellen zijn geschat om de associatie tussen de risicoscore van de STarT Back Screening Tool en het

type beenpijn met de beperkingen in activiteiten bij aanvang, de snelheid in afname van de beperkingen en bij follow-up na twaalf maanden te beschrijven. Een hogere risicoscore op de STarT Back Screening Tool was geassocieerd met hogere beginwaarden van beperkingen in activiteiten, sneller herstel in de eerste 6 weken en nog steeds een hogere score voor beperkingen in activiteiten na 12 maanden follow-up. Beenpijn zonder zenuwwortelprikkeling en uitstralende beenpijn met zenuwwortelprikkeling waren geassocieerd met slechtere beginwaarden van beperkingen in activiteiten bij lage rugpijn. De associatie tussen beenpijn en beperkingen in activiteiten was niet aanwezig voor het herstel in de snelheid van afname of na 12 maanden follow-up.

In **hoofdstuk 6** hebben we het hersteltraject van pijn en beperkingen in activiteiten beschreven bij volwassenen met lage rugpijn in de eerstelijnszorg. Groeimengmodellen werden gebruikt om pijnscores en invaliditeitsscores in de loop van de tijd te modelleren. De analyses identificeerden twee hersteltrajecten voor zowel de pijn als de beperkingen: traject één met een hoge beginwaarde voor beperkingen en pijn met een onvolledig herstel na twaalf maanden follow-up, traject twee met een gemiddelde/lage beginwaarde voor beperkingen en pijn en een volledig herstel na twaalf maanden follow-up. Voor de hersteltrajecten van beperkingen in activiteiten zijn de beginwaarde voor pijn en de risicoscore van de STarT Back Screening Tool geïdentificeerd als voorspellers voor de klasse-indeling. Voor de pijntrajecten zijn de duur van de rugpijn en de risicoscore van de STarT Back Screening Tool geïdentificeerd als voorspellers voor de klasse-indeling.

DATA MANAGEMENT

For each study of this PhD involving participant data, the research protocol was submitted to the medical ethical committee Radboud CMO, Nijmegen, the Netherlands. The medical ethical committee has given approval to conduct these studies (Radboud CMO file numbers: 2020-6675, 2020-6295). The cohort study was registered in Clinicaltrials.gov (109643). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

The audio recordings of the interviews described in chapter 3 were collected via an online video meeting with the participant. The data of the cohort studies in chapters 4, 5, and 6 were collected via a secured electronic health record platform Fysiomanager. The contact details of the patients that participated have been discarded before data analysis. All electronic health record data from chapters 4, 5, and 6 were collected by the involved healthcare providers, and no identifying patient information was shared with the researchers. Identifying information of the participants of the interviews in chapter 2 were stored separately from the data, in a secured folder to which only the main researcher and the quality officer had access. The identifying information was deleted after finishing the respective studies. Recordings of the focus groups and interviews were deleted, only the (anonymized) transcripts/summaries are saved.

Until chapter 6 of this PhD thesis has been published, the raw and processed data and accompanying files (descriptive files, syntaxes, etc.) of the projects of this thesis will be stored in a folder on the department server of IQ healthcare which is accessible only by the main researchers of this project. Thereafter, the data will be stored on the secured IQ healthcare archive server in a folder called "Data proefschrift Gijs" for 15 years, which is accessible only by the secretary of IQ healthcare. Because the participants of the studies in this PhD did not give informed consent for sharing their data publicly, requests for data can be made via receptie.iqh@radboudumc. nl. A suitable way to share the data will then be sought.

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ABOUT THE AUTHOR

Gijs Lemmers was born on March 16th of 1984 in Haps, the Netherlands.

He completed pre-university school (VWO) in 2002 at the Merlet College in Cuijk. In 2006, he graduated for the study Physical Therapy at the HAN University of Applied Sciences in Nijmegen, followed by the pre-Master of Science Physical Therapy Sciences at the Utrecht University. In 2011, he finished Manual Therapy at the SOMT University in Amersfoort. Afterwards he started the Master after Master of Science in Manual Therapy at the University of Brussels, Belgium, which he finished in 2013. He expects to complete his training to become an epidemiologist in 2024.

