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Outcomes Important To Measure For Patients Following Lumbar Spinal Fusion Surgery

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Supervisor: Rushton, Alison, *The University of Western Ontario* A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences © Onyinyechukwu C. Umemba 2023

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Abstract

This thesis aimed to investigate the outcomes that are important to measure for patients following LSFS. First, a systematic review identified outcomes that have been measured for patients from existing LSFS literature. Findings from 50 included studies found 35 outcomes have been measured. Second, a secondary analysis of qualitative study explored patients' perceptions identifying 25 outcomes perceived as important to measure. Synthesis of findings across studies showed variability of outcomes and different perspectives reflecting that the outcomes measured in research are sometimes the same, but they can also vary from what patients perceive as important. These outcomes were related to 3 ICF components of body functions, activities and participation and environmental factors, with the activities and participation component highly representative of outcomes important to measure. It was also noted that the ICF did not encompass some outcomes reported. Results were inconclusive in recommending important outcomes following LSFS; therefore, further research conducting a primary qualitative study is needed.

Keywords

Outcomes, lumbar spinal fusion surgery, systematic review, qualitative study.

Summary for Lay Audience

Research has used various outcomes to investigate low back pain. However, due to the diversity of the lumbar spinal fusion population, such as differences in surgical fusion levels, and type of surgical procedure, it is not sure if the outcomes used to assess LBP reflect the outcomes important for patients following LSFS. A systematic review was carried out investigating the outcomes that have been measured as reported in existing LSFS literature. There were 50 articles included, and 35 outcomes were identified. Findings showed that pain, walking, carrying out daily routine, and disability are outcomes frequently reported by the included quantitative and qualitative studies. A secondary analysis of qualitative study was also done, which explored patients' perception of important outcomes to measure following LSFS. Findings showed 25 outcomes were identified with walking, pain relief, and the ability to perform functional activities without pain being the outcomes frequently reported. The results from the two studies were merged, and the synthesis showed a variation of outcomes important to measure for patients. Synthesis showed that the outcomes used in research are sometimes the same and can be very different from what patients think is important to measure. This variation was also shown in the different ICF components of body functions, activities and participation, and environmental factors as outcomes reflected different patterns. This means that what we are doing in literature at the moment in using outcomes may not optimal as there were differences in patients' perspectives. It was also noted that the ICF did not reflect some outcomes reported in research and by patients. Therefore, future work is needed as the results were inconclusive and specific outcomes could not be recommended as important.

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Chapter 1

1 Introduction

1.1 Low back pain

Low back pain (LBP) is a symptom rather than a disease identified by the location of pain, commonly between the posterior lower rib border and the buttock creases (Dionne et al., 2008; Hartvigsen et al., 2018a). One or both legs can also be affected, and some individuals with LBP experience neurological problems in their lower limbs (Hartvigsen et al., 2018a). According to the updated International Association for the Study of Pain definition, pain is "an unpleasant sensory and emotional experience associated with, or resembling that associated with actual or potential tissue damage." An individual's experience of pain varies, and this is impacted by biological, psychological and social variables (Raja et al., 2020). Globally, LBP is the most common musculoskeletal problem and poses an enormous economic burden on individuals, families, industries, and governments (Hooten & Cohen, 2015). It also significantly affects activity limitation and work absenteeism (Lee et al., 2015). According to the Global Burden Diseases 2019 study, in 13 out of 21 world regions, LBP was the leading cause of disabilityadjusted life years (combined years of life lost in a population owing to early mortality and years lived with disability) (Murray, 1996; Wu et al., 2020). Itz et al. (2013), reported that most acute LBP episodes resolve within a few weeks, but about 60% of individuals will experience chronic or recurrent pain. Chronic LBP has been recognized as a disease owing to its clinical course instead of being seen as a symptom (Treede et al., 2015), and it is prevalent, particularly among individuals of older ages, individuals with more baseline pain, depression, and fear of pain persistence (Knezevic et al., 2021).

1.2 The basis for treatment frameworks

According to recommendations, to assess and manage LBP patients in both the acute and chronic stages, adopting a biopsychosocial (BPS) framework is recommended; given the recognition of LBP as a BPS phenomenon (Bernstein et al., 2017; Delitto et al., 2012; Foster et al., 2018; Qaseem et al., 2017). The International Classification of Functioning, Disability, and Health

(ICF) is a recommended biopsychosocial framework established by the World Health Organization (WHO) in 2001 which integrates the elements of biological, psychological, and social levels of health (World Health Organization, 2001). This classification's approach for evaluating individuals with diseases differs from the previously used biological theory framework, which had a narrow focus. This biological theory viewed that the experience of LBP was directly caused by physical factors and attempted to treat symptoms by targeting tissues thought to be at fault (Melzack & Wall, 1965; Waddell, 1987). The BPS framework was created to broaden the concept of health. It also emphasizes the dynamic interactions between a diverse range of biological, psychological, and social factors that can influence a person's experience of LBP (Engel, 1977; Gatchel & Turk, 2008). The BPS framework encourages professionals to diagnose diseases appropriately, set specific goals, identify the causes and contributing factors to these diseases, and plan more effective interventions (Steiner et al., 2002). Researchers in physiotherapy have supported using this framework as it relates to the underlying causes of LBP. They reported, in contrast to the biological theory, that in addition to biological factors, psychological factors (behaviours, beliefs, depression, anxiety, and fear) and social factors (financial, family, and work-related issues) are related to patient outcomes (Pincus et al., 2002; Waddell, 1987). The factors contributing to an individual patient's experience of LBP vary considerably, thus the need for an individualized approach to assessment and management.

1.3 Management of LBP

Depending on the underlying cause, there are numerous management options for LBP. Nonpharmacological treatments such as self-management, complementary medicine, physical therapy, psychological therapy, and interdisciplinary rehabilitation have been advocated as the first line for management of LBP (Foster et al., 2018; Qaseem et al., 2017). Patients for whom these treatments do not work are then managed through pharmacological care. Spinal surgery, such as decompression surgery, spinal fusion surgery and disc arthroplasty, is indicated in a minority of patients with chronic LBP who have not responded to management options (Morlion, 2013).

Lumbar spinal fusion surgery (LSFS) is a surgical treatment that fuses two or more vertebrae to stabilize painful spinal segments. The current recommendation for using LSFS is chronic back

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and/or leg pain of degenerative or spondylolisthetic origin that has not responded to conservative treatment, where it can stabilize the spine (Rushton et al., 2018; Willems et al., 2011). Although the surgery produces a high incidence of radiographic fusion, many patients still report poor outcomes such as discomfort, functional limitation, inability to return to work, and chronic opioid pain medication use (Lall & Restrepo, 2017). Therefore, according to the National Institute for Health and Care Excellence recent guideline (NICE, 2021), this management option should not be used in patients with LBP unless it is part of a randomized controlled trial as it necessitates further investigation. However, evidence in conflicting and for the appropriate indications, LSFS can have good outcomes. For example, in a large systematic review and meta-analysis, <u>Koenders et al. (2019)</u>, reported a decrease in back pain, leg pain, and disability outcomes following LSFS. Previous research has shown the outcomes following LSFS are affected by the heterogeneity of patients undergoing LSFS, including different levels of fusion, use/non-use of instrumentation, type of fusion surgical procedure, presence of co-morbidities, and patient factors such as weight and fitness (Rushton et al., 2015). Therefore, this heterogeneity makes the LSFS population an important group to study.

1.4 Outcomes and outcome measures used following LSFS

According to <u>Donabedian (1988)</u>, outcomes are the results of health care for individuals, reflecting recovery and improvements in health status. These outcomes are measured at various time points, reflecting short, middle, and long-term results (Porter, 2010). According to <u>Stamm et al. (2019)</u>, these outcomes include the measurement of clinical signs and symptoms; however, they also include quality of life, functioning, pain, and fatigue. There are different types of outcomes. Outcomes can be patient-reported outcomes (PROs) which report directly from the patient (Weldring & Smith, 2013). Clinician-reported outcomes (ClinROs) are a report from a trained healthcare professional after observing a patient's health condition (Powers et al., 2017). Observer-reported outcomes (ObsROs) are a report by a parent, caregiver, or someone who observes the patient daily (McKown et al., 2020). In contrast, performance-based outcomes (PerfOs) are based on standardized task(s) actively undertaken by a patient according to a set of instructions (Walton et al., 2015). Outcomes, thus, reflect accurate measures of the quality of interventions, and therefore improving outcomes should be the ultimate goal for patient care (Porter, 2010).

An outcome measure is the tool used to assess a patient's status and may provide a score, result, interpretation, and sometimes a risk categorization of the patient's score (Clarke, 2007; Fetters & Tilson, 2012). Various measures to assess outcomes after LSFS include the use of patientreported outcome measures (PROMs) such as questionnaires and scales (Reiman & Manske, 2011); impairment-based outcome measures which assess the structure or function of a specific body part such as range of motion, muscle strength (Reiman & Manske, 2011); functional performance-based tests such as timed up and go and 6-min walk test which evaluate performance on a specified task in a standardized environment (Taylor et al., 2016); and physical outcome measures such as accelerometry which measures activity in a natural setting (Taylor et al., 2016). PROMs are the most frequently used measure which ascertains patients' perspectives of their symptoms and captures information about their lived experiences, functional status, and health-related quality of life (Stokes et al., 2017; Weinfurt & Reeve, 2022). Some frequently used PROMs and the outcomes they measure include the Oswestry Disability Index (ODI) and Roland Morris Disability (RMD) questionnaires which assesses disability and physical functioning, Visual Analogue Scale (VAS) and Pain Numerical Rating Scale (PNRS) to assess low back pain intensity, the Short Form Health Survey 12 for health-related quality of life following LSFS, Work Ability Index (WAI) to frequently assess work ability following LSFS (Stamm et al., 2019; Stokes et al., 2017). Measuring outcomes at baseline may help determine the course of treatment intervention and once commenced, may be used in serial assessments to determine whether the patient has demonstrated any change. For consistency in measuring outcomes at baseline and serial assessment, a benchmark of outcomes to measure is needed. Williamson et al. (2012), described core outcome sets (COS) as an agreed set of outcomes that should be measured and reported as a minimum in all clinical trials for specific health conditions. COS have been developed and used for specific health conditions such as LBP to reduce inconsistent outcomes measured and reported across clinical trials and interventions (Clarke, 2007). Such a set does not limit the measurement to the recommended measures within each domain of the COS or the choice of the primary outcome. Still, it mandates collecting and reporting the COS alongside the outcomes of interest (Kirkham et al., 2013).

Various COS for LBP has been established to set a minimum standard for reporting outcomes, reduce the risk of selective reporting bias, reduce heterogeneity and enable comparison of results across studies (Webbe et al., 2018). An example is the ICF Core Sets, a subset of the 1400

categories of the ICF developed by clinical experts from various fields to increase the applicability of the ICF for clinical assessments and research (Cieza et al., 2019; Stucki et al., 2002). Furthermore, the core outcomes of pain intensity (back and leg), function, symptom-specific well-being, disability (work), disability (social role), and satisfaction with treatment have been proposed, studied and validated widely for evaluation of the effectiveness of LBP diagnosis and management (Bombardier, 2000; Deyo et al., 1998; Mannion et al., 2005; Ostelo & de Vet, 2005). However, an updated COS by Chiarotto et al. (2015), which included patient representatives in its development, recommends physical functioning, pain intensity, number of deaths and health-related quality of life as the core outcomes to measure for LBP.

The success of surgical treatment is frequently measured by outcomes such as pain and improvement of function, which are primarily subjective (Försth et al., 2016). Patients' perspectives are therefore important to include in assessing outcomes and evaluating the effectiveness of clinical interventions, especially for patients experiencing chronic health conditions such as LBP, as this gives full insight into their lived experiences (Weinfurt & Reeve, 2022).

<u>Boyce & Browne (2013)</u>, reported that using individual PROMs can inform dialogue between the patient and the practitioner, assisting in identifying and discussing the most important outcome for the patient. Therefore, it allows the practitioner to ensure that intervention plans align with the patient's priorities while accelerating the process of determining the most important outcome for the patient. When used over time, these data can focus on what is most important and whether or not the intervention is functioning as expected (Fokter & Yerby, 2006; McCormick et al., 2013). However, despite the advocacy of inclusion of patient perspectives in PROMs, previous research has shown that the majority of PROMs were developed based on the opinions of clinical experts, with little input from patients; thus, PROMs may not truly capture patients' perspectives of important outcomes (Kreiner et al., 2013; Rushton et al., 2020; Staniszewska et al., 2012).

<u>Whitebird et al. (2020)</u>, revealed that though PROMs provide a view into the patient experience, they may not give a clear picture of patients' expectations unless constructed based on patients' perceptions of their preferred outcomes. An illustration of this is captured in a study by <u>Wiering</u>

et al. (2018), who found that after hip/knee surgery, patients' choices and expectations for specific outcomes shaped their perceptions of the post-operative effectiveness of their surgery. Whitebird et al. (2020), further reported that after spinal discectomy/laminotomy or spinal fusion surgery, pain relief, returning to everyday life, and an active lifestyle were outcomes reported as important to measure. The outcomes reported by previous studies were not specific to the LSFS population but generalized to the LBP population. Therefore, it cannot be assumed that the outcomes reported by previous studies fully reflect the specific outcomes that are important to measure for patients who underwent LSFS. Furthermore, <u>Rushton et al. (2022)</u>, documented that catastrophizing thoughts, pain, depression, and poor health-related quality of life were significant experiences of patients after LSFS, it is necessary to measure the outcomes important to patients' experiences of treatment interventions.

1.5 Gap in current knowledge

Previous literature has investigated outcomes important to measure following spinal discectomy/laminotomy or spinal fusion surgery, focusing on pain relief, returning to an active lifestyle, and returning to everyday life. However, these outcomes do not fully reflect the outcomes that are important to measure for patients who have had LSFS, nor do they reflect these patients' perspectives of outcomes important to measure following LSFS. Studies have also shown that patients who underwent LSFS present with complaints that may differ from the general LBP population. The fusion level may also vary across patients, thus making this population important to study. Therefore, an enhanced understanding of the important outcomes to measure for patients after LSFS may help inform treatment interventions to aid their recovery process and assist healthcare professionals' evaluation of treatment effectiveness.

1.6 Aim and objectives of the thesis

This thesis aims to investigate the outcomes that are important to measure for patients following LSFS.

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Objectives

- 1. To identify the outcomes that have been measured for patients following LSFS
- 2. To explore patients' perceptions of important outcomes following LSFS

1.7 Thesis Overview

This thesis focuses on the outcomes important to measure following LSFS. It begins with a systematic review in Chapter 2, which identified outcomes that have been measured for patients following LSFS as identified in the existing literature, addressing objective 1. In Chapter 3, a qualitative study explored patients' perceptions of important outcomes following LSFS, addressing objective 2. Chapter 4 provides an overall discussion synthesizing the findings from both studies (systematic review and qualitative study), evaluating their strengths, limitations, clinical and research implications, and future directions of this work. Chapter 5 provides a conclusion for the thesis.

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Chapter 2

2 WHAT ARE THE OUTCOMES MEASURED FOLLOWING LUMBAR SPINAL FUSION SURGERY? A SYSTEMATIC REVIEW AND NARRATIVE SYNTHESIS

2.1 Abstract

Background: COS have been validated and recommended for LBP assessment and intervention. Studies have used these COS for LBP and LSFS; however, the outcomes that have been measured following LSFS have not been researched. This study aimed to identify the outcomes that that have been measured for patients following LSFS.

Methods: A systematic review was conducted, searching key databases (PubMed, MEDLINE, EMBASE, Scopus, and Web of Science) using predefined search terms from inception to 31 December 2021. The reference lists of included studies were also searched. Qualitative, quantitative, and mixed-method studies that reported outcomes for adult patients who underwent LSFS were included. Radiological outcomes were excluded. The Quality Assessment for Diverse Studies (QuADS) tool was used to assess study quality. Using the ICF framework, a narrative synthesis categorized data into components, chapters, and domains.

Results: 50 studies were included (48 quantitative, 1 qualitative, 1 mixed-method). 35 outcomes were identified as outcomes that have been measured following LSFS. Pain, walking, carrying out daily routine, and disability are outcomes reported by the quantitative and qualitative studies therefore, they reflect frequent outcomes measured following LSFS. Finding from the qualitative data studies showed patients are concerned explicitly with outcomes such as doing house chores, driving, and moving around following LSFS. Findings from the quantitative data studies showed outcomes such as gait, mental and neurological functions are frequently measured by researchers following LSFS. When mapped to the ICF, the important outcomes reflect the ICF components of body functions (23%, reflecting quantitative data studies), activities and participation (49%, reflecting qualitative data studies), and environmental factors (20%, reflecting qualitative data studies), and environmental factors (20%, reflecting qualitative data studies), patient satisfaction, and quality of life.

Conclusions: All components of the ICF except body structures reflected outcomes important to measure following LSFS. Pain, walking, carrying out daily routines, and disability emerged as the most frequent outcomes measured, as reported by the qualitative and quantitative data studies. However, due to the variability and the differences in outcomes from the quantitative and qualitative data studies, further research is needed to explore patients' perceptions of the important outcomes to measure following LSFS.

2.2 Introduction

Low back pain (LBP) is a common problem with significant socio-economic and psychosocial consequences. The heterogeneity of assessed outcomes makes it difficult to evaluate the consequences of LBP and the effects of interventions. A uniform approach to measuring outcomes for gauging clinical intervention effectiveness is required (Kaiser et al., 2016). Established COS help to reduce heterogeneity in gauging the effectiveness of clinical intervention by standardizing outcomes and outcome measures (Chiarotto et al., 2015; Mannion et al., 2005; Ostelo & de Vet, 2005).

It is generally and long accepted that the effectiveness of any LBP intervention should also be assessed in the context of the patient's perception of the benefits obtained, typically in terms of how it affects their pain, level of daily activity limitation, ability to work, quality of life, etc. (Deyo et al., 1994). This is further corroborated by <u>Murray et al. (2012)</u>, who concluded that LBP outcomes are best measured using PROMs, which objectively measure patients' subjective outcomes (e.g. functional health status, quality of life). Previously, outcomes were usually assessed based on surgeons' and clinicians' subjective views to determine the progress of interventions (Teles et al., 2016), which is now acknowledged as problematic. This was evident in the proposed COS by <u>Bombardier (2000)</u>, which predominantly had clinicians experienced in pain medicine, outcome research and development of questionnaires as the stakeholders who determined the outcomes measured in the COS.

<u>Newman & Benz (1998)</u>, recorded that renewed interests in investigating the importance of patients' subjective views and perspectives using qualitative methods have been increasing since the emergence of the biopsychosocial model of health care. This is corroborated by <u>Abbott et al.</u> (2011), who linked patients' experiences of their back problem, recovery and expectations post

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LSFS to several the ICF. Furthermore, the updated COS for LBP by <u>Chiarotto et al. (2015)</u>, introduced patients into their Delphi study to inform its development, and several new outcomes were proposed. A Numeric Rating Scale (NRS) was recommended for pain intensity; the Oswestry Disability Index version 2.1a (ODI 2.1a) and 24-item Roland Morris Disability Questionnaire (RMDQ-24) for physical functioning; the Short Form Health Survey 12 (SF12) and 10-item PROMIS Global Health (PROMIS-GH-10) for Health-related quality of life, and to assess the number of deaths, a simple statement on the number of deaths was recommended (Chiarotto et al., 2018). This use of the updated outcomes is evident in recent studies, as <u>Szadkowski et al. (2021)</u>, documented the measurement of pain, disability, and physical and mental function outcomes in patients after they underwent anterior lumber interbody fusion. These outcomes were measured using VAS, ODI, and SF-12 physical and mental components, which are some of the recommended measures by <u>Chiarotto et al. (2018)</u>.

A large systematic review and meta-analysis by <u>Koenders et al. (2019)</u>, explored outcomes following LSFS but limited them to prospective cohort studies and excluded randomized control trials. However, this study aims to investigate outcomes frequently measured following LSFS including all research designs hence the need for this study.

2.3 Objective

To identify the outcomes that have been measured for patients following LSFS.

2.4 Methods

A systematic review and narrative synthesis was carried out according to a predefined study protocol following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA; <u>Page et al., 2021</u>). The Cochrane handbook also aided protocol development (Higgins & Cochrane Collaboration, 2020).

2.4.1 Eligibility Criteria

Inclusion criteria

Eligibility for study inclusion used the Sample, Phenomenon of Interest, Design, Evaluation, Research Type (SPIDER) tool, designed to include a qualitative evidence synthesis (Cooke et al., 2012).

(S) Sample: studies with adult patients >18 years who underwent LSFS.

(PI) Phenomenon of Interest: Studies that documented and measured outcomes except for radiological outcomes following LSFS.

(D) Design: Any study that described the sampling strategy, data collection procedures, and type of data analysis of qualitative, quantitative, or mixed-method study designs (Creswell & Plano Clark, 2018; Hannes, 2011; Higgins & Cochrane Collaboration, 2020)

(E) Evaluation: any study reporting on the outcomes following LSFS.

(R) Research type: Qualitative, quantitative and mixed-method research articles were included in this review.

Exclusion criteria

Studies that documented radiological outcomes only following LSFS.

Studies not published in English.

2.4.2 Information sources

Searches were conducted using PubMed, Medline (Ovid), Scopus, EMBASE, and Web of Science. Each database was searched by the primary researcher (OU) from inception to 31 December 2021. The search strategy was specific to each database used. Additionally, a manual search of the reference lists of the included studies was conducted to find studies that did not appear in the databases searched. However, grey literature was not searched therefore, a potential limitation is that this review may not accurately reflect all of the research in this field.

2.4.3 Search strategy

The primary researcher (OU) developed the search strategy in discussion with the advisory team. The search strategy was created for Medline and subsequently adapted for the other databases. The key terms used for the search included the categories of outcome (items 1-5 Table 1) and LSFS (items 6-9 Table 1). A list of synonyms was used within the search for all key terms. Table 1: Medline OVID search strategy

1.	Treatment Outcome/ or Core outcome domain.mp.
2.	Treatment Outcome/ or Clinical Trials as Topic/ or Randomized Controlled Trials
	as Topic/
3.	Core outcome sets. mp. or Research Design/ or Delphi Technique/
4.	Outcome measures. mp. or Outcome Assessment, Health Care/
5.	Treatment Outcome/ or core outcome domains. mp.
6.	Spinal Fusion/ or lumbar spinal fusion surgery. mp.
7.	Lumbar spinal fusion surgery .mp.
8.	Lumbar arthrodesis .mp.
9.	Spinal Fusion/ or lumbar fixation.mp.
10.	1 or 2 or 3 or 4 or 5
11.	6 or 7 or 8 or 9
12.	10 and 11

Example of adaptation to a different database: Scopus

TITLE-ABS-KEY

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((core AND outcome*) OR (outcome AND measure*) OR (outcome AND assessment))
AND (measure*) AND ((lumbar AND spinal AND fusion AND surgery) OR (LSFS) O
R (lumbar AND arthrodes*) OR (lumbar AND fixation)) AND (LIMIT TO (PUBSTAGE
,"final")) AND (LIMIT-TO (OA, "all")) AND (LIMIT
TO (DOCTYPE, "ar") OR LIMIT-TO (DOCTYPE, "re")) AND (LIMIT
TO (SUBJAREA, "MEDI") OR LIMIT-TO (SUBJAREA, "NEUR") OR LIMIT-
TO (SUBJAREA, "HEAL") OR LIMIT-TO (SUBJAREA, "NURS")) AND (LIMIT-
TO (LANGUAGE, "English")) AND (LIMIT-TO (SRCTYPE, "j"))
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2.4.4 Data management

Search results were stored on Endnote V.X8 (Clarivate Analytics) software programme, where duplicates were established and eliminated.

2.4.5 Study selection

Study selection involved two stages. The first stage of the selection process involved the primary researcher reading through research titles and abstracts using the eligibility criteria (van Tulder et al., 2003). Studies whose titles and abstracts were not relevant to the objective of this study were excluded. If the exclusion of a study was not certain based on the information provided in the title and abstract, it was graded as 'potentially relevant' (Centre for Reviews and Dissemination, 2009). The second stage involved retrieving the full text of potentially relevant studies, which was assessed for eligibility by the primary researcher (Furlan et al., 2015). However, because a single reviewer carried out the selection of studies without the input of a second or third reviewer, this introduces a risk of selection bias. Records were kept for each stage, and a PRISMA flow chart was recorded (Moher et al., 2009).

2.4.6 Data items and extraction

Data were extracted from the studies included in the review using a standardized data extraction tool from the Joanna Briggs Institute qualitative data extraction (Appendix 1; Aromataris E, 2020). This tool was modified to extract data from the different study designs in this review. The data extracted included specific details about the author & country, study participant characteristics, study design, timeframe, outcomes and outcome measures that were significant to the objective. Findings were extracted separately for each study by the primary researcher.

2.4.7 Quality assessment of individual studies

An assessment of study quality was carried out to improve the rigour, validity, and trustworthiness of the results of this systematic review (Butler et al., 2016). The researcher utilized a validated quality assessment tool, QuADS (Appendix 2). The QuADS tool is one of the few practical tools that can be used to assess quality across a wide range of study designs and is an extension of the Quality Assessment Tool for Studies with Diverse Designs (QATSDD). The QATSDD tool was found to have some limitations in its ease of use outside of the field of

psychology, so it was revised, enhanced, and adapted into an updated version, QuADS, to make it more applicable to health services researchers evaluating the quality of methods, evidence, and reporting in multi- and/or mixed-methods studies (Harrison et al., 2021). This QuADS tool was chosen for this review because of its established reliability and validity when assessing the quality of various study designs (Arbour-Nicitopoulos et al., 2018). It also allows for a quick, integrated evaluation across a body of evidence within a review (Lamore et al., 2017). The QuADS provides a framework to consider methodological and evidence quality and define constraints in the study reporting quality (Harrison et al., 2021).

The QuADS consists of 13 reporting criteria rated on a scale of 0 to 3 (not at all/ slightly/ moderately/ completely). These standards apply to both quantitative and qualitative research. Despite the use of the QuADS for studies with multiple designs, the tool lacks distinction between scores and could not be categorized. Therefore, the quality of included studies in this study was determined a-priori by a study by <u>Graham-Clarke et al. (2018)</u>, which was categorized into low, moderate and high quality using <25%, 25-75% and >75% scores, respectively. The evaluation of the quality of included studies was also carried out by the primary researcher alone, which may also introduce bias into the review.

2.4.8 Data Synthesis

A narrative synthesis was conducted separately for the extracted qualitative and quantitative data following previously recommended guidance for a narrative synthesis in systematic reviews (Popay et al., 2006). This was done in 2 stages and reviewed by the advisory team to ensure all relevant data were analysed (Thomas & Harden, 2008a).

Stage 1:

All studies were categorized into quantitative or qualitative data studies from the quantitative, qualitative data and mixed-method design. Qualitative data and quantitative data from mixed-method design (Abbott et al., 2011) were categorized as qualitative data study and quantitative data study respectively. Information containing outcomes and outcome measures used in each study were extracted for the quantitative data studies, while outcomes only were extracted for qualitative data studies. These outcomes were grouped and the frequency of which each

outcomes were measured was reported within the qualitative and quantitative data studies. The frequency and percentage of the different outcome measures used in each outcome were reported for the quantitative data studies only.

Stage 2:

Identified outcomes (from quantitative and qualitative data studies) were mapped to the World Health Organization's ICF framework. Outcomes were mapped directly to the components, chapters, and domains of the ICF (Bowling, 2010; World Health Organization, 2001).

2.4.9 Integration of synthesized data

The outcomes identified from the qualitative and quantitative data studies were compared using tables, pie charts, and flowcharts to determine similarities or contrasts within specified ICF components, chapters, and domains (Sandelowski et al., 2006).

2.4.10 Ethics

There was no research ethics required for this systematic review as no patient data were collected.

2.5 Results

2.5.1 Study selection

The search strategy identified 13246 potentially relevant articles. 13158 were excluded for irrelevant titles and participants, and 2 duplicates were removed. After a full-text assessment of 86 articles, 4 opinion pieces, 30 articles not specific to LSFS, and 2 articles with radiological outcomes were excluded. After searching the reference lists of included studies, 13 potentially relevant new studies were identified; 3 were excluded for being duplicates, and 10 were excluded after full-text screening for non-specificity to LSFS. Following exclusions, 50 studies were included. The study selection process is illustrated in a PRISMA flowchart (Figure 1).



Figure 1: PRISMA flowchart of article search and selection (Page et al., 2021)

2.5.2 Study characteristics

Of the 50 included studies, 48 were quantitative, 1 was qualitative, and 1 was a mixed-method study. A total of n=242,516 participants were included in this review. There were 7 different research designs across included studies: 29 retrospective cohort studies, 12 prospective cohort studies, 5 randomized control trials, 1 observational study, 1 retrospective comparative analysis, 1 Interpretative Phenomenological Analysis and 1 mixed-method study. The studies were conducted across 18 countries, with the most prevalent in the USA, Sweden, Singapore, and China. The studies were published between 2006 and 2021. Table 2a, 2b, and 2c displays the characteristics of the included quantitative studies, qualitative and mixed-method study respectively.
	Country			Age (mean ± S.D or otherwise	
Author citation	(study)	n	Sex (n)	stated)	Measurement Timeframe
					Preop & Postop at 1, 3, 6, and 12 weeks, 6 months, 1 year, a
Akgul et al., 2021.	Turkey	39	M=21, F=18	58.2 ± 8.4	thereafter, once a year.
Asher et al., 2016.	USA	3073	M= 1557, F= 1516	60.2 ± 13.5	Preop, 3 & 12 months postop
Berg et al., 2009.	Sweden	152	M= 62, F= 90	39.4 ± 8.0	Preop, 1 & 2 years Postop
Berjano et al., 2021.	Switzerland	1243	M= 472, F= 771	56.0	Preop and 6 months Postop
Bisson et al., 2021.	USA	608	M= 258, F= 350	59.9 ± 11.3	Preop, 1 & 2 years Postop
Boden et al., 2020.	Georgia	972	M= 555, F= 417	62.6 ± 12.8	Preop, 3 & 6 Month Postop
					Preop, 1 month, 3 months, 6 months, 12 months & 24 month
Cho et al., 2021.	South Korea	76	M=40, F=36	65.3 ± 9.0	Postop
Coronado et al., 2020.	USA	53	M= 19, F= 34	63.1 (59.7, 66.4 for 95% CI)	6 weeks, 3 months, 6 months Postop
Divi et al., 2021.	USA	494	M= 303, F= 191	58.4 (55.7, 61.1 for 95% CI)	Preop, 3 & 6 months Postop
Ganesan et al., 2018.	India	53	Not given	54.6 ± 7.9	Preop, 1 &2 Years Postop
Geoghegan et al.,					
2021.	USA	144	M= 79, F= 65	53.9 ± 10.4	Preop, 6 weeks, 12 weeks, 6 months, 1 & 2 years Postop
Gilmore et al., 2019.	Australia	233	M= 118, F= 115	61.0	Preop and 6 months Postop
Goh et al., 2019.	Singapore	168	M= 49, F= 119	59.0 ± 7	Preop, 1, 3, 6 months, and 2 years Postop
Goh et al., 2020.	Singapore	96	M= 34; F= 62	44.0 ± 6.5	Preop, 1, 3, 6 months, and 2 years Postop
Goh et al., 2021.	Singapore	799	M= 267, F= 532	59.7 ± 11.5	Preop & 1 month, 3 months, 6 months Postop
Goyal et al., 2021.	USA	391	M= 212, F= 179	62.0 (61.0 for 95% CI)	Preop, and 1-year postop
Haddas et al., 2021.	USA	66	M= 19, F= 25	60.0 ± 12.3	Preop, 3 months Postop
Han et al., 2021.	China	61	M= 27, F= 34	50.4 ± 16.0	Preop, 1, 3, 6 months Postop
Houten et al., 2006.	USA	33	M= 19, F= 14	42.0	Preop, range 3–57 months Postop
					Preop, 3 months, 6-month Postop & range of 20–36 months
Huang et al., 2021.	China	61	M= 36, F= 25	72.3 ± 3.4	Postop

 Table 2a: Baseline demographic characteristics of quantitative studies



	Country			Age (mean ± S.D or otherwise	
Author citation	(study)	n	Sex (n)	stated)	Measurement Timeframe
Jacob et al., 2021.	USA	740	M= 451, F= 289	51.7 ± 12.0	Preop, 12 weeks, 6mths, 1&2 Years
Jakobsson et al.,					
2019.	Sweden	118	M= 81, F= 94	46.5 ± 8.0	Preop, 3 months, 6 months, and 12 months Postop
Jenkins et al., 2021.	USA	171	M= 107, F= 64	40.9 ± 7.5	Preop, 6weeks, 12weeks, 6months, 12 months
Kaye et al., 2019.	USA	416	M= 203, F= 213	63.7 ± 11.2	Preop and 18 months Postop
Le et al., 2020.	USA	76	M= 30, F= 46	62.1	Preop, 12 & 15 months Postop
	Germany &				
Lenz et al., 2020.	USA	32	M= 19, F= 13	59.2 ± 15.3	Preop, 12 months, 24 months, and 36 months Postop
Lim et al., 2020.	Singapore	296	M= 94, F= 202	$M = (56.1 \pm 11.6); F = (52.2 \pm 3.2)$	Preop, 2 & 5 years Postop
Lim et al., 2018.	Singapore	217	M= 84, F= 133	61.0 ± 11.1	Preop, 12 & 24 months Postop
Lin et al., 2021.	China	52	M= 34, F= 18	\geq 18 years. No mean reported	Preop, 3 months, 6 months & 1 year Postop
Oestergaard et al.,					
2013.	Denmark	82	M= 44, F= 38	51.3 ± 9.9	Preop, 3 months Postop, 6 months Postop, 12 months Postop
Marbacher et al.,					
2016.	Switzerland	707	M= 229, F= 478	58.4 ± 4.3	Preop & 12months post op
Master et al., 2021.	USA	248	M= 122, F= 126	62.2 ± 11.9	Preop, 6 weeks, 6 months, 12 months, 24 months Postop
Min & Yoo., 2012.	Korea	127	M = 47, F = 80	56.78	Preop, 12 months Postop
Moses et al., 2021.	USA	164	M= 79, F= 85	57.9	Preop, 6 weeks postop, 3, 6 & 12 Months Postop
Olivera et al., 2021.	Brazil	71	M= 38, F= 33	44.5 ± 15.2	Preop, 1 & 3 years postop
				LDH (45.0 \pm 14.0); LSS (67.0 \pm	
Parai et al., 2017.	Sweden	94132	Not given	12.0); DDD (47.0 ± 13.0)	Preop & 12 months Postop
				LDH (45.0 ± 14.0); LSS (67.0 ±	
Parai et al., 2019.	Sweden	98732	M= 48379, F= 50373	12.0); DDD (47.0 ± 13.0)	Preop, 1&2 years Postop
Park et al., 2011.	Korea	66	M= 20, F= 46	57.5	Pre & 6 months and at least 24 months Post-op
Park et al., 2021.	USA	31765	M= 16671, F= 15086	59.5 (59.2–59.7 for 95% CI)	Preop, 12 months, 24 months Postop
Saban et al., 2007.	USA	57	M= 27, F= 30	53.4 ± 11.3	Preop, 3 months Postop



	Country			Age (mean ± S.D or otherwise	
Author citation	(study)	n	Sex (n)	stated)	Measurement Timeframe
Schiedt et al., 2019.	Germany	58	Not given	\geq 18 recruited. No mean reported	Preop & 7 days, 3 and 12 months Postop
Sielatycki et al.,					
2021.	USA	208	Not given	56.7 ± 11.8	Preop, 3 months & 6 months Postop
Szadkowski et al.,					
2021.	France	41	M= 17, F= 24	46.4 ± 11.7	Pre & 12 months Postop
Takahashi et al.,					
2011.	Japan	78	M= 36, F= 42	58.6 ± 8.3	Preop & 6, 12, 24 months Postop
Triebel et al., 2016.	Sweden	4780	M= 2251, F= 2529	46.0 ±10.0	Preop, 1 & 2 years Postop
Tuomainen et al.,					
2020.	Finland	96	M= 57, F= 39	58.0 ± 9.8	3 months, 5 & 10 years
Yang et al., 2020.	China	22	M= 8, F= 14	53.0	Preop, 2, 12, 24, 36 months postop
Yoo et al., 2019.	USA	101	M= 58, F = 43	57.0	Preop, 6 months Postop

LDH: lumbar disc herniation, LSS: lumbar spinal stenosis, DDD: degenerative disc disease, CI: Confidence interval.

Table 2b: Baseline demographic characteristics of the qualitative study

Author.	Country	(n)	Gender (n)	Age (mean or otherwise stated)	Measurement Timeframe
Rushton et al., 2020.	UK	28	M= 14, F= 14	> 18 years	Preop, 12 months postop

Table 2c: Baseline demographic characteristics of the mixed-method study.

Author.	Country	(n)	Gender (n)	Age (mean or otherwise stated)	Measurement Timeframe
Abott et al., 2011.	Sweden	20	M= 10, F= 10	53.7 ± 9.1	Preop & 3 months Postop







2.5.3 Quality of studies

The quality score of the included studies ranged from 56 - 95%. The scores are detailed in Appendix 3. Most articles were of high quality (n=27, 54%), while 23 (46%) were of moderate quality. The major issues identified that affected quality were limited information on the choice of framework, recruitment data, and justification for the choice of the analytic method. A summary is provided in Table 3 below.

	Quality		
Author, year	score of	Quality	
and country	study (%)	rating	Issues affecting quality of study
(Abbott et al.,			Minimal information on recruitment data,
2011). Sweden	85	high	strengths, and limitations of the study
			No recruitment data was provided, as well as no
			justification for the analytic method selected.
(Akgul et al.,			Limited information on study design and
2021). Turkey	56	moderate	rationale for the choice of data collected.
			In general reference to broad theories, a more
			suitable design could have been used, and only a
(Asher et al.,			basic explanation for the choice of data
2016). USA	82	high	collection tool was provided.
(Berg et al.,			No specific theory was mentioned or highlighted
2009). Sweden	82	high	to buttress the topic
			The format for data collection could benefit from
(Berjano et al.,			refinement and be more specific. Also, no
2021).			sufficient information on the strength and
Switzerland	59	moderate	limitations of the study.
			There was no detailed information on the
(Bisson et al.,			theoretical approach adopted as well as the
2021). USA	69	moderate	research design used for the study.
			Little evidence of the consideration of the
			required sample was provided, the rationale for
(Boden et al.,			the choice of data collection was not properly
2020). Georgia	69	moderate	detailed, also recruitment data was not complete.
(Cho et al.,			Minimal and basic recruitment data was
2021). South			provided, and sample characteristics were not
Korea	74	moderate	properly detailed
(Coronado et			Sufficient but incomplete recruitment data, little
al., 2020). USA	95	high	justification of method of analysis provided
			The framing of the collection tool was quite
(Divi et al.,			broad, with limited details on the stages of data
2021). USA	90	high	collection
(Ganesan et al.,			A very limited explanation for the choice of data
2018). India	69	moderate	collection tool selected
			No explicit discussion of theories, incomplete
(Geoghegan et			recruitment data, and insufficient justification for
al., 2021). USA	90	high	the analytic method selected

Table 3: Quality appraisal of included studies using QuADS tool.

	Quality		
Author, year	score of	Quality	
and country	study (%)	rating	Issues affecting quality of study
			No detailed justification for the choice of the
(Gilmore et al.,			analytic method, no complete data allowing for a
2019). Australia	95	high	full picture of recruitment outcomes
(G. SH. Goh et			No theoretical framework explained no clear
al., 2020).			description of the research setting, target
Singapore	79	high	population, and study design
(G. S. Goh et			No explanatory theoretical framework,
al., 2020).			description of research settings not in detail, and
Singapore	77	high	the research design are not properly detailed.
(G. S. Goh et			
al., 2021).			Strength and limitations are not explanatory, and
Singapore	77	high	limited information on underpinning theory
			The study design only addressed an aspect of the
(Goyal et al.,			project, no detailed theoretical framework and
2021). USA	64	moderate	research design
			Strength and limitations are not explanatory, and
(Haddas et al.,			limited information on underpinning theory and
2021). USA	82	high	research design
			The design is appropriate though an additional
			design would be more comprehensive. There
(Han et al.,			was no evidence of consideration of the sample
2021). China	77	high	required.
(Houten et al.,			Study limitations are not overtly stated. The
2006). USA	64	moderate	theoretical framework was not identified.
			The data collection procedure was only briefly
			outlined and not explained. Some recruitment
			data were provided but not complete. The
(Huang et al.,			method of analysis was appropriate but could
2021). China	72	high	have been better
			Limitation and strength of the study was not
(Jacob et al.,			highlighted, and recruitment data were not
2021). USA	85	high	provided
			Little information on the theoretical
(Jakobsson et			underpinning was provided. Recruitment data
al., 2019).			and justification for analytic data were not
Sweden	56	moderate	provided

	Quality		
Author, year	score of	Quality	
and country	study (%)	rating	Issues affecting quality of study
			Reference was made generally to concepts, but
(Jenkins et al.,			no identification of specific theories and study
2021). USA	82	high	aims not overtly written
			No specific identification of theories and
(Kaye et al.,			concepts that informed the work, research aim,
2020). USA	82	high	and study setting was not properly outlined
			Theoretical underpinning is missing, only a few
(Le et al., 2021).			concepts are explained, no clear description of
USA	59	moderate	the research setting and target population
(Lenz et al.,			Strength and limitations are sparingly written, no
2020). Germany			explicit theoretical underpinning and clear
& USA	74	moderate	research setting
(W. S. R. Lim et			No detailed justification for the choice of the
al., 2020).			analytic method, no complete data allowing for a
Singapore	77	high	full picture of recruitment outcomes
(J. B. T. Lim et			Theoretical underpinning is missing, only a few
al., 2018).			concepts are explained, no clear description of
Singapore	72	moderate	the research setting and target population
(Lin et al.,			Insufficient justification was provided for the
2021). China	90	high	analytic method used
			Limited information on the theoretical
(Oestergaard et			underpinning research aims and setting not
al., 2013).			properly discussed, justification for analytic
Denmark	59	moderate	method not properly discussed.
(Marbacher et			Very limited justification for the choice of the
al., 2016).			analytic method provided minimal recruitment
Switzerland	74	moderate	data provided.
			Research aim mentioned but lacking in detail,
(Master et al.,			theoretical underpinning also lacking in details,
2021). USA	67	moderate	same as research setting and population
			No theoretical underpinning was broadly
(Min & Yoo,			explained, and evidence of stakeholder input was
2013). Korea	82	high	not substantiated
			Only a few considerations of stakeholders were
(Moses et al.,			reported, strength and limitations were not
2021). USA	67	moderate	properly highlighted
(Oliveira et al.,			Limited report on the consultation with
2021). Brazil	77	high	stakeholders in the planning of study design, also

	Quality		
Author, year	score of	Quality	
and country	study (%)	rating	Issues affecting quality of study
			on strength and limitations of sampling and
			analytic approach
			Limited explanation was provided for the
			theoretical framework for the study. There was
(Parai et al.,			an incomplete discussion on the strength and
2018). Sweden	77	high	limitations of the study
			Limited justification was provided for the choice
(Parai et al.,			of analytic tool, limited information on the
2019). Sweden	74	moderate	method of analysis and role of stakeholder
			The method of analysis is suitable, however not
(Y. Park et al.,			in full detail; role of stakeholders was not
2011). Korea	82	high	outrightly stated
			Only a general description of the research area
			was given, lacking in detail; evidence of
(SJ. Park et al.,			stakeholder input, strengths and limitations were
2021). USA	77	high	not available
(Saban et al.,			No detailed explanation of the research design
2007). USA	72	moderate	used, research setting and the target population.
			Theoretical framework and how they informed
			the literature were not stated, strengths and
(Scheidt et al.,			limitations of the study were not detailed and
2019). Germany	67	moderate	recruitment data not complete
			Limited rationale for the choice of data
			collection tools was provided. Evidence for the
(Alex Sielatycki			considerations for samplings was limited. The
et al., 2021).			involvement of relevant stakeholders was not
USA	77	high	properly stated
(Szadkowski et			Good theoretical framework, aim and design
al., 2021).			properly stated. However, insufficient
France	90	high	justification for the analytic method
			Limited mention of concept relevant to the
			study, little consideration of some of the research
(Takahashi et			stakeholders, basic outline of the data collection
al., 2011). Japan	59	moderate	procedure
			Minimal and basic recruitment data was
(Triebel et al.,			provided, and sample characteristics were not
2017). Sweden	74	moderate	properly detailed

	Quality		
Author, year	score of	Quality	
and country	study (%)	rating	Issues affecting quality of study
			Identification of concepts that frame the study
(Tuomainen et			but not in detail. Aims were stated but not
al., 2020).			explicit, and strength and limitations were also
Finland	67	moderate	stated but not explicit
			Limited information on the theoretical
			underpinning research aims and setting not
(Yang et al.,			properly discussed, justification for analytic
2020). China	82	high	method not properly discussed.
			No thorough discussion of strengths and
			limitations, insufficient evidence on stakeholder
(Yoo et al.,			considerations, insufficient recruitment data and
2019). USA	67	moderate	justification for the analytic method
			There was an explicit discussion of the theories
			that inform the study. Also, there were a
(Rushton et al.,			discussion of some key strength and weaknesses
2020). UK	87	high	of the study though not evidently thorough

2.5.4 Results of syntheses

A total of 35 outcomes were reported in the included studies, with 12 outcomes arising from the quantitative data studies, 19 from the qualitative data studies and 4 from the qualitative and quantitative data studies. These outcomes mapped to 3 ICF components (body functions, activities and participation, and environmental factors). The findings demonstrate that the ICF component "activities and participation" contained 17 outcomes (49%) measured following LSFS, which comprised mostly of qualitative data studies. The component "body functions" contained 8 outcomes (23%) measured following LSFS, which comprised mostly quantitative data studies. The component "environmental factors" contained 7 outcomes (20%) measured following LSFS, which comprised mostly qualitative data studies.

Some outcomes did not map to the ICF. Specifically, 3 outcomes (9%) measured following LSFS did not map and comprised mostly quantitative data studies. Figure 2 shows the pie chart distribution of outcomes mapped to the components of the ICF and outcomes that did not map to the ICF. Figure 3 shows the mapping of outcomes according to the components of the ICF.



Figure 2: Pie chart distribution of outcomes mapped to the components of the ICF and outcomes in domains not within the ICF



Figure 3: Mapping of outcomes according to components of the ICF.

Colour code:

Contains quantitative and qualitative data studies Contains qualitative data studies only

Contains quantitative data studies only

OUTCOMES MEASURED ACCORDING TO THE COMPONENTS OF THE ICF

BODY FUNCTIONS (Quantitative data studies)

Within this component of the ICF, 8 outcomes (22.9%) were assessed by the included studies, which were linked to 4 chapters and 8 domains of the ICF. The outcomes and outcome measures reported in this component are shown in Table 3 below.

Sensory Functions and Pain chapter

Sensation of pain (b280) domain

Sensation of pain was assessed by most studies (n=44, 88%) with representation of four constructs: pain intensity, comparison of pain intensity post-surgery, pain catastrophizing thoughts, and confidence despite pain intensity.

The most prevalent construct was pain intensity measured by 41 studies, with VAS (n=27, 62.8%) being the prevalent outcome measure used preoperatively and within the range of 3 - 54 months post-surgery. The Numerical Pain Rating Scale (NPRS; n=11, 25.6%), LBP Rating Scale (pain intensity domain; n=1, 2%), and Core Outcome Measure Index (pain intensity domain; n=2, 4%) were also used to assess pain intensity felt in the back and leg. Four studies assessed the comparison of pain intensity post-surgery using Global assessment of pain (n=3, 6.9%) and Global perceived effect score (n=1, 2%). The Pain Catastrophizing Scale (n=1, 2%) was to assess the pain catastrophizing thoughts, and Pain Self Efficacy Questionnaire (n=1, 2%) was used to determine confidence despite pain intensity. Twenty three studies (53.4%) that measured the sensation of pain were of high quality, while 21 (47.7%) studies were of moderate quality.

Function Of The Cardiovascular, Heamatological, Immunological And Respiratory System chapter

Function of the cardiovascular, heamatological, immunological and respiratory system unspecified (b499) domain

Two studies (20%) assessed the complications associated with LSFS and the maximum oxygen uptake during timed aerobic tests following LSFS. The Swedish spine study grading and Astrand fitness test were used to measure these outcomes respectively. These studies were of high and moderate quality, respectively.

Neuromusculoskeletal And Movement-Related Functions chapter

Gait pattern function (b770) domain

Only 2 (4%) recent studies by <u>Haddas et al. (2021)</u> & <u>Scheidt et al. (2019)</u> which were of high quality and moderate quality respectively, assessed gait functions. The outcome measure adopted in these studies was the gait deviation index (GDI) which assessed the abnormal gait patterns, gait cadence analysis, and spatiotemporal gait parameters, which assessed stride length, step length, stance phase, walking speed, and foot rotation.

Functions of the joints and bones unspecified (b729) domain

Three studies (6%) assessed the functions of the bones and joints related to motor functions using the Japanese Orthopedic Association Score. Two studies (66.7%) were of high quality, while 1 study (33.3%) was of moderate quality.

Neuromusculoskeletal and movement-related functions unspecified (b799) domain

Five studies (10%) assessed the neurogenic and neurological symptoms of participants using the North American Spine Society (NASS) Neurogenic Symptoms Score (n=4, 8%) and Self-reported Neurological Deficits (n=1, 2%). Three studies (60%) were of high quality, while 2 studies (40%) were of moderate quality.

Sensations related to muscles and movement functions (b780) domain

Only 1 (2%) moderate quality study used Frankel's grading to assess neurological functions; sensory and motor functions.

Movement functions (b789) domain

Three studies (6%) assessed movement functions representing 3 constructs; functional mobility, preoperative functional activity and physical capacity. Functional mobility was measured using Timed up and go (n=1, 2%), preoperative functional activity was measured using IPAQ-short form (n=1, 2%) and physical capacity was measured using construct-specific global perceived effect (GPE) scale (n=1,2%).

Mental Functions chapter

Global mental function (b139) domain

Seven studies (14%) assessed the mental functions of participants with representation by four constructs; anxiety, depression, mood, and demoralization. Anxiety was measured using the generalized anxiety disorder 7-item scale, depression was measured using patient health questionnaire depression scale, patient health questionnaire-9 (PHQ-9), anxiety and depression were measured by Dallas Pain Questionnaire, and hospital anxiety & depression scale, demoralization was measured using the demoralization scale, and mood was measured using POMS-brief form. The POMS-Brief Form (mood) was used in the USA in 2007, and there was no record of assessment of participant's mental function till 2019 & 2021 when 2:3 studies were documented, respectively. Three studies (42.9%) were of high quality, and 4 studies (57.1%) were of moderate quality.

		Functions of the						
		cardiovascular,						
		haematological,						
Author, year.		immunological, and						
Country	Sensory Functions and Pain	respiratory systems	Neuro	musculo	skeletal and mover	nent-related functio	ns	Mental Functions
	b280	b499	b770	b729	b799	b780	b789	b139
						Frankel's grading		
Akgul et al.,						(neurological		
2021. Turkey						function)		
Asher et al.,								
2016. USA	NPRS (intensity for back and leg pain)							
		Swedish spine study grading						
	VAS (0-100) (intensity for back and leg	(Complications and reoperations,						
Berg et al,	pain), (GA) of Pain (pain relief 1 & 2	including patients scheduled for						
2009. Sweden	years postop)	reoperation)						
Berjano et al.,								
2021.								
Switzerland	COMI (intensity back pain)							
Bisson et al.,								
2021. USA	NPRS (intensity for back and leg pain)							
Boden et al.,								
2020. Georgia	VAS (0-100) intensity back pain							
Cho et al.,								
2021. South	VAS (0-10) (intensity for back and leg							
Korea	pain)							
							TUG	
Coronado et al.,							(functional	
2020. USA							mobility)	
Divi et al.,	VAS (0-10) (intensity for back and leg							
2021. USA	pain)							

Table 4: Outcomes and outcome measures according to body functions (quantitative data studies)

Ganesan et al.,	VAS (0-10) (intensity for back and leg					
2018. India	pain)					
Geoghegan et	VAS (0-10) pt satisfaction of back & leg					
al., 2021. USA	pain					
					IPAQ-short	
				Self-reported	form (pre-	Generalised Anxiety
Gilmore et al.,				Neurological	operative	Disorder 7-item scale,
2019. Australia	NPRS intensity for back and leg pain)			Deficits	activity)	PHQ depression Scale
				NASS		
Goh et al.,	VAS (0-10) (intensity for back and leg			neurogenic		
2020. Singapore	pain)			symptom score		
Goh et al.,						
2020. Singapore	NRS (intensity for back and leg pain)					
				NASS		
Goh et al.,	VAS (0-10) (intensity for back and leg			neurogenic		
2021. Singapore	pain)			symptom score		
Goyal et al.,	VAS (0-10) (intensity for back and leg					
2021. USA	pain)					
		Gait Deviation Index				
		(measure gait				
Haddas et al.,	VAS (0-10) (intensity for back and leg	abnormality), STGP-				Demoralization scale
2021. USA	pain)	1				(distress)
Han et al.,	VAS (0-10) (intensity for back and leg					
2021. China	pain)					
Huang et al.,			JOA			
2021. China	VAS (0-10) (intensity for back pain)		score			
Jacob et al.,	VAS (0-10) (intensity for back and leg					
2021. USA	pain)					(PHQ-9)
	VAS (0-100) (intensity for back and leg					
	pain), Pain Catastrophizing Scale (Pain					
	catastrophizing thoughts), GPE					Hospital Anxiety and
Jakobsson et al.,	(perceived change in back pain post-				GPE (physical	Depression Scale
2019. Sweden	surgery)				capacity)	(depression)

Jenkins et al.,	VAS (0-10) (intensity for back and leg				
2021. USA	pain)				
Le et al., 2020.					
USA	VAS (0-10) (intensity for back pain)				
Lenz et al.,					
2020. Germany	COMI (0-10) (intensity for back and leg				
& USA	pain)				
			NASS		
Lim et al.,			Neurogenic		
2020. Singapore	NPRS (intensity for back and leg pain)		Symptoms Score		
			NASS		
Lim et al.,	NPRS (0-10) (intensity for back and leg		Neurogenic		
2018. Singapore	pain)		Symptoms Score		
Lin et al., 2021.					
China	VAS (0-10) (intensity for back pain)				
Oestergaard et					
al., 2013.					DPQ (anxiety &
Denmark	LBPRS (intensity for back pain)	Astrand fitness test			depression)
Marbacher et					
al., 2016.					
Switzerland	COMI (intensity for back and leg pain)				
Master et al.,					
2021. USA	PSEQ (confidence despite pain)				(PHQ-9) (depression)
Min & Yoo.,					
	VAS (0-10) (intensity for back and leg				
2012. Korea	VAS (0-10) (intensity for back and leg pain)				
2012. Korea Moses et al.,	VAS (0-10) (intensity for back and leg pain) VAS (0-10) (intensity for back and leg				
2012. Korea Moses et al., 2021. USA	VAS (0-10) (intensity for back and leg pain) VAS (0-10) (intensity for back and leg pain)				
2012. Korea Moses et al., 2021. USA Olivera et al.,	VAS (0-10) (intensity for back and leg pain) VAS (0-10) (intensity for back and leg pain)				
2012. Korea Moses et al., 2021. USA Olivera et al., 2021. Brazil	VAS (0-10) (intensity for back and leg pain)VAS (0-10) (intensity for back and leg pain)NPRS (intensity for back pain)				
2012. Korea Moses et al., 2021. USA Olivera et al., 2021. Brazil	 VAS (0-10) (intensity for back and leg pain) VAS (0-10) (intensity for back and leg pain) NPRS (intensity for back pain) VAS (0-100) (intensity for back and leg 				
2012. Korea Moses et al., 2021. USA Olivera et al., 2021. Brazil	 VAS (0-10) (intensity for back and leg pain) VAS (0-10) (intensity for back and leg pain) NPRS (intensity for back pain) VAS (0-100) (intensity for back and leg pain), (GA) of Pain (post-surgery 				
2012. Korea Moses et al., 2021. USA Olivera et al., 2021. Brazil Parai et al.,	 VAS (0-10) (intensity for back and leg pain) VAS (0-10) (intensity for back and leg pain) NPRS (intensity for back pain) VAS (0-100) (intensity for back and leg pain), (GA) of Pain (post-surgery intensity comparison for back and leg 				

	VAS (0-100) (intensity for back and leg			
	pain), (GA) of Pain (post-surgery			
Parai et al.,	intensity comparison for back and leg			
2019. Sweden	pain)			
Park et al.,				
2011. Korea	Pain dominance and duration			
Park et al.,	VAS (0-10) (intensity for back and leg			
2021. USA	pain)			
Saban et al.,				
2007. USA	NPRS (0-10) (intensity for back pain)			
Schiedt et al.,		Gait cadence and		
2019. Germany	NPRS (intensity for back pain)	STGP-2		
Sielatycki et al.,				
2021. USA	NRS (intensity for back and leg pain)			
Szadkowski et				
al., 2021.	VAS (0-10) (intensity for back and leg			
France	pain)			
Takahashi et al.,	VAS (0-10) (intensity for back and leg		JOA	
2011. Japan	pain)		Score	
Triebel et al.,	VAS (0-100) (intensity for back and leg			
2016. Sweden	pain)			
Tuomainen et				
al., 2020.	VAS (0-100) (overall pain intensity),			
Finland	NRS -II (LBP at rest & while walking)			
Yang et al.,			JOA	
2020. China	NPRS (intensity for back and leg pain)		Score	
Yoo et al.,	VAS (0-10) (intensity for back and leg			
2019. USA	pain)			

Key: Sensation of Pain (**b280**), Gait Pattern Function (**b770**), Function of the cardiovascular, heamatological, immunological and respiratory system unspecified (**b499**), Functions of the Joints and Bones, other specified and unspecified (**b729**), Neuromusculoskeletal and movement-related functions unspecified (**b799**), Sensations related to muscles and movement functions (**b780**), Movement functions (**b789**), Global Mental Function (**b139**), **VAS**: Visual analogue scale, **NRPS**: Numerical pain rating scale, **NRPS**: North American Spine Society, **STGP-1**: Spatiotemporal gait parameters (Step time, cadence, walking speed), **STGP-2**: Spatiotemporal gait parameters (stride width, step length, stance phase and foot rotation), **JOA**: Japanese Orthopedic Association, **PHQ-9**: Patient Health Questionnaire-9, **STSFC**: Spine Tango Surgery Form for comorbidity, **GTO**: Global Treatment Outcome, **GPE**: Global Perceived Effect, **GA**: Global assessment of pain, **PSEQ**: Pain Self Efficacy Questionnaire, Profile of Mood States-Brief Form (**POMS-Brief**).

POMS-Brief Form
(mood)

BODY FUNCTIONS COMPONENT OF THE ICF (Qualitative data study)

Only one outcome (2.9%) was reported, which was linked to one domain and chapter, as shown in Table 4.

Sensory Functions and Pain chapter

Sensation of pain (b280) domain: Participants in <u>Rushton et al. (2020)</u>, reported pain intensity as an outcome measured following LSFS.

Table 5: Outcomes measured according to Body functions (qualitative data study)

Author, year. Country	Sensory Functions and Pain chapter
Rushton et al., 2020. UK	Sensation of pain (b280) domain: pain intensity

All the outcomes described in this component's quantitative and qualitative data studies and their mapping to the ICF are shown in Figure 4 below.



ACTIVITIES AND PARTICIPATION COMPONENT OF THE ICF (quantitative data studies)

Within this component, 12 quantitative data studies generated 4 outcomes (11.4%) linked to 3 chapters and 4 domains of the ICF. The outcomes and outcome measures reported in this component are shown in Table 6 below.

Mobility chapter

Mobility, other specified (d498) domain

Three studies (6%) assessed outcomes on fear avoidance and fear of movement. The outcome of fear avoidance was assessed using the fear avoidance belief questionnaire (FABQ) and Tampa Scale of Kinesophobia (TSK), which assessed the construct "fear of movement". Two (66.7%) of the studies that measure fear avoidance were of moderate quality, while 1 (33.3%) which combined TSK and FABQ was of high quality.

Walking (d450) domain

Five studies (10%) assessed walking under various constructs. Comfortable walking speed was assessed using 10-minute walk test and 6-metre walk test, steps per day was assessed using Triaxial Accelerometer, total walking time was assessed using ActivPAL3 Accelerometer, and walking distance was assessed by self-report. Three studies (60%) were of moderate quality, while 2 (40%) were of high quality.

General Tasks And Demands chapter

Carrying out daily routine (d230) domain

Three studies (6%) assessed the ability to carry out physical functioning using the PROMIS-PF tool. Two (66.7%) of the studies were of high quality while 1 (33.3%) was of low quality.

Major Life Areas chapter

Work and employment (d859) domain

Five studies (n=5, 10%) used the Prolo scale score (economic subscale), Kirkaldy-Willis criteria, NASS modified functional scale, DPQ (work and leisure) and work ability index to measure participants' functionality as it relates to return to work. Four studies (80%) were of moderate quality, while 1 (20%) was of high quality.

Table 6: Outcomes and outcome measures according to activities and participation(quantitative data studies)

Author, year. Country	Mobility		General tasks and demands	Major Life Areas
	Mobility, other specified d498	Walking d450	Carrying out daily routine d230	Work and Employment d859
Akgul et al., 2021. Turkey				Kirkaldy-Willis criteria (functional outcomes)
Coronado et al., 2020. USA		TMW (comfortable walking speed), Triaxial Accelerometer		
Gilmore et al., 2019. Australia		ActivPAL3 Accelerometer (total walking time)		
Goh et al., 2021. Singapore				NASS questionnaire (RTW)
Haddas et al., 2021. USA	TSK, FABQ			
Houten et al., 2006. USA				Prolo scale score
Jacob et al., 2021. USA			PROMIS-PF	
Jakobsson et al., 2019. Sweden	TSK			
Jenkins et al., 2021. USA			PROMIS-PF	
Oestergaard et al., 2013. Denmark		6-minutes walk test		DPQ (work & leisure)
Master et al., 2021. USA	TSK	Triaxial Accelerometer (steps per day)	PROMIS – PF (physical function),	
Tuomainen et al., 2020. Finland		Self-reported walking distance		Work Ability Index

TSK: Tampa Scale for Kinesiophobia, FABQ: Fear Avoidance Belief Questionnaire, PROMIS-PF: Patient-Reported Outcomes Measurement Information System Physical Function, NASS (RTW): North American Spine Society (return to work), DPQ: Dallas Pain Questionnaire

ACTIVITIES AND PARTICIPATION COMPONENT OF THE ICF (qualitative data studies)

Within this component, the 2 qualitative data studies gave rise to 15 outcomes (42.9%) linked to 6 chapters and 15 domains which is shown in Table 7 below.

Major life areas chapter

Participants from <u>Abbott et al. (2011)</u>, reported the remunerative employment (d850) as an outcome measured.

Community, social and civic life chapter

Participants from <u>Abbott et al. (2011)</u>, reported recreation and leisure (d920) as an outcome measured.

General tasks and demands chapter

Participants in <u>Rushton et al. (2020)</u>, reported that pacing difficulties; carrying out daily routine (d230), and returning to activities of daily living; General tasks and demands, unspecified (d299) were outcomes measured.

Mobility chapter

Participants from <u>Abbott et al. (2011)</u> reported that changing and maintaining body position (d410–d415), driving (d475), lifting and carrying objects (d430), walking and moving around (d450–d465), and using transport (d470) were the outcomes measured.

Domestic life chapter

Participants from <u>Abbott et al. (2011)</u> reported that the acquisition of goods and services (d620), preparing meals (d630), and doing housework (d640) were the outcomes measured.

Interpersonal interactions and relationships chapter

Participants from <u>Abbott et al. (2011)</u> and <u>Rushton et al. (2020)</u> reported that family relationships (d760) and re-establishing roles and relationships, social engagement, and return to social activities: General interpersonal interactions, other specified and unspecified (d729) were outcomes measured respectively.

Author,		Community,				
year.	Major life	social and	General tasks and			Interpersonal interactions and
Country	areas	civic life	demands	Mobility	Domestic life	relationships
				Changing and maintaining body	Acquisition of goods and	
				position (d410–d415), Driving	services (d620), Preparing	
				(d475), Lifting and carrying	meals (d630), Doing	
Abott et	Remunerative			objects (d430), Walking and	housework (d640), Caring	
al., 2011.	employment	Recreation and		moving around (d450–d465),	for household objects	
Sweden	(d850)	leisure (d920)		Using transport (d470)	(d650)	Family relationships (d760)
			General tasks and			General interpersonal
			demands, unspecified			interactions, other specified and
			(d299): Returning to			unspecified (d729): Re-
Rushton et			activities of daily living,			establishing roles and
al., 2020.			Carrying out daily routine			relationships, social engagement,
UK			(d230): pacing difficulties			and return to social activities.

 Table 7: Outcomes measured according to activities and participation (qualitative data studies)

All the outcomes described in this component's quantitative and qualitative data studies and their mapping to the ICF are shown in Figure 5 below.



Figure 5: Mapping of outcomes within the activities and participation component of the ICF.

Colour code:



ENVIRONMENTAL FACTORS COMPONENT OF THE ICF (quantitative data studies)

Within this component, 2 quantitative data studies gave rise to 1 outcome (2.9%) linked to 1 chapter and 1 domain. The outcomes and outcome measures reported in this component are shown in Table 8 below.

Support And Relationships chapter

Support and relationships unspecified (e399) domain

Two studies (n=2, 4%) assessed two constructs: participants' perceived availability of social support and social concerns using the Medical Outcomes Study Social Support Survey and Dallas pain questionnaire. They were moderate quality studies (100%).

 Table 8: Outcome measured according to environmental factors (quantitative data studies)

Author, year. Country	Support And Relationships chapter
	Support and relationships unspecified (e399) domain
Oestergaard et al., 2013. Denmark	Dallas Pain Questionnaire (social concerns)
Saban et al., 2007. USA	Medical Outcomes Study Social Support Survey

ENVIRONMENTAL FACTORS COMPONENT OF THE ICF (qualitative data studies)

Within this component, the 2 qualitative data studies gave rise to 6 outcomes (17.1%) that were linked to 3 chapters and 6 domains, as shown in Table 8 below.

Support and relationships chapter

Participants from both articles reported that support and relationships from the immediate family (e310), and family support were outcomes measured following LSFS.

Products and technology chapter

Participants from <u>Abbott et al. (2011)</u> reported that personal consumption (e110), personal indoor and outdoor mobility and transportation (e120) were the outcomes measured following LSFS.

Services, systems and policies chapter

Participants from <u>Abbott et al. (2011)</u> reported that services, systems and policies for social security (e570), healthcare (e580), labour and employment (e590) were the outcomes measured following LSFS.

Author,			Services, systems and
year.	Support and		policies
Country	relationships	Products and technology	
			services, systems and
	Support and	personal consumption	policies for social security
Abott et al.,	relationships from	(e110), personal indoor	(e570), healthcare (e580),
2011.	the immediate family	and outdoor mobility and	labour and employment
Sweden	(e310)	transportation (e120)	(e590).
Rushton et			
al., 2020.	Family support		
UK	(e310)		

All the outcomes described in this component's quantitative and qualitative data studies and their mapping to the ICF are shown in Figure 6 below.



Figure 6: Mapping of outcomes within the environmental factors component of the ICF.



OUTCOMES IMPORTANT TO MEASURE BUT COULD NOT BE MAPPED TO THE ICF (quantitative data studies)

Three outcomes (8.6%) could not be mapped to the ICF, and the outcomes and outcome measures reported are shown in Table 9 below.

Disability

Disability was assessed by most studies (n=46, 92%). Most studies were of high quality (n=26, 56.5%), while 20 (43.5%) were of moderate quality. Four outcome measures were used to evaluate disability across studies: the Oswestry Disability Index (ODI, n=44, 88%), Roland Morris Questionnaire (RMQ, n=1, 2%), Core Outcome Measures Index (n=2, 4%), and the Global treatment outcome scale (n=1, 2%). Two studies used both ODI and COMI to measure disability pre-and post-operatively.

Quality of life

Quality of life was assessed by 28 studies (56%). Most of the studies were of high quality (n= 15, 53.6%), while 13 (46.4%) were of moderate quality. Seven outcome measures were used to evaluate quality of life across studies: the Short Form 12, Short Form-12 version 2, SRS-30 physical function/activity, Short Form 36, EQ-5D, COMI, and GTO Score. The Short Form was used as a stand-alone or combined with other outcome measures for quality of life (n=20, 40%). Five studies used SF-36 physical and mental components only (n=5, 10%), all SF-36 components (n=3, 6%), and SF-36 physical component score only (n=2, 4%). Furthermore, few studies used SF-12 physical and mental components (n=7,14%), SF-12v2 for physical and mental components (24%) used the EQ-5D alone or in combination with other outcome measures, 1 study (2%) used the SRS-30 function/activity, and 1 study (2%) used the COMI.

Patient Satisfaction

Patient satisfaction was assessed by 17 studies (34%). Nine (52.9%) of these articles were of high quality, while 8 (47.1%) were of moderate quality. Eight outcome measures were used to evaluate patient satisfaction across studies: Patient satisfaction questionnaire (n=2, 4%), NASS satisfaction questionnaire (n=5, 10%), Likert scale (n=2, 4%), Four-point satisfaction scale (n=1, 2%), MCID achievement score for VAS, ODI & PROMIS-PF (n=1, 2%), Self-assessment of satisfaction (n=1, 2%), Satisfaction with outcome scale (n=1, 2%), and Patient-reported outcome for Satisfaction (n=4, 8%).

Author, year.			
Country	Disability	Quality of life	Patient Satisfaction
Abbott et al.,			
2011. Sweden	ODI	SF-36; EQ5D	
	ODI disease-		
Asher et al., 2016.	specific physical		
USA	disability	EQ-5D	
Berg et al., 2009.	ODI disease-		Patient satisfaction
Sweden	specific function	SF-36; EQ-5D	questionnaire
Berjano et al.,			
2021. Switzerland	ODI	SF-36 (PMCs)	
Bisson et al.,			NASS satisfaction
2021. USA	ODI	EQ-5D	questionnaire
Boden et al., 2020.		SF-36 and SF-12v2	
Georgia	ODI	(both PMCs)	
Cho et al., 2021.			
South Korea	ODI	EQ-5D	
Coronado et al.,			
2020. USA	ODI	SF-12 (PCs), EQ-5D	
Divi et al., 2021.			
USA	ODI	SF-12 (PMCs)	
Ganesan et al.,			
2018. India	ODI		
Geoghegan et al.,			
2021. USA	ODI		
Gilmore et al.,			
2019. Australia	ODI	SF-36 (PCs)	Likert scale
Goh et al., 2019.			
Singapore	ODI	SF-36(PMCs)	
Goh et al., 2020.			
Singapore	ODI	SF-36 (PMCs)	
			NASS questionnaire
Goh et al., 2021.			(satisfaction &
Singapore	ODI	SF-36 (PMCs)	expectation fulfilment)
Goyal et al., 2021.		OE 10 (DMC)	
	ODI	SF-12 (PMCs)	
Haddas et al.,			
2021. USA	ODI		Four raint actions
Han et al., 2021.	ODI		Four-point satisfaction
Unina Huong et el	UDI		scale
Hualig et al.,	ODI		
2021. Clilla	ODI		MCID achievement score
Jacob et al., 2021.	ODI	SE_{12} (PMCs)	(VAS ODI PROMIS-PF)
Jakobsson et al		51 12 (11005)	
2019. Sweden	ODI		
Jenkins et al			
2021. USA	ODI	SF-12 (PCs)	
Kave et al., 2019.			
USA	ODI	SF-12 (PMCs), EO-5D	
Le et al., 2020.			
USA	ODI		
Lenz et al., 2020.	ODI, COMI		
Germany & USA	(disability)	EQ-5D, COMI (QoL)	
Lim et al., 2020.			NASS outcome
Singapore	ODI	SF-36 (PMCs)	assessment instrument
Lim et al., 2018.			
Singapore	ODI	SF-36 (PMCs)	NASS questionnaire

 Table 10: Outcomes not reflected in the ICF (quantitative data studies)

Lin et al., 2021.			
China	ODI		
Oestergaard et al.,			
2013. Denmark	ODI, DPQ		
Marbacher et al.,	GTO Score, COMI		Patient rate satisfaction
2016. Switzerland	(disability)	COMI (QoL)	questionnaire
Master et al.,			
2021. USA			Likert scale
Min & Yoo.,			
2012. Korea	ODI		
Moses et al., 2021.		SF-12 (PMCs), SRS-	
USA	ODI	30 function/activity	
Olivera et al.,			
2021. Brazil	RMQ	EQ-5D, SF-12	
Parai et al., 2017.			
Sweden	ODI	SF-36 (PMCs); EQ-5D	
Parai et al., 2019.			Self-assessment of
Sweden	ODI	EQ-5D	satisfaction
Park et al., 2011.			
Korea	ODI		
	-		
Park et al., 2021.	-		NASS Patient Satisfaction
Park et al., 2021. USA	ODI		NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007.	ODI		NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA	ODI ODI	SF-12v2 (PMCs)	NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al.,	ODI ODI	SF-12v2 (PMCs)	NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany	ODI ODI ODI	SF-12v2 (PMCs)	NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al.,	ODI ODI ODI	SF-12v2 (PMCs)	NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA	ODI ODI ODI ODI	SF-12v2 (PMCs)	NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al.,	ODI ODI ODI ODI	SF-12v2 (PMCs)	NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France	ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs)	NASS Patient Satisfaction Index
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al.,	ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs)	NASS Patient Satisfaction Index Patient satisfaction
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan	ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs)	NASS Patient Satisfaction Index Patient satisfaction questionnaire
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan Triebel et al.,	ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs)	NASS Patient Satisfaction Index Patient satisfaction questionnaire
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan Triebel et al., 2016. Sweden	ODI ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs) EQ-5D	NASS Patient Satisfaction Index Patient satisfaction questionnaire
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan Triebel et al., 2016. Sweden Tuomainen et al.,	ODI ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs) EQ-5D	NASS Patient Satisfaction Index Patient satisfaction questionnaire Satisfaction with outcome
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan Triebel et al., 2016. Sweden Tuomainen et al., 2020. Finland	ODI ODI ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs) EQ-5D	NASS Patient Satisfaction Index Patient satisfaction questionnaire Satisfaction with outcome scale
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan Triebel et al., 2016. Sweden Tuomainen et al., 2020. Finland Yang et al., 2020.	ODI ODI ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs) EQ-5D	NASS Patient Satisfaction Index Patient satisfaction questionnaire Satisfaction with outcome scale
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan Triebel et al., 2016. Sweden Tuomainen et al., 2020. Finland Yang et al., 2020. China	ODI ODI ODI ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs) EQ-5D	NASS Patient Satisfaction Index Patient satisfaction questionnaire Satisfaction with outcome scale Satisfaction rating
Park et al., 2021. USA Saban et al., 2007. USA Schiedt et al., 2019. Germany Sielatycki et al., 2021. USA Szadkowski et al., 2021. France Takahashi et al., 2011. Japan Triebel et al., 2016. Sweden Tuomainen et al., 2020. Finland Yang et al., 2020. China Yoo et al., 2019.	ODI ODI ODI ODI ODI ODI ODI ODI ODI	SF-12v2 (PMCs) SF-12 (PMCs) EQ-5D	NASS Patient Satisfaction Index Patient satisfaction questionnaire Satisfaction with outcome scale Satisfaction rating Patient-reported outcome

ODI: Oswestry Disability Index, **RMQ**: Roland - Morris Questionnaire, **EQ-5D**: EuroQOL five dimensions, **SF-12**: Short Form 12, **SF-12v2**: Short Form-12 version 2, SRS-30 function/activity, **SF-36**: Short Form 36, **PCs**: Physical component score, **PMCs**: Physical and mental component score,

OUTCOMES NOT REFLECTED IN THE ICF (qualitative data study)

Only one high quality study reported an outcome (2.9%) as important to measure, as shown in Table 11 below.

Disability

Participants in <u>Rushton et al. (2020)</u>, reported that disability was an outcome measured following LSFS. 2 constructs were reported; managing impairment and reclaiming physical & functional ability.

 Table 11: Outcomes not reflected in the ICF (qualitative data study)

Author, year. Country	Disability (not defined)
	Managing impairment
Rushton et al., 2020. UK	Reclaiming physical and functional ability.

All the outcomes not classified by the ICF in both quantitative and qualitative data studies were distributed using a flowchart, as shown in Figure 7 below.



Figure 7: Outcomes not reflected in the ICF

Colour code:

Quantitative and qualitative data studies

Qualitative data studies only

Quantitative data studies only
2.6 Discussion

This is the first systematic review to investigate outcomes that have been measured following LSFS. From the results of this study, 35 outcomes have been measured following LSFS with the representation of these outcomes across 3 components of the ICF. The ICF component of "body structures" was not reflected in the identified outcomes in this review. This may be attributed to the exclusion of studies that documented radiological outcomes as this may have identified body structures. Results indicate that pain, walking, carrying out daily routine and disability were reported by both quantitative and qualitative data studies. While these outcomes were reported, the included studies also reported a high variability of outcomes. The findings from this study illustrate that the COS for LBP defined by Chiarotto et al. (2015), consisting of physical functioning, pain intensity, and health-related quality of life outcomes was well represented by some of the included studies.

Body functions component of ICF

Findings from this review demonstrate that the body functions component of the ICF mapped to the second highest number of outcomes, with more quantitative (8 outcomes) than qualitative data studies (1 outcome). Sensation of pain, function of the cardiovascular, heamatological, immunological and respiratory system unspecified, functions of the bones and joints as it relates to motor functions, gait pattern function, neuromusculoskeletal and movement-related functions unspecified, sensations related to muscles and movement functions, global mental functions, and movement functions were the key ICF domains represented by the outcomes arising from quantitative data studies while sensation of pain was the only ICF domain represented by the qualitative data study. The representation of more quantitative data studies and outcomes in this component with various mapping to ICF chapters and domains suggests that this component of the ICF may be more reflective of outcomes that are frequently measured in research studies (retrospective cohort studies, prospective cohort studies, randomized control trials, observational study, retrospective comparative analysis).

Sensation of pain was a frequently recurring domain within the sensory functions and pain chapter reported by both quantitative and qualitative data studies. The high frequency of

sensation of pain domain mapped by included studies (88%) was also characterized by different constructs of pain, namely pain intensity, which was the most frequently reported construct, comparison of pain intensity post-surgery, pain catastrophizing thoughts, and confidence despite pain intensity. This finding is consistent with <u>Dutmer et al. (2019)</u>, who reported that chronic pain intensity is consistent in patients following LSFS. This review also suggests that VAS is an outcome measure in research consistently used to measure pain intensity over time. This is consistent with findings by <u>Chapman et al. (2011)</u>, who reported evidence for validity of the VAS to measure pain intensity in a chronic LBP population.

Furthermore, global mental function was the only domain within the mental functions chapter highlighted in this component as identified in the quantitative data studies, thus suggesting its importance in research. Although only mapped to 14% of the included quantitative data studies, the breadth of constructs measured within, including anxiety, depression, mood, and demoralization, highlight its importance. Pincus et al. (2002), advocated the importance of using the BPS model to explain how psychological outcomes such as distress and depression may contribute to an individual's perception of disease. It is unsurprising that recent studies reported this domain (Gilmore et al., 2019; Jacob et al., 2021; Master et al., 2021; Oestergaard et al., 2013). The various constructs measured are also consistent with reports of anxiety and depression being present in 30% of patients undergoing spinal surgery and a significant level of mental distress existing in patients presenting with chronic LBP (Arts et al., 2012; Singhal et al., 2021).

Another important finding demonstrated that the neuromusculoskeletal and movement-related functions chapter had the highest number of domains mapped in this component. Gait pattern function, functions of the joints and bones unspecified, sensations related to muscles and movement functions, movement functions, and neuromusculoskeletal and movement-related functions unspecified. The breadth of domains identified by the quantitative data studies may suggest the importance of this chapter in research. The Neuromusculoskeletal and movement-related functions unspecified domain mapped the highest number of quantitative data studies (10%) reporting neurogenic and neurological symptoms as an important outcome to measure. This is consistent with reports documenting the importance of neurological deficits experienced

by patients following LSFS, which affected other outcomes such as physical function (<u>Gilmore</u> et al., 2019).

Activities and participation component of ICF

Findings from this study show that activities and participation had the largest number of outcomes mapped to this component, with more qualitative data studies (15 outcomes) than quantitative data studies (4 outcomes). The representation of more qualitative data studies and outcomes with mapping to all 6 ICF chapters highlighted in this component and 15 domains suggests that this component of the ICF may be more reflective of outcomes that patients perceive as important to measure. Despite the variability of outcomes within the qualitative data studies and the breadth of mapped ICF domains and chapters, the frequency of reports of outcomes to measure is low. This can be attributed to the low number of qualitative studies in the review. The breadth of outcomes in the qualitative studies and the difference in outcomes arising from quantitative or qualitative data studies supports further research to explore patients' perspectives on important outcomes following LSFS. This difference in outcomes between the qualitative and quantitative data studies suggests that what is presently being measured in research may not fully reflect patients' perceptions of outcomes that are important to measure.

Three chapters (community, social & civic life, domestic life, and interpersonal interactions & relationships) were specific to the qualitative data studies only where patients reported domains such as preparing meals, doing housework, family relationships, acquisition of goods and services, and recreational and leisure activities. This suggests the importance of outcomes related to this chapter to patients. Although outcomes within these chapters did not frequently appear, as few qualitative studies were included, the breadth of outcomes supports the need for using a range of outcomes following LSFS and the importance of functional activities of daily living, recreational activities, and being independent to patients. The inability to perform these functional activities is a burden to themselves and their family. In line with findings from this review, a study by <u>Damsgaard et al. (2017)</u>, reported the importance patients who had spinal fusion surgery placed on their ability to participate in everyday life of their families, engage in friendships, and leisure activities, therefore, these were important to measure as outcomes.

Similarly, Rushton et al. (2020), highlighted the importance of social interactions and relationships to patients after LSFS, highlighting their importance to measure as an outcome.

Findings from this study also identified 3 chapters (major life areas, mobility, and general tasks and demands) within the activities and participation component that mapped outcomes from the quantitative and qualitative data studies. Some domains were specific to quantitative, qualitative, or both data studies within these chapters. Walking and carrying out daily routine reflected outcomes from both studies thus suggesting they are frequently measured in research and are also important to patients. Findings from this component were interesting, particularly for the mobility chapter of the ICF. One qualitative study (Abbott et al., 2011) documented 6 outcomes that patients identified, including driving, walking, moving around, changing and maintaining body positions, lifting and carrying objects, and using transport. This contrasted with 7 quantitative studies measuring 3 outcomes relating to mobility focusing on fear avoidance, fear of movement and walking (Coronado et al., 2020; Gilmore et al., 2019; Haddas et al., 2021; Jakobsson et al., 2019; Master et al., 2021; Oestergaard et al., 2013; Tuomainen et al., 2020). The high frequency of outcomes reported by patients suggests that mobility plays a significant role for them and, therefore, should be measured following LSFS. Walking was an outcome reported by both quantitative and qualitative data studies reflecting the importance of measuring this in research (quantitative data) and for patients (qualitative data), thus suggesting the importance of measuring this outcome following LSFS. This aligns with Gilmore et al. (2019) and Coronado et al. (2020), who reported the importance of walking following LSFS, as patients who could walk also noticed improvement in other outcomes such as disability and physical functions.

Environmental factors component of the ICF

Environmental factors was the least mapped component of the ICF, with more outcomes reported by the qualitative (6 outcomes) than quantitative data studies (1 outcome). The representation of more qualitative data studies and outcomes with mapping to all 3 ICF chapters highlighted in this component suggests that this component of the ICF may be more reflective of outcomes that patients perceive should be measured. Findings suggest that support and relationship was the only chapter reported by both quantitative and qualitative data studies reflecting the importance

of measuring this in research (quantitative data) and for patients (qualitative data), posits the importance of measuring this outcome following LSFS. This study suggests that following LSFS, patients are concerned with outcomes of family support, healthcare needs, government policies, and availability of indoor and outdoor mobility/ transportation, as they are outcomes that define recovery and should be measured (Abbott et al., 2011). The findings from this review are consistent with <u>Rushton et al. (2020)</u>, who highlighted the importance of aids and support as the lack of this outcome has negative effects on the recovery of patients following LSFS, thus important to measure as an outcome. <u>Greenwood et al. (2022)</u> also reported the importance of support from family and friends following LSFS, as this links the gap between hospital and home, highlighting the importance of measuring.

Outcomes not reflected in the ICF

Findings from this review identified 3 outcomes that were not reflected in the ICF, with more reports from quantitative than qualitative studies data. Disability was the most frequently recurring outcome identified, suggesting the importance of measuring disability in research and its importance to patients following LSFS. This is consistent with the recommendation by Bombardier (2000) and Chiarotto et al. (2015), who reported disability as part of a COS for LBP.

The findings from this review suggest that quality of life recommended as part of a COS for LBP is well represented by the quantitative study data reflecting its importance as an outcome measured in research investigating LSFS. This is consistent with <u>Lubelski et al. (2021)</u>, who reported that the quality of life of a patient is one of the few outcomes of LSFS that should be measured.

Patient satisfaction was another outcome well represented by the quantitative studies data, and it captures that the quality of treatment provided should be measured following LSFS. This suggests that research investigating LSFS are concerned with the patient's satisfaction with the intervention therefore should be measured. This finding is consistent with <u>Yoo et al. (2019)</u>, who reported the importance of patient satisfaction with treatment as knowledge of this outcome informs spine surgeons and patients of factors that can influence recovery.

Outcome measures reported

Previous studies have reported that PROMs are mostly used to assess patients following LSFS and in clinical research (Stokes et al., 2017; Weinfurt & Reeve, 2022), but findings from this study showed ranges of outcome measures used, such as self-reported measures/PROMs, e.g. VAS, ODI, self-reported walking distance; physical outcome measures, e.g. Triaxial accelerometer, ActivPAL3 accelerometer; functional performance-based tests, e.g. Astrand fitness test,10-meter walk test; impairment-based tests, e.g. Frenkel's grading. Although this range of outcome measures used can be attributed to the multiple constructs the measures are trying to capture.

Findings from this study also acknowledged the use of the COS tools recommended by <u>Chiarotto</u> <u>et al. (2018)</u>, although this was observed in the ICF body functions component where VAS and NRS were commonly used to assess pain intensity. The other recommended tools which were commonly used measured outcomes that were not mapped to the ICF, i.e. ODI and RMQ, which measured disability and SF-12, which assessed the quality of life. This suggests that the recommended COS tools may not fully capture the variability of outcomes that have been frequently measured.

2.7 Strengths and Limitations

This is the first systematic review to research the outcomes that have been measured as identified in the literature following LSFS. The use of the ICF framework to categorize identified outcomes reported by both quantitative and qualitative data studies for consistency and to enable comparison is a strength. This study was also conducted according to a-priori protocol to reduce the risk of bias.

However, some limitations of this study must be acknowledged. The processes of determining eligibility, data extraction and quality assessment were not done in duplicate, posing the risk of selection, reporting bias, and bias in assessment (Stoll et al., 2019). The search strategy was not discussed with the health sciences librarian hence may not have been optimal, and some studies may have been missed. It is also important to note that this review does not accurately reflect all

of the research in this field because while electronic databases were retrieved, the grey literature was not searched.

2.8 Conclusion

This systematic review describes the outcomes that have been measured in research and for patients following LSFS. All components of the ICF except body structures are reflected in the outcomes measured. The ICF body functions component reflects the outcomes commonly measured in research investigating LSFS. The activities and participation, and environmental factors components mostly reflect the outcomes that patients view as important to measure following LSFS. Pain, walking, carrying out daily routines, and disability emerged as the most important outcomes, as qualitative and quantitative data studies measured these outcomes. The qualitative data studies reflected frequent outcomes such as getting house chores done, moving around, and driving, reflecting the outcomes that patients view as important. Other outcomes, such as gait, mental and neurological functions, were reflected by the quantitative data studies and thus are outcomes that have been frequently measured in research.

2.9 Recommendation

Nineteen outcomes were identified from qualitative data studies (n=2) compared to 12 outcomes identified from the 48 quantitative data studies, highlighting that further research is needed to explore patients' perceptions of outcomes important to measure following LSFS.

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Chapter 3

3 PATIENTS' PERCEPTIONS OF IMPORTANT OUTCOMES TO MEASURE FOLLOWING LUMBAR SPINAL FUSION SURGERY: A QUALITATIVE STUDY

3.1 Abstract

Background: With an emphasis on patient-centered care, understanding the outcomes that patients value the most following treatment interventions is becoming increasingly important to measure clinical effectiveness. Studies have investigated patients' outcomes and journeys following spinal surgery, but there is limited knowledge of patients' perceptions of important outcomes to measure following LSFS.

Methods: A secondary data analysis of interview data collected 12 months post-LSFS was conducted using an inductive qualitative thematic approach of 3 stages. Stage 1: Results patients wanted to achieve following LSFS were recorded as important outcomes to measure following LSFS. Stage 2: Analysis was completed for each participant and then synthesized across all participants to create themes reflecting outcomes perceived as important to patients. Stage 3: These themes were mapped to the ICF framework.

Results: Data from 13 participants were analyzed, contributing to 25 themes reflecting patients' perceptions of outcomes important to measure following LSFS. Findings demonstrate that walking, pain relief, and the ability to perform functional activities without pain were perceived by patients as the most important outcomes to measure following LSFS. These outcomes are reflected in three of the four components of the ICF: body functions (20%), activities and participation (44%), and environmental factors (8%), but not body structures. It was not possible to map 28% of outcomes to the ICF, including satisfaction with recovery and getting off pain medications.

Conclusion: Important outcomes were reflected in three of four components of the ICF. Pain relief within the body functions component was an outcome frequently reported as important to measure. A key area of focus for outcomes important to measure was the activities and participation component of the ICF, where walking and the ability to perform functional

activities without pain were outcomes frequently reported. The environmental factors component was the least represented, with outcomes related to support and relationships being the only chapter highlighted as important to measure. Other outcomes, such as satisfaction with recovery and getting off pain medications, were also frequently highlighted as important, but not captured using the ICF pointing to its lack of comprehensiveness. Overall, patients' perspectives of important outcomes to measure following LSFS demonstrated variation, as reflected by the breadth of outcomes and ICF components, chapters, and domains.

3.2 Introduction

Improved quality of life and positive patient outcomes such as improvement in pain levels, functional status, symptom and symptom burden, personal experience of care, and health-related behaviours such as anxiety and depression have been a focus in LSFS (Gentry & Badrinath., 2017). These outcomes serve as indicators of the effect of an intervention on a participant's clinical or functional status to evaluate the intervention's effectiveness (Macefield et al., 2014). Given that effectiveness is inevitably multifaceted, it has been argued that no one outcome accurately represents how the intervention for any condition has turned out (Porter, 2010). According to previous studies, certain functional outcomes, such as the capacity to perform activities of daily living like walking, working, caring for oneself, strength, endurance, and flexibility, contribute significantly to patient satisfaction and treatment success (Turk et al., 2003; Curb et al., 2006). Therefore, a multidimensional approach to measuring outcomes is required to provide valuable clinical indicators to evaluate improvement and recovery after spinal surgery (Curb et al., 2006; Lee et al., 2015). Means to measure outcome after LSFS include the use of PROMs such as questionnaires and scales (Reiman & Manske, 2011); impairment-based outcome measures such as range of motion and muscle strength (Reiman & Manske, 2011); functional performance-based tests such as timed up and go, 6-min walk test (Taylor et al., 2016); and physical outcome measures such as accelerometry (Taylor et al., 2016).

Previous studies have demonstrated that although PROMs are frequently used, using them alone does not adequately describe the post-surgical outcomes and that a combination of measures is required to assess patients' outcomes and measure the effectiveness of an intervention (Bolink et al., 2015; Hossain et al., 2015; Mizner et al., 2011). A comprehensive approach is a patient-centred strategy reflecting patients' perspectives on important outcomes. Evidence supports that

this patient-centred strategy has improved patient-clinician communication and patients' quality of life, lengthening patients' survival and reduced emergency visits to the hospital post-surgery (Basch et al., 2016; Kotronoulas et al., 2014). Highlighting the significance of active patient involvement in their care (Hartvigsen et al., 2018b; Wiering et al., 2017), measures have been developed and tested to ensure patients' voices are captured, and these measures reflect what is important to patients (Marshall et al., 2006; Selby & Velikova, 2018). Furthermore, Whitebird et al. (2020), documented that despite using validated PROMs such as the ODI, Oxford Knee Score, and Oxford Hip Score after joint and spinal surgeries, it is uncertain whether patients think the information garnered is relevant to their intervention and outcome.

To assess what is important to patients with LBP, a BPS framework is recommended (Buchbinder et al., 2018). The ICF is the global reference for describing functioning and disability and adopts a BPS framework (World Health Organization, 2001). Research has shown that using a BPS framework captures important patient outcomes and significantly contributes to clinical practice compared to a conventional biomedical approach (Coenen et al., 2006; Kirchberger et al., 2009; Stallinga et al., 2014). This BPS framework was adopted by <u>Abbott et al. (2011)</u>, who concluded that patients' expectation of important outcomes following LSFS related to the ICF components of body functions, body structure, activities and participation, and environmental factors. Furthermore, this BPS framework was also adopted by previous studies that examined the comprehensiveness of the ICF core set from the perspective of patients with LBP (Bautz-Holter et al., 2008; Lygren et al., 2014; Mullis et al., 2007) reporting that the ICF core set captures the challenges faced by patients with LBP. However, other studies reported that all aspects of the ICF framework are not addressed by LBP-specific outcome measures, as specific outcomes that patients with LBP reported were not captured by these measures (Calmon Almeida et al., 2020; Ibsen et al., 2019; Nicol et al., 2021).

With a more significant emphasis on patient-centered care, understanding the outcomes patients value the most following treatments are becoming increasingly important in evaluating clinical effectiveness (Solberg et al., 2017). Patients are generally enthusiastic about their recovery post-LSFS, but this is not often reflected in RCT outcome data. Therefore, their perception of the important outcomes following surgical management is important to help evaluate clinical effectiveness as, presently, although PROMs are commonly used, there are issues with their

content validity, and it is also unclear whether patients think they are relevant to their surgery. We may, therefore, not be measuring the best outcomes that patients perceive as important (Skevington et al., 2005; Greene, 2012).

3.3 Rationale for the study

According to Whitebird et al. (2020) reporting on patients who had spinal surgery, patient's perceptions of relevant outcomes include freedom from pain, ability to move again and return to an active lifestyle following spinal surgery. Achievement of these outcomes has been shown to influence their perception of recovery. However, these outcomes were not specific to the LSFS population and may not fully reflect the views of patients who receive LSFS.

Patients' perceptions and expectations of outcomes following LSFS may be clarified by including them more directly in their care and treatment, encouraging their active involvement in their treatment plan and recovery. Although there is little research on this topic in the lumbar spine surgery literature, one study investigating patients who underwent LSFS demonstrated that outcomes related to the physical, emotional, functional and social aspects of patients' lives are affected after LSFS (Rushton et al., 2020). Therefore, evaluating and setting intervention goals should comprise the interrelationship between these physical, emotional, functional and social outcomes. For an effective evaluation of LSFS intervention to be attained, a proper understanding of patients' perceived outcomes important to measure is necessary (Hartvigsen et al., 2018b; Saban & Penckofer, 2007).

3.4 Research Objective

To explore patients' perceptions of important outcomes following LSFS.

3.5 Methods and analysis

3.5.1 Design

This study is a secondary analysis of the 12-month follow-up interview data collected by Rushton et al. (2020). A secondary analysis of qualitative data involves utilising available data to proffer answers to research problems not explored in the original study (Hinds et al., 1997; Long-Sutehall et al., 2011). The primary study focused on understanding patients' lived experiences following LSFS and consisted of patient diaries and two interviews at two weeks and 12 months post-surgery. This secondary analysis was focused on the outcomes patients perceive as important to measure, defined as outcomes that patients wanted to achieve after LSFS. The 12-month follow-up time point is critical to understand participants' perspectives of important outcomes because of the high dissatisfaction rate and level of improvement reported long-term post-LSFS (Soegaard et al., 2007). The use of semi-structured interview data enabled depth and breadth of understanding of participants' viewpoints and experiences (Alshenqeeti, 2014). This study is reported according to the standards for reporting qualitative research to ensure quality in reporting, i.e., COnsolidated criteria for REporting Qualitative research (O'Brien et al., 2014).

3.5.2 Paradigm and Theoretical framework

The primary study used an interpretative phenomenological analysis (IPA) approach to understand the various experiences of individuals following LSFS. This approach followed an interpretative pathway capturing participants' lived experiences during their journey through recovery post-LSFS (Rushton et al., 2020). The IPA approach acknowledges that these lived experiences reflect the participant's worldview, and the researcher's experiences influence interpretation (Smith et al., 2009).

For this study, this research assumed a constructivist paradigm. <u>Bogna et al. (2020)</u>, described a paradigm as an orientation or theoretical concept utilized by researchers in their investigation. Constructivism analyzes social discourse through observations and interviews, focusing on world views, subjective meanings, and perspectives within social contexts. It relies on researchers' beliefs and opinions to identify patterns and themes in the complexity of participants' views, rather than narrowing down to specific categories or ideas (Ponterotto, 2005). This study utilized a different methodological approach because a secondary analysis was done, and the primary researcher did not conduct the interviews. Data from the participants' transcripts were analyzed using an inductive qualitative thematic analysis is a method that entails searching across a data set to identify, analyze, and report repeated patterns (Braun & Clarke, 2013). It is a way of describing data, but it also includes interpretation in the selection of codes and the creation of themes. This approach was utilized because it was anticipated that it would provide an in-depth

understanding of participants' perception of outcomes important to measure following LSFS without any prior assumption, focus mainly on patterns of meaning across the dataset, grouping them into similarities, generating new meanings and identifying emergent themes without the need for interacting with participants (Braun & Clarke, 2013).

3.5.3 Reflexivity

Rushton et al. (2020), carried out the primary study, where participants were recruited and thoroughly informed about the study by a clinical site lead/research nurse. The non-involvement of the primary researcher in the recruitment process eliminated selection bias. Field notes were recorded during the interview, the interviewer also used a reflexive diary, and coding was carried out by the two experienced researchers who openly discussed and acknowledged all preconceived beliefs that might potentially impact data.

For this study, the research team comprised the primary researcher, a female MSc student (OU) at the University of Western Ontario, and an advisory team. The advisory team comprised a senior academic (AR) and a post-doc associate (KK) at the University of Western Ontario. Reflexivity was ensured in this study through proper familiarization with the primary study (Rushton et al., 2018, 2020), frequent debriefing sessions with the principal investigator of the primary study and a senior academic well-versed in the field of qualitative research to ensure codes generated accurately captured patients' views. Furthermore, reflexivity was ensured through the documentation of the codes generated and tracking changes made as each stage progressed, and discussion of OU's previous knowledge of ICF mapping to avoid influencing the data coding and theme generation. Prior to this MSc, OU's 3 years experience as an internationally trained physiotherapist granted exposure to a different healthcare system and cultural perspectives of various patients who had undergone LSFS. This interaction helped OU anticipate and appreciate the diversity of patients experiences and perspectives following LSFS.

Rigor

Rigor is essential to determine the quality and trustworthiness of the qualitative research process (Mays & Pope, 2000). In the primary study, before the 12-month follow-up interview, the participants had already engaged with the interviewer and were aware of the purpose of the

research, thus establishing prior knowledge and relationships. The interview sessions were recorded, and the transcribed audio was given to the participants to crosscheck to eliminate misrepresentations of their perspectives.

For this study, to ensure quality assurance, the primary researcher thoroughly read through the transcribed dataset to ensure proper interpretation and the advisory team supervised, challenged codes and themes generated by the primary researcher (OU) and ensured the implementation of the research design facilitating dependability (Guba, 1981).

3.5.4 Participant selection

Primary data were collected via a purposive sample from adult participants undergoing up to 4level LSFS for back pain and/or leg pain from a degenerative cause (including isthmic spondylolisthesis) recruited from 4 UK spinal surgical centres via a purposive sampling technique. These participants were first approached face-to-face and then contacted via telephone by the site lead/ research nurse. Forty-three participants were initially recruited pre-surgery and informed about the study by a clinical site lead/ research nurse (Rushton et al., 2020). Subsequently, twelve participants withdrew because they could not commit, and three did not proceed to surgery; therefore, twenty-eight participants completed the data collection process. Thirteen participants subsequently completed the second interview at the 12-month follow-up; therefore, these were included in this study. This is consistent with Smith et al. (2009), who recommended limiting the number of participants to 3–16 for qualitative studies, as saturation of information is likely to have been met with this sample.

3.5.5 Eligibility Criteria

The eligibility of participants selected in the primary research by Rushton et al. (2020), maintained in this study, are detailed below.

Inclusion criteria

Adult patients (\geq 16 years) willing to consent and able to communicate in English who were undergoing up to four-level instrumented LSFS for degenerative back pain and/or leg pain, including isthmic spondylolisthesis.

Exclusion criteria

Individuals who were undergoing LSFS for a traumatic or pathological spinal fracture, malignancy, infection, or deformity requiring more than four level instrumentation and revision fusion surgery and with poor communication in English.

3.5.6 Setting

An in-depth semi-structured audio interview between the researcher and the participant which lasted for approximately 60 minutes, was collected at a National Health Service Trust site-based location in the UK.

3.5.7 Data collection

The follow-up interview was done 12 months post-surgery. The interviewer used a topic guide (Appendix 5), which evolved from the analysis of the first interview and patient diary. The participant introduced new insights to the interview, expressing areas of interest not covered by the topic guide.

3.5.8 Data analysis

The data from the 13 participants who completed the 12-month follow-up interview was used for this secondary analysis. All the transcripts were aggregated into a new dataset and sorted into folders for each participant. Inductive thematic analysis was adopted as the analysis method of the study as the generated codes and themes were data-driven and did not fit into any pre-existing coding frame, which was done in three stages (Nowell et al., 2017; Thomas & Harden, 2008b).

Stage 1:

Reading through the descriptive responses of each participant, transcribed interview data were coded line-by-line according to its meaning and content.

Stage 2:

The codes generated across each participant were grouped into related areas, and new codes were formed to reflect the meaning of the groups of initial codes. These new codes were termed the interpretative constructs that were further grouped into related areas as required. This gave rise to themes representing the outcomes patients wanted to achieve after LSFS.

Stage 3:

These themes were then mapped to the component, chapter, and domain levels of the ICF classification documented in the researcher's preliminary systematic study. Themes that did not fit into the ICF classification maintained their interpretative constructs and were termed emerging themes (Mayring, 2014).

For credibility and dependability, frequent debriefing with senior researchers well-versed in qualitative research ensured the analyzed data were examined in-depth (Connelly, 2016; Shenton, 2004)

3.6 Ethical considerations

Ethical approval for this study was sought from the ethical review board at the University of Western Ontario, with agreement from the sponsor (University of Birmingham) for the use of data through a signed data-sharing agreement (Appendix 4). Data was received in its anonymized form, and analysis presented aggregated data so that no respondent could be identified.

3.7 Results

Thirteen participants who completed the second interview at the 12-month follow-up were used for this study. Seven (53.8%) of the participants were female, while 6 (46.2%) were male, as shown in Table 12. Data analysis generated 25 outcomes, with walking, pain relief, and performing functional activities without pain being the outcomes most reported by participants as important to measure following LSFS (Table 13).

 Table 12: Baseline characteristics of participants

Gender	Total (n)
Female	7
Male	6
Age	
25-34	1
45-54	3
55-64	5
65-74	4

Table 13: Description of outcomes

Codes arising from analysis of individual interviews (participant ID)	Interpretative constructs arising from analysis across interviews	Participants reporting constructs (n)	Themes (Outcomes)	Participants reporting themes
Ability to walk quickly during short walks (R017)	Ability to walk quickly during short walks	1	Walking	10
Increasing the duration of walking (R009)	Increasing the duration of walking	1		
Progressively increase walking distance (S033)	Progressively increase walking distance	1		
Walking without being in absolute agony (S026)	Walking without being in absolute agony	1		
Walking long distance without numbness on leg (R003)	Walking long distance without numbness on leg	1		
Walking with walking stick (S032)	Walking with walking stick	2	-	
Walking (R016) Walking (S029) Ability to walk (R008)	Walking	3		
Pain relief (R008) Free from pain (G056) Pain relief (S033)	Pain relief	3	Pain relief	6
Permanent pain relief on back of leg (S030) Relieve dull ache at the lower back and leg, no pain that doesn't worsen (R008) Relieve pain on the legs (S029) Pain intensity relief on back and leg (S032)	Pain relief on lower back and/or leg	4		
Walking long distance without pain on leg (R003) Walking without pain (R016) Walking long distance without pain (S033) Sitting for long without pain as intense as pre-surgery state (R001) Running without pain (R017)	Perform functional activities without pain	6	Perform functional activities without pain	6
Driving (R008) Driving (R001)	Driving	3	Driving	4
Driving (S032) Driving long distance (R017) Carrying out activities independently (R008) Do things independently (S029) Independently do things (S032) Performing activities independently (S033) Independently go out for activities (S029)	Driving long distance Performing independent activities	1 4	Performing independent activities	4
Satisfaction with ability to live a normal life post-LSFS (G056) Satisfaction with living a normal life without excruciating pain (S030) Satisfaction with progress in post-surgical recovery (S024) Satisfaction with level of improvement in recovery following LSFS (S026) Satisfaction with ability to walk quite long distances (G056)	Satisfaction with recovery	4	Satisfaction with recovery	4
Confidence to walk without anxiety due to previous falls (R008) Confidently walking with one stick (S024) Confidence to get out of bed, and go up the stairs without pain (R008) Confidence in social interactions (S032)	Confidence in performance of functional activities	3	Confidence in performance of functional activities	3
Start yachting lessons (R008) Return to golf course (R016) Participating in swimming (R016)	Ability to perform leisure activities	3	Ability to perform leisure activities	3
Involving in family gathering (S030) Social interaction with people (S033). Going out to meet friends (R001)	Ability to involve in social interaction	3	Ability to involve in social interaction	3
Getting off pain-medications (R008) Getting off pain-medications (G056) Getting off pain-medications (R001)	Getting off pain-medications	3	Getting off pain- medications	3

Ability to support spouse (R008)	Ability to support family and	2	Ability to support	2
Rendering support to others (S033)	Irrends		family and friends	
Performing domestic chores (R017) Cleaning the house (S029)	Ability to perform household chores	2	Ability to perform household chores	2
Support from experts to achieve a healthy	Support from experts to	1	Mental health	2
mental state (R016)	achieve a healthy mental		concerns	
	state			
Relief from psychologically dark mental	Relief from psychologically	1		
feelings (S032)	dark mental feelings			
Lose weight via mobility & exercises	Lose weight via mobility &	1	Lose weight via	1
(\$032)	exercises		mobility &	
			exercises	
Feeling sensation (relieve numbress) on	Feeling sensation (relieve	1	Feeling sensation	1
the left toe and leg (R003)	numbress) on the left toe and		(relieve numbness)	
	leg		on the left toe and	
	8		leg	
Ability to increase heart rate	Ability to increase heart rate	1	Ability to increase	1
(cardiopulmonary fitness) via jogging	via jogging without		heart rate via	
without damaging spine (R008)	damaging spine		iogging without	
	88 -F		damaging spine	
Moving without stiffness of legs, back	Moving without stiffness of	1	Moving without	1
(R008)	legs back	-	stiffness of legs.	-
(1000)	1-85, 0001		back	
Moving without apprehension / fear of	Moving without	1	Moving without	1
reiniury to surgical site (R008)	apprehension / fear of	-	apprehension / fear	-
Tenijary to surgiour site (11000)	reiniury to surgical site		of reiniury to	
			surgical site	
Resuming full shift at work (R001)	Ability to resume full shift at	1	Ability to resume	1
	work		full shift at work	
Active involvement with grandchildren	Active involvement with	1	Active involvement	1
(R003)	grandchildren		with grandchildren	
Ability to get back to pre-injury functional	Ability to get back to pre-	1	Ability to get back	1
state (R003)	injury functional state		to pre-injury	
			functional state	
Sustaining the benefits from the results of	Sustaining the benefits from	1	Sustaining the	1
LSFS (R009)	the results of LSFS		benefits from the	
			results of LSFS	
Engaging in prescribed exercises to build	Engaging in prescribed	1	Engaging in	1
up strength for recovery (R017)	exercises to build up strength		prescribed exercises	
	for recovery		to build up strength	
			for recovery	
Going to the gym and exercising within	Going to the gym and	1	Going to the gym	1
pain limitations (R001)	exercising within pain		and exercising	
	limitations		within pain	
			limitations	
Knowledge on milestone of physical	Knowledge on milestone of	1	Knowledge on	1
capabilities to attain post LSFS (R008)	physical capabilities to attain		milestone of	
	post LSFS		physical	
			capabilities to attain	
			post LSFS	

3.7.1 Outcomes important to measure

WALKING

Walking was the most frequently reported outcome important to measure, with 10 participants (76.9%) highlighting 7 different constructs within walking following LSFS. One construct focused on generalized walking, while the other constructs had distinct walking aims such as the ability to walk quickly during short walks, increasing the duration of walking, progressively increasing walking distance, walking without being in absolute agony, walking long distance without numbness on legs, and walking with a walking stick. Three participants (23.1%) reported generalized walking as an important outcome to measure following LSFS.

"I intend to walk. I have done some walking. I strapped my leg up. Walking. I've spoken to a few of my friends from WI and we're setting a little walking thing up with the aims of getting better each time, each week" – R016 (p15, 421-424).

Seven participants (53.8%) who reported the 6 remaining constructs highlighted distinct aims they wanted to achieve with walking, including speed, distance, and frequency. One participant (n=1, 7.8%) reported that the ability to walk quickly during short walks was important to measure and expressed frustration without being able to achieve it.

"Because of the weakness in my right leg, I couldn't walk very quickly and that vaguely frustrated me" – R017 (p6, 157-158).

One participant (7.8%) reported that increasing the duration of walking was an important outcome to measure.

"We want to get away on holiday and things like that, we're going away soon and I'm a little bit worried that I'll spoil it for everybody because I'm going to walk around too much" - R009 (p9, 200-202).

One participant (7.8%) reported that the ability to progressively increase walking distance was an important outcome to measure.

"When I went for a walk, I'd go for a two mile walk and then a three-mile walk, then it got to four miles" – S033 (p3, 67-68).

One participant (7.8%) reported that walking without being in absolute agony was an important outcome to measure.

"I don't want to run a marathon, don't get me wrong, but I wanted some sort of normality where I could walk more than a mile without being in absolute agony" – S026 (p7, 181-183).

One participant (7.8%) reported that walking long distances without numbress in the leg was an important outcome to measure.

"I did an awful lot of walking over there, which I wouldn't have been able to do prior to the operation because obviously I was getting the numbness, pains when I was walking, I was probably doing a half a mile then I'd have to stop because my leg was aching so much. I was averaging, possibly walking about 15km a day over there without any concerns whatsoever" – R003 (p4, 89-93)

Two participants (15.4%) reported that the ability to walk with a walking stick was an important outcome to measure.

"No, I'm very optimistic that one day I shall walk with one stick again" – S024 (p10, 262).

PAIN RELIEF

Pain relief was also frequently reported as an outcome important to measure with 6 participants (46%) highlighting 2 constructs within pain relief following LSFS, and one participant reporting both constructs. One construct focused on generalized pain relief while the other focused on pain relief in the lower back and/or leg. Three participants (23.1%) reported generalized pain relief as an important outcome as opposed to the other construct, which reports a specific location where pain relief was needed.

"I was just delighted that the pain had gone, that was the main thing" – R008, (p14, 348-349)

Four participants (30.8%) reported pain relief in the lower back and/or leg as an important outcome to measure.

"the main problem was the sciatic pain down the back of my leg which was stopping me doing anything, basically. I couldn't walk more than 20 yards without it flaring up and being absolutely excruciating" – S030 (p4, 106-109).

PERFORM FUNCTIONAL ACTIVITIES WITHOUT PAIN

The ability to perform functional activities without pain was reported by 6 participants (46.2%) as an outcome important to measure.

"The main thing is I'm functioning as I was before all this started a few years ago and the brilliant thing is the pain has been eliminated, which is amazing. That's the main thing" -R008 (p17, 435-436).

DRIVING

Driving was reported as an important outcome to measure with 4 participants (30.8%) highlighting two constructs within driving. One construct focused on generalized driving and the other focused on driving long distance. Three participants (23.1%) reported generalized driving as an important outcome to measure.

"I can go out and drive... so I do feel better" – R001 (p9, 220).

One participant (7.8%) reported driving long distance as an important outcome to measure.

"Then in fact, she was really, really pleased with my progress. In May I wanted to do a rather crazy holiday, get the ferry to Santander and then drive about 200 miles a day down to Malaga" – R017 (p5, 136-139).

ABILITY TO PERFORM INDEPENDENT ACTIVITIES

The ability to perform activities independently was reported by 4 participants (30.8%) as an important outcome to measure.

"Then, as long as I can get about and not be a burden to anyone, I'll be over the moon, as most people would" - R008 (p19, 486-487)

ABILITY TO PERFORM LEISURE ACTIVITIES

The ability to perform leisure activities and participate in sports they loved was reported by 3 participants (23.1%) as an important outcome to measure.

"But cycling, you know, I was eager to get back on the bike really but that did take some time because I've got an exercise bike at home" – S029 (p6, 156-158)

ABILITY TO INVOLVE IN SOCIAL INTERACTIONS

The ability to be involved in social interactions was reported by 3 participants (23.1%) as an important outcome to measure.

"I can go out and meet my friends, so I do feel better" – R001 (p9, 220).

CONFIDENCE IN PERFORMANCE OF FUNCTIONAL ACTIVITIES

Confidence in the performance of functional activities was reported by 3 participants (23.1%) as an outcome important to measure.

"I could have done with, and I said to you this before, I was only in hospital two nights and I wasn't quite ready, I think another night or two really would have just given me the confidence. Physiotherapy-wise, that was a big push to get me out of that bed and up those stairs; ..." – R008 (p9-10, 230-236)

MENTAL HEALTH CONCERNS

Mental health concerns was reported as an important outcome to measure with 2 participants (15.4%) highlighting two constructs within driving. One construct focused on support from experts to achieve a healthy mental state after LSFS and the other focused on relief from

psychologically dark mental feelings. One participant (7.8%) reported support from experts to achieve a healthy mental state after LSFS as an important outcome to measure.

"I think it was probably when I realised, after a couple of months, that nothing was happening. That's when I got in touch with people. Then, of course, from there... When you're sent from pillar to post and you eventually... Then the doctor has to re-send to tell them that I wanted therapy... I need therapy." – R016 (p8, 223-226)

One participant (7.8%) reported that relief from psychologically dark mental feelings as an outcome important to measure.

"The past probably four or five months, I've been in some pretty dark places regarding how I am with my physical state, which combines both my spinal op and also my rheumatoid arthritis and that's been a psychological input [** 0:11:03] from the osteo" – S032 (p5, 130-133).

ABILITY TO PERFORM HOUSEHOLD CHORES

The ability to perform household chores was reported by 2 participants (15.4%) as an important outcome to measure.

"Well, it's very irritating, because I can't do what I would like to do. The cleaner is on holiday, I've tried myself to tidy up as good as I could. It's only a little flat but it still needs cleaning" – S029 (p6, 139-141).

ABILITY TO SUPPORT FAMILY AND FRIENDS

The ability to support family and friends was reported by 2 participants (15.4%) as an important outcome to measure.

"My husband always says, "Do what you feel you can do," but because he's been ill, I feel I want to support him as much as I can" – R008 (p19, 481-482)

ACTIVE INVOLVEMENT WITH GRANDCHILDREN

Active involvement with grandchildren was reported by 1 participant (7.8%) as an outcome important to measure.

"It's the same old thing, it's grandchildren, you don't want to be the person sat in the background watching the grandchildren. You want to be the person up with the grandchildren" - R003 (p5, 120-122)

RELIEVE NUMBNESS FROM LEFT TOE AND LEG

Relieving numbress from the left toe and leg was reported by 1 participant (7.8%) as an important outcome to measure.

"If you remember I had a problem with the left leg and toe, it was quite numb and not getting the feeling back. That concerned me" - R003 (p2, 46-47)

RESUMING FULL SHIFT AT WORK

The ability to resume full shift at work was reported by 1 participant (7.8%) as an important outcome to measure.

"I was finishing at, so like half a day and I sort of said to my manager, "I feel all right to do the full shift," because I'm going home and I'm not really doing anything. I sort of said I'd stay the full shift and then I had another" – R001 (p5, 104-107).

ABILITY TO INCREASE HEART RATE VIA JOGGING WITHOUT DAMAGING SPINE

The ability to increase heart rate via jogging without damaging the spine was reported by 1 participant (7.8%) an important outcome to measure.

"I think I did ask the surgeon at my last one-to-one at the hospital about jogging and those sorts of things. Trying to get your heart rate up but not damage your spine" -R008 (p7, 166-167)

LOSE WEIGHT VIA MOBILITY & EXERCISES

The ability to lose weight via mobility and exercises was reported by 1 participant (7.8%) as an outcome important to measure.

"My goal setting is to lose weight;" "So, I've now started doing a little bit more exercise, trying to get a little bit more mobile, doing probably half an hour on an exercise bike four or five times a week" – S030 (p6, 158; p2, 36-38)

MOVING WITHOUT STIFFNESS

The ability to move without the stiffness of legs, and back was reported by 1 participant (7.8%) as an important outcome to measure.

"But just stiffness, stiffness of the lower limbs, stiffness of the back and I'm desperate, I used to be able to touch my toes in the bath and things like that, I can just about do it but everything is stiffer, that's all I can sort of say really" – R008 (p6, 136-138).

MOVING WITHOUT APPREHENSION OR FEAR OF REINJURY

The ability to move without apprehension or fear of reinjury to the surgical site was reported by 1 participant (7.8%) as an important outcome to measure.

"I'm still a bit apprehensive, especially, I'd love to do some stretching, but again, knowing how far to push that is, I suppose in the back of your head you're always terrified that there's going to be a snap and we're back to square one. I think walking, low impact type of stuff is good" – R008 (p7, 173-176)

SATISFACTION WITH RECOVERY

Satisfaction with recovery was reported by 4 participants (30.8%) as an important outcome to measure.

"The main positive feelings are that I can lead a much more normal life than I could before. Apart from vigorous exercise, I am much more able, so that's fantastic" –G056 (p12, 327-329)

GETTING OFF PAIN MEDICATIONS
Getting off pain medications was reported by 3 participants (23.1%) as an important outcome to measure.

"And I think, I personally think now that I've been through it, getting off the medication was the hardest thing that I've ever done" - R001 (p17, 389-390).

GETTING BACK TO PRE-INJURY FUNCTIONAL STATE

The ability to get back to pre-injury functional state was reported by 1 participant (7.8%) as an outcome important to measure.

"It's just I suppose I want to get back to how I was before and sometimes that might not happen" – R003 (p4, 78-79)

SUSTAINING THE BENEFITS OF LSFS

The ability to sustain the benefits from LSFS was reported by 1 participant (7.8%) as an important outcome to measure.

"Apart from that no, I'd hoped it would last another 10 years, hopefully it still will" – R009 (p11, 242)

ABILITY TO ENGAGE IN PRESCRIBED EXERCISES

The ability to engage in prescribed exercises to build up strength for recovery was reported by 1 participant (7.8%) as an important outcome to measure.

"I think I was very, very fortunate because pre-op I wanted to do exercises to build up strength. You start from a higher level; you're obviously going to deteriorate when you have the procedure. But if your body vaguely knows what it should be doing, my theory was, and it was slightly stronger, your recovery would be quicker" – R017 (p5, 126-131).

ABILITY TO GO TO THE GYM AND EXERCISE WITHIN PAIN LIMITATIONS

The ability to go to the gym and exercise within pain limitations was reported by 1 participant (7.8%) as an important outcome to measure.

"I think what it was is like, obviously because I was in a lot of pain and I had sort of a restriction, I just felt like, what can I do? If I can't do that, even though I enjoy it, but now I can go to the gym, but I know my limitations" – R001 (p9, 217-220).

KNOWLEDGE ON MILESTONES OF PHYSICAL CAPABILITIES TO ATTAIN POST-LSFS

Knowledge on the milestones of physical capabilities to attain post-LSFS was reported by 1 participant (7.8%) as an important outcome to measure.

"If there was just a tiny bit more guidance on what not to do possibly, it's all right to work within your own limitations physically, but things absolutely to avoid. I guess I did have a little bit of information about that, but could have done with a little booklet maybe on discharge about the physical type side of things, maybe" – R008 (p11, 261-264).

3.7.2 Categorization of outcomes according to the ICF

Outcomes important to measure were mapped to the ICF and mapped to 3 ICF components (body functions, activities and participation, and environmental factors). The findings demonstrate that the ICF component "activities and participation" represented 44% of outcomes participants deemed important to measure, followed by "body functions" (20% of outcomes) and "environmental factors" (8% of outcomes). Figure 10 shows the representation of outcomes arising within the components and highlights that 28% of outcomes could not be mapped to the ICF.



Figure 8: Pie chart distribution showing the number of outcomes arising within components of the ICF and those not mapped to the ICF.

BODY FUNCTIONS COMPONENT OF THE ICF

This component of the ICF captured 5 outcomes perceived as important to measure, with participants' descriptions of important outcomes related to pain relief, mental health concerns, feeling sensation (relieving numbness) on the left toe and leg, ability to increase heart rate via jogging without damaging spine, and confidence in the performance of functional activities. These 5 outcomes were mapped to 3 chapters and 5 domains of the body functions component of the ICF, as shown in Figure 9 and Table 14 below.



Figure 9: Mapping of outcomes within the body function component of the ICF

Outcomes identified by participants	Domains of ICF	Chapters of ICF	Frequency of participants
Pain relief	b 280 pain		
Feeling sensation (relieve numbness) on the left toe and leg	b265 Touch function	Sensory functions and pain	7
Mental health concerns	b 198 Mental functions, other specified	Mental functions	
Confidence in performance of functional activities	b 126 Temperament and personality functions		4
Ability to increase heartrate via jogging without damaging spine	b 410 Heart functions	Functions of the cardiovascular, haematological, immunological and respiratory systems	1

Table 14: Outcomes categorized according to the body functions component of the ICF

Sensory function and pain chapter

Within this ICF chapter, 7 participants (53.8%) reported two outcomes as important to measure. These two outcomes were pain relief and relieving numbress on the left toe and leg, which were mapped to the domains: pain (b 280) and touch functions (b 265) respectively. Six participants (46.1%) reported pain relief, while 1 participant (7.8%) reported relieving numbress on the left toe and leg as important outcomes to measure.

Mental functions chapter

Within this ICF chapter, 4 participants (30.8%) reported two outcomes important to measure: mental health concerns and confidence in performance of functional activities, which were mapped to two ICF domains mental functions other specified (b 198), and temperament and personality functions (b 126), respectively. One participant (7.8%) reported mental health concerns as important to measure, 2 participants (15.4%) reported confidence in performance of functional activities, while 1 participant (7.8%) reported both confidence in performance of functional activities and mental health concerns as outcomes important to measure.

Functions of the cardiovascular, haematological, immunological and respiratory systems chapter

One participant (7.8%) reported one outcome within this ICF chapter: the ability to increase heart rate via jogging without damaging the spine, which was mapped to the ICF domain heart functions, other specified (b 4108).

ACTIVITIES AND PARTICIPATION COMPONENT OF THE ICF

This component of the ICF captured 11 outcomes participants reported as important to measure. Participants' description of important outcomes related to walking, performing functional activities without pain, moving without stiffness of legs, back, moving without apprehension / fear of reinjury to surgical site, driving, performing independent activities, performing leisure activities, ability to involve in social interaction, ability to perform household chores, ability to resume full shift at work, ability to lose weight via mobility & exercises. These outcomes were mapped to 7 chapters and 10 domains of the ICF and therefore had the highest representation of outcomes important to measure following LSFS as shown in Table 15 and Figure 10 below.



Figure 10: Mapping of outcomes within the activities and participation component of the ICF

Table 15: Outcomes categorized according to activities and participation component of theICF

Outcomes identified by participants	Domains of ICF	Chapters of ICF	Frequency of participants
Walking	d 450 walking		
Perform functional activities without pain	d 498 Mobility, other specified		
Moving without stiffness of legs, back	d 410 Changing basic	Mobility	11
Moving without apprehension/fear of reinjury to surgical site	body position		
Driving	d 475 Driving		
Performing independent activities	d 220 Undertaking multiple tasks	General tasks and demands	4
Ability to perform leisure activities	d 920 Recreation and leisure	Community, social and civic life	3
Ability to involve in social interaction	d 799 Interpersonal interactions and relationships, unspecified	Interpersonal interactions and relationships	3
Ability to perform household chores	d 640 Doing housework	Domestic life	2
Ability to resume full shift at work	d 850 Remunerative employment	Major life areas	1
Lose weight via mobility & exercises	d 570 Looking after one's health	Self-care	1

Mobility chapter

Within this chapter, 11 participants (84.6%) reported 5 outcomes as important to measure. These outcomes were mapped to 4 domains of the ICF as described: Walking, performing functional activities without pain, and driving were mapped to walking (d 450), mobility, other specified (d 498), and driving (d 475) respectively while the outcomes, moving without stiffness of legs, back and moving without apprehension/fear of reinjury to the surgical site were mapped to the domain changing basic body position (d 410).

One participant (7.8%) reported the outcomes of walking, driving, moving without stiffness of legs and back, moving without apprehension/fear of reinjury to the surgical site, and performing functional activities without pain as important to measure. One participant (7.8%) reported that the ability to drive and perform functional activities without pain were important outcomes to measure. One participant (7.8%) reported the outcomes of walking and driving as important to measure. Four participants (30.8%) reported walking, and the ability to perform functional activities without pain as important to measure, and 4 participants (30.8%) reported walking only as important to measure.

General tasks and demands chapter

Within this chapter, 4 participants (30.8%) reported the ability to perform independent activities as an important outcome to measure. This outcome was mapped to ICF's undertaking multiple tasks (d220) domain.

Community, social and civic life chapter

Within this chapter, 3 participants (23.1%) reported the ability to perform leisure activities they loved as an important outcome to measure, and this was mapped to the recreation and leisure (d 920) domain of the ICF.

Interpersonal interactions and relationships chapter

Within this chapter, 3 participants (23.1%) reported the ability to involve themselves in social interactions as an important outcome to measure. This outcome was mapped to the interpersonal interactions and relationships, unspecified (d 799) domain of the ICF.

Domestic life chapter

Within this chapter, 2 participants (15.4%) reported the ability to perform household chores as important to measure. This outcome was mapped to the doing housework (d 640) domain of the ICF.

Major life areas chapter

Within this chapter, 1 participant (7.8%) reported the ability to resume full shift at work as an important outcome to measure. This outcome was mapped to the remunerative employment (d 850) domain of the ICF.

Self-care chapter

Within this chapter, 1 participant (7.8%) reported the outcome of losing weight via mobility and exercises as important to measure. This outcome was mapped to the looking after one's health (d 570) domain of the ICF.

ENVIRONMENTAL FACTORS COMPONENT

This component of the ICF captured 2 outcomes perceived as important to measure with participants' description of these outcomes related to active involvement with grandchildren and the ability to support family and friends. These 2 outcomes were mapped to one chapter and one domain of the ICF, as shown in Figure 11 and Table 16 below. This component was, therefore, the least represented component of the ICF.



Figure 11: Mapping of outcomes within the environmental factors component of the ICF

Outcomes identified by participants	Domain of ICF	Chapter of ICF	Frequency of participants
Active involvement with grandchildren Ability to support family and friends	e 398 Support and relationships, other specified	Support and relationships	2

Table 16: Outcomes categorized according to environmental factors component of the ICF

Support and relationships chapter

Within this chapter, 3 participants (23.1%) reported two outcomes as important to measure. One participant (7.8%) was concerned with being actively involved with grandchildren, while 2 participants (15.4%) reported concern with the ability to support family and friends. These outcomes were mapped to the support and relationships, other specified (e398) domain of the ICF.

Outcomes not reflected in the ICF

Seven outcomes reported by 9 participants as important to measure, could not be mapped to the ICF: ability to get back to pre-injury functional state, satisfaction with recovery, getting off pain medications, sustaining the benefits from the results of LSFS, engaging in prescribed exercises to build up strength for recovery, going to the gym and exercising within pain limitations, and knowledge on the milestone of physical capabilities to attain post-LSFS (Table 17, Figure 12).



Figure 12: Outcomes not reflected in the ICF

Table 17: Outcomes not reflected in the IC
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Outcomes identified by participants	participants (n)
Satisfaction with recovery	4
Getting off pain-medications	3
Ability to get back to pre-injury functional state	1
Sustaining the benefits from the results of LSFS	1
Engaging in prescribed exercises to build up strength for recovery	1
Going to the gym and exercising within pain limitations	1
Knowledge on milestone of physical capabilities to attain post LSFS	1

Three participants (23.1%) reported concern with getting off pain medications and/or satisfaction with recovery, going to the gym and exercising within pain limitations, and knowledge on the milestone of physical capabilities to attain post-LSFS were important outcomes to measure. Three participants (23.1%) reported that the outcome satisfaction with recovery was important to measure. For one participant (7.8%), the ability to get back to pre-injury functional state was important. One participant (7.8%) reported that sustaining the benefits from the results of LSFS was important. One participant (7.8%) reported that engaging in prescribed exercises to build up strength for recovery was an important outcome.

3.8 Discussion

This is the first study to explore patients' perceptions of important outcomes to measure following LSFS. Results indicate that walking, pain relief, and the ability to perform functional activities without pain were the outcomes most frequently perceived by patients as important. While these outcomes were frequently reported, high variability of individualized outcomes important to measure was noted amongst participants. This is in line with Ibsen et al. (2019), who found that patients with LBP emphasized the importance of addressing specific, self-identified concerns rather than just ticking boxes in PROMs or questionnaires that may not adequately represent how they were affected in their daily lives. This study mapped these important outcomes to 3 components of the ICF, with some outcomes not possible to be mapped using the ICF framework. Findings supported variability in perceived important outcomes.

Body functions component of the ICF

The chapters of sensory function and pain, mental functions, and functions of the cardiovascular, haematological, immunological, and respiratory systems contained domains that reflected patients' perceptions of important outcomes to measure following LSFS. This contrasts with previous findings on patients' experiences, recovery and expectations post-LSFS, where their responses were linked to the chapters of sensory functions and pain, psychological functions, and neuromusculoskeletal and movementrelated functions (Abbott et al., 2011). Although this contrast can be partially attributed to the different purposes of the research, it is interesting because this study found that patients expressed the importance of their mental state, confidence, and ability to increase heart rate without any damage to the spine as any affectation of these outcomes may affect their recovery process. Also, the lack of representation of mental functions and functions of the cardiovascular, haematological, immunological, and respiratory systems in previous studies suggests that patients placed minimal importance on these chapters. Although these chapters were reflected in this study, only 3 participants reported them, suggesting patients' gradual awareness of the effects of outcomes relating to them, thus highlighting the importance.

Participants frequently reported pain relief as an important outcome to measure. Different constructs of pain, including generalized pain relief and pain relief in the back/leg, were highlighted by participants, thus showing pain felt following LSFS is not just restricted to the site of surgery, and relief of pain is of importance to participants as it can interfere with their daily activities and routine. This concurs with the findings from previous studies investigating patients who had joint and spinal surgeries, who reported that decreasing pain was a major reason for surgery and pain relief in specific activities was an important outcome (Wiering et al., 2018; Whitebird et al., 2020).

Activities and Participation component of the ICF

This ICF component contained the most outcomes reported by participants highlighting 7 chapters: mobility, general tasks and demands, community, social and civic life, interpersonal interactions and relationships, domestic life, major life areas, and self-care as important to measure. This is in line with a study by Mullis et al. (2007), who reported that patients with LBP cited items classified within the activities and participation component as the most difficult to do because of LBP. Findings from this qualitative study linked 11 outcomes to 10 out of 16 domains categorized by the ICF. The high representation of different outcomes in this component also aligns with Abbott et al. (2011), who linked patients' expectations post LSFS to 21 of the 49 activities and participation domains in the ICF. This strongly suggests that after LSFS, patients are concerned with outcomes that affect their participation in activities and thus are very important to measure.

Findings from this qualitative study demonstrate that most participants emphasized mobility chapter, where each participant reported one or more outcomes relating to mobility as important to measure following LSFS. Within this chapter, 10 out of 13 participants reported different aspects of walking as an important outcome they wanted to achieve following LSFS. This corroborates studies that have shown the importance of increased walking time and speed immediately following surgery, as an increase in these outcomes could signify a successful surgical procedure and long-term functional recovery (Gilmore et al., 2019; Rasmussen et al., 2019). It is also important to highlight the

variability of walking constructs described by participants, such as duration, frequency and speed of walking, further demonstrating the need for individualization of measures to help evaluate clinical effectiveness.

Another frequently reported outcome was the ability to perform functional activities without pain, and functional activities, including sitting, walking, and running, were highlighted as important. With pain being the major limitation, pain resolution is a crucial factor affecting the functional outcome participants sought. This is in line with the results from Wiering et al. (2018), who reported the importance of pain and functional impairment outcomes, as limitations arising from these outcomes affect patients' ability to engage in their usual routine activities after hip and knee surgery.

Environmental factors component of the ICF

This ICF component was the least represented, with only 2 participants highlighting the support and relationships chapter. Two outcomes were linked to one domain within this chapter. This minimal representation is in line with <u>Abbott et al. (2011)</u>, who linked patients' expectations post LSFS to 7 of the 49 domains of environmental factors in the ICF. Findings suggest that few patients felt that outcomes related to rendering support and being involved in family life are important to measure, as these feelings of commitment and community may impact their health. This is in line with Whitebird et al. (2020), who highlighted the importance some patients placed on their return to their previous responsibilities of taking care of other family members after joint and spinal surgeries.

Outcomes not mapped to the ICF

Participants described outcomes they perceived as important to measure following LSFS that could not be mapped to the ICF; precisely 28% of important outcomes could not be mapped. This demonstrates the uniqueness and variation of participants' views when describing outcomes important following LSFS. Also, given that these outcomes were not mapped to the ICF, it demonstrates the focus of the ICF framework, as findings suggest it may not fully cover all the outcomes reported by patients who underwent

LSFS. This contrasts with previous studies that examined the comprehensiveness of the ICF core sets from patients' perspectives and found that this framework reflected all the outcomes patients with LBP wanted to achieve (Bautz-Holter et al., 2008; Lygren et al., 2014; Mullis et al., 2007). Patient satisfaction with recovery was an outcome perceived as important in this study that did not map to the ICF. Some patients expressed positive satisfaction, and some expressed negative satisfaction, while some still anticipated more results from the effects of LSFS. This is consistent with findings from previous studies that linked patient satisfaction to their quality of life and expectation fulfilment after spinal surgery (Cobo Soriano et al., 2010; Krauss et al., 2020; Sielatycki et al., 2016). Another outcome not captured by the ICF yet frequently highlighted as important to measure was the ability to get off pain medications. Findings showed patients were concerned with this outcome to avoid addiction and reduce the side effects they feel by using these pain medications despite these medications helping with pain levels. This is consistent with findings from previous studies that demonstrated the importance of reducing the use of opioids in patients after spine fusion as it correlated with poorer outcome values (Tank et al., 2018; Khor et al., 2018). Other outcomes such as the ability to get back to pre-injury functional state, sustaining the benefits from the results of LSFS, engaging in prescribed exercises to build up strength for recovery, going to the gym and exercising within pain limitations, and knowledge on the milestone of physical capabilities to attain post-LSFS were reported by participants albeit sparingly. This also suggests that there are specific outcomes patients deem important to measure but were not reflected in the ICF.

Outcome measures

The qualitative study was not focused on outcome measures; however, this study identified variations in the outcomes that need to be measured. Therefore, this puts the focus on the range of outcome measure types to assess the different constructs to enhance clinical effectiveness (Reiman & Manske, 2011; Taylor et al., 2016). The variation of outcomes identified shows the range of outcome measures that can be used to assess the ranges of outcomes reported in this study to enhance clinical effectiveness.

Other findings

Findings from this study demonstrate that although some outcomes patients perceive as important to measure are represented within the ICF framework, the ICF component of "body structures" lacks representation. This lack of representation may be ascribed to the level of patients' knowledge of anatomical changes in body structures, as research has shown that this component is mainly reported by clinicians who are well-informed about the anatomical changes associated (Ewert et al., 2004). This is corroborated by (<u>Gradinger et al., 2011</u>), who reported that the anatomical changes associated with body structure component were rarely highlighted as important by patients with sleep disorders who had problems with functioning. While in LSFS literature, the body structure was reported as the least linked ICF component suggesting its importance (Abbott et al., 2011)

Findings supported variability in perceived important outcomes. This variability was observed as different outcomes were perceived as important to measure by different participants, giving rise to a significant breadth of outcomes that could not be synthesized across participants. These outcomes were also mapped to a large breadth of ICF domains, chapters, and components. This suggests the importance of identifying patients' individual rehabilitation outcomes and how they should be incorporated into their assessment to help evaluate clinical effectiveness (Calmon Almeida et al., 2020; Ibsen et al., 2019; Nicol et al., 2021).

3.9 Strengths and limitations

The use of the ICF framework, which addresses the biological, psychological, and social aspects of outcomes as a guide for consistency, is a strength of this study. The use of an inductive approach of thematic synthesis ensured that the themes were identified directly from the data. For credibility and dependability, frequent debriefing with senior researchers well-versed in qualitative research ensured that the analyzed data were examined in-depth (Connelly, 2016; Shenton, 2004). The documentation and thorough

adherence to the research methodology ensured that the findings of the analyzed data were consistent.

However, it should be noted that this study has some limitations. As a secondary data analysis, the research question differs from the primary study, so participants could have provided more information regarding the outcomes patients perceive as important to measure after LSFS. Therefore, this prompts the need for a primary qualitative study exploring the outcomes important to patients. Furthermore, it was noted that the data collection was limited to the UK; this may not reflect the outcomes important to patients in other countries.

3.10 Conclusion

This study has demonstrated that walking, pain relief, and the ability to perform functional activities without pain are most frequently perceived by patients as important to measure following LSFS. Important outcomes were reflected in three of four components of the ICF. Pain relief within the body functions component was an outcome frequently reported as important to measure. A key area of focus for outcomes important to measure was the activities and participation component of the ICF, where walking and the ability to perform functional activities without pain were outcomes frequently reported; thus, emphasis needs to be placed on this component to evaluate clinical effectiveness. The environmental factors component was the least represented, with outcomes related to support and relationships being the only chapter highlighted as important to measure. Other outcomes, such as satisfaction with recovery and getting off pain medications, were also frequently highlighted as important but not captured using the ICF. Overall, patients' perspectives of important outcomes to measure following LSFS demonstrated variation, as reflected by the breadth of outcomes and ICF components, chapters, and domains.

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Chapter 4

4 Discussion of the thesis

4.1. Introduction

Overall, this thesis aimed to investigate the outcomes that are important to measure for patients following LSFS. This aim was achieved through two research objectives. Objective 1 was to identify the outcomes that are important to measure for patients following LSFS. This was done by conducting a systematic review (Chapter 2) which synthesized the existing literature. Objective 2 was to explore patients' perceptions of important outcomes following LSFS. This was done by conducting a qualitative study (Chapter 3) that explored patients' perceptions of important outcomes to measure following LSFS.

4.2 Systematic review findings

Chapter 2 aimed to identify the outcomes that have been measured for patients following LSFS. Findings from this review showed that 35 outcomes had been measured for patients following LSFS across included studies, with the bulk of outcomes from the 2 qualitative data studies included. Nineteen outcomes were identified from qualitative data studies, 12 from quantitative data studies, and 4 from both. Pain, walking, carrying out daily activities, and disability reflect outcomes frequently measured for patients, as indicated by the quantitative and qualitative data studies (S.-J. Park et al., 2021; Rushton et al., 2020; Yoo et al., 2019). Patients are concerned explicitly with outcomes including doing house chores, moving around, driving, following LSFS as indicated by the qualitative data study (Abbott et al., 2011). Gait, mental, and neurological functions are outcomes frequently measured in research following LSFS as indicated by the quantitative data studies (Haddas et al., 2021; Jakobsson et al., 2019; Master et al., 2021; Oestergaard et al., 2013).

Additionally, this review concluded that all components of the ICF except body structures were reflected in the outcomes measured following LSFS. The ICF component of body functions reflects outcomes mostly from quantitative data studies and, therefore, outcomes commonly measured in research. The ICF components of activities and participation, and environmental factors mostly reflect outcomes from the qualitative data studies suggesting that they reflect patients' views of outcomes to measure following LSFS. 8% of outcomes reported as frequently measured for patients were not covered by the ICF.

4.3. Qualitative study findings

In Chapter 3, the qualitative study explored patients' perceptions of important outcomes following LSFS directly using data that captured the patients' voices. Findings identified 25 outcomes perceived as important to measure by patients. Walking, pain relief, and the ability to perform functional activities without pain were the most common outcomes participants felt were important to measure following LSFS. Other outcomes, such as satisfaction with recovery and getting off pain medications, were also frequently highlighted as important. Findings also suggested that the ICF components "body functions", "activities and participation", and "environmental factors" encompassed 72% of outcomes patients perceive as important to measure. 28% of outcomes perceived as important were not captured using the ICF framework pointing to the lack of comprehensiveness of the ICF framework (Ibsen et al., 2019).

4.4. Synthesis of findings across both studies

Synthesis across both studies was done where each component was merged to create a synthesis which reflected the outcomes important to measure for patients following LSFS (Heale & Forbes, 2013; Noble & Heale, 2019). The synthesis further showed that the three ICF components of body functions, activities and participation, and environmental factors were represented in both studies (Figure 13). The largest number of outcomes were linked to the activities and participation ICF component, as seen below.



Figure 13: Components of the ICF represented in thesis

Colour code:	
Systematic review and qualitative study	
Qualitative study only	
Systematic review only	

Body functions component of the ICF

Synthesis of findings across both studies showed that one chapter (neuromusculoskeletal and movement-related functions), which reflected the largest range of outcomes, was only specific to the systematic review. Within this chapter, all the domains were specific to the quantitative studies included, as no outcome was added from the qualitative data studies. This suggests that patients have not raised any area of concern within this chapter, and perhaps this pattern may be explained because the clinical assessment of LBP by clinicians drives this chapter (Petersen et al., 2017).

The other three chapters, i.e. sensory function and pain, mental functions, and functions of the cardiovascular, haematological and respiratory system, reflected outcomes from both studies. Synthesis of findings across both studies showed that within the sensory function and pain chapter, sensation of pain domain frequently highlighted pain as an important outcome to measure, while touch functions domain was specific to the qualitative study only (Figure 14). The consistent report of pain across both studies, particularly the focus on pain intensity, demonstrates the importance to patients and research. This is in line with recommendations for the recent COS for LBP, where pain intensity was highlighted (Chiarotto et al., 2015). However, only 25.6% of studies in the systematic review used the NRS tool, which was recommended in the COS (Chiarotto et al., 2018).

Synthesis across both studies showed that although the mental functions, and functions of the cardiovascular, haematological and respiratory system chapters, reflected outcomes from both studies, these outcomes were specific to domains which did not overlap. This suggests that patients have specific outcomes they deem important to measure compared to what is frequently measured in research. This is consistent with previous research highlighting that there is usually a clinician-patient mismatch of outcomes important to measure for patients following spinal surgery (Hartmann et al., 2020). However, there is no existing information for LSFS.



Figure 14: Mapping of all outcomes within body function component after synthesis across studies



Activities and participation component of the ICF

From the synthesis of findings across studies, the ICF component of activities and participation was the most representative of all outcomes identified as important in this thesis (Figure 13). As shown in Figure 15 below, this ICF component linked the largest numbers of chapters, domains and outcomes. This demonstrates the breadth of outcomes important within the activities and participation ICF component and the importance of measuring this component for patients after LSFS. This is consistent with Fehrmann et al. (2019), who identified 23 out of 29 categories within the activities and participation component of the ICF that are important to patients with LBP.

Synthesis across both studies showed 1 out of 7 chapters was specific to the qualitative study only, i.e., self-care showing how important outcomes relating to this are important to patients. This is in line with <u>Abbott et al. (2011)</u>, who highlighted that outcomes relating to self-care are commonly measured following LSFS, therefore, are important.

The synthesis also showed that the other 6 chapters reflect outcomes from both studies. Each chapter reflected outcomes from the two studies and either the systematic review or qualitative study only. However, mobility and general tasks and demands chapters reflected outcomes from both studies, the systematic review and qualitative study. The outcomes identified within domains such as remunerative employment, recreation and leisure, carrying out daily routine, mobility other specified, changing and maintaining body positions, driving and walking were reflected in both studies. This suggests that patients are concerned with outcomes relating to these domains, and they have also been measured in research. While the outcomes within domains that were specific to the systematic review (such as work and employment, lifting and carrying objects, and using transport) suggest, they have been consistently measured in research. The outcomes specific to the qualitative study (such as undertaking multiple tasks and moving around) suggest that they are outcomes that patients perceive are important to measure.

The mobility chapter encompassed most outcomes (e.g., walking, driving, lifting and carrying objects, maintaining body positions) that are important to measure for patients following LSFS. This is consistent with a previous study by Froud et al. (2014), who highlighted the importance of mobility in patients with LBP in terms of loss of function on patients with LBP and their ability to perform daily activities. This shows mobility is an important outcome to measure for patients.



Figure 15: Mapping of all outcomes within activities and participation component after synthesis across studies

Colour code: Systematic review and qualitative study Qualitative study only Systematic review only
Environmental factors component of the ICF

Synthesis across both studies highlights that the ICF component of environmental factors reflected the least number of identified outcomes (Figure 13). This is in line with <u>Abbott</u> <u>et al. (2011)</u>, where patients who underwent LSFS highlighted the importance of 7 environmental factors domains out of 49 ICF domains in which they expected improvement, therefore, highlighting their importance.

The synthesis across studies further identified 2 chapters that were specific to the systematic review. Within the chapters, all the domains identified, such as healthcare, product and technology, systems and policies, were specific to the qualitative data studies included. No outcome was added from the quantitative data studies. This suggests that patients are concerned with how outcomes related to this component can affect their recovery; therefore, they are important to measure. This is in line with <u>Nicol et al. (2021)</u>, who reported that product and technology, systems and policies are not fully addressed in LBP assessments , but they are important as these outcomes affect patients' recovery.

Synthesis across studies also demonstrates that only support and relationships chapter reflected outcomes from both studies (Figure 16). Findings from the systematic review focused on receiving support from others, while findings from the qualitative study focused on supporting others. This shows that patients are concerned with outcomes relating to support and relationships, which have also been measured in research. This is consistent with Whitebird et al. (2020), who documented the importance of patients being able to support and provide care for others after undergoing spinal and joint surgery.



Figure 16: Mapping of all outcomes within environmental factors component after synthesis across studies



Outcomes not reflected in the ICF

Synthesis across studies identified 9 outcomes that could not be mapped to the ICF, with satisfaction with recovery reported as important to measure in both studies (Figure 17). However, there were also key differences between studies. Synthesis showed that 6 of these outcomes were specific to the qualitative study highlighting the importance of measuring these outcomes to patients. The systematic review highlighted the importance of measuring disability and quality of life following LSFS showing that these outcomes are frequently measured by researchers. Previous studies addressed the comprehensiveness of the ICF, where it was documented that while the framework outlined specific outcomes patients with LBP wanted to achieve, it did not contain some important outcomes they reported (Bautz-Holter et al., 2008; Cieza et al., 2019; Ibsen et al., 2019; Lygren et al., 2014).

However due to the objective of this thesis which was not limited to functioning and disability, the outcomes not reflected in the ICF points to the outcomes that are not classified under functioning and disability which are the focus of the ICF. This suggests that the ICF is a comprehensive framework when it relates to outcomes that concerns functioning and disability. However, beyond the scope of the ICF, there are varieties of outcomes patients perceive as important to measure following LSFS.



Figure 17: Outcomes not reflected in the ICF after synthesis across studies

Colour code: Systematic review and qualitative study Qualitative study only Systematic review only

Outcome measures reported in this thesis

Findings from the systematic review and qualitative study challenge the prevalent use of PROMs as there are ranges of other types of outcome measures that can be used, such as physical outcome measures, functional performance-based tests, and impairment-based tests (Reiman & Manske, 2011; Stokes et al., 2017; Taylor et al., 2016). However, looking at the variation of outcomes to be measured, future investigation needs to be carried out to develop outcome measures that will effectively assess the range of outcomes that have been identified.

Other findings

The synthesis across studies showed a wide variation of outcomes which may reflect the heterogeneity of the LSFS population (Rushton et al., 2015). The results from this thesis further challenge the COS recommended by <u>Chiarotto et al. (2015)</u>, as the systematic review reflected the COS as the different domains recommended by the COS were reported, i.e. pain intensity, health related quality of life, and physical functioning. However, the insights gained directly from the patients challenge this due to the variation of outcomes reported; therefore, the qualitative study challenges the COS.

4.5. Strengths and limitations of the thesis

A key strength of this thesis is the use of the ICF framework consistently as a guide in this thesis to map outcomes identified and facilitate the synthesis of data within and across studies. Through several debriefing sessions between the primary researcher and the advisory committee, the likelihood of deducing themes in qualitative study based on the primary researcher's preliminary knowledge from the systematic review was minimized.

However, a key limitation of the systematic review must be acknowledged. Selection of studies, data extraction and evaluation of the quality of included studies in the systematic review was carried out by a single reviewer, the primary researcher. Therefore, this introduces a risk of bias in the review, limiting the confidence in findings. As a secondary qualitative