His professional career as a physical therapist, started in 2006 at the Maasziekenhuis Pantein in Boxmeer (2006-2008) and at Fysiotherapie Haps in Haps (2006-2012). As a lecturer internship manual therapy for the SOMT University he supervised physical therapists who studied manual therapy (2011-2023). In 2012 he started working at Fysius Rugexperts (2012-2023). Here, he focused more and more on education, health policy, complex diagnostics, medical partnerships, and science.

In 2017, this resulted in the start of his PhD-trajectory at the Radboud University Medical Center. In 2021, he also started working as a scientific researcher at the Radboud University Medical Center in the Inabled Cities project. In this international project he researched the barriers and facilitators for physical activity in elderly people in Mediterranean countries. He was also responsible for the data analysis and evaluation of the pilot activities to improve physical activity engagement. Currently, he researches the evaluation and monitoring of guideline adherence in community nursing.

In 2023, he stopped working as a physical/manual therapist and he started working as a senior supervisor at the Dutch Healthcare Authority (NZa). Currently

he is the project manager of the projects Monitor Health Insurance Market and Working with Health Goals. He is also active in the projects on Risk Equalization, Risk Selection, and Dutch Healthcare Authority Science.

Scientific publications

Three-dimensional kinematics of the cervical spine using an electromagnetic tracking device. Differences between healthy subjects and subjects with non-specific neck pain and the effect of age.
Lemmers GPG, Heijmans MWM, Scafoglieri A, Buyl R, Staal JB, Schmitt MA, Cattrysse E.
Clinical Biomechanics (Bristol, Avon). 2018 May;54:111-117. doi: 10.1016/j.clinbiomech.2018.03.012. Epub 2018 Mar 17.

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Research profiles

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PHD PORTFOLIO OF P.G. LEMMERS (GIJS)

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PhD period: 01/07/2017 – 01/07/2023	
PhD Supervisors: prof. dr. Philip van der Wees, prof. dr. Gert Westert	
PhD Co-supervisors: dr. Bart Staal, dr. René Melis	
Training activities	**Hours**
Courses	
Scientific Writing for PhD candidates (2018)	84
V10 Epidemiologie (2019) - EPIDM	56
RIHS - Introduction course for PhD candidates (2019) - Radboudumc	15
RIHS PhD introduction course (2019)	21
Kwalitatief onderzoek in de gezondheidszorg (2019) - Radboud UMC	28
EBROK course Radboudumc (2019) - Radboudumc	42
BMS61 Statistical Modeling in Medical Research (2022) - The Department for Health Evidence of the Radboud university medical center	84
BMS84 Longitudinal and multilevel data analysis (2022)	84
PhD-defense: answering questions (2022) - Radboudumc	2
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Seminars	
Fair data sharing (2022)	2
How to chair a session (2022)	2
Radboud Research Rounds (3x) (2018-2022)	6
Refereersessies IQ Healthcare (4x) (2018-2023)	8
Research Integrity Round (2023)	2
How to prepare for your PhD defense (2023)	2
Conferences	
Annual Congress Society for Back Pain Research (2018) - poster presentation	14
World Congress on Low Back Back and Pelvic Girdle Pain (2019) - oral presentation	48
Back & Neck Pain Research Forum (2021) - poster presentation	24
PhD retreat Radboudumc (2022) - oral presentation	12
Back & Neck Pain Research Forum (2023) - 3 poster presentations	24
Other	
European Union Project: InAbled Cities (2021-2023)	200
Teaching activities	
Lecturing	
Masterclasses state of the art low back pain (10x) (2017-2023)	20
Supervision of internships / other	
Supervision Master student internship (8x) (2017-2023)	120
Supervision Bachelor student internship (2x) (2017-2021)	30
Total	**940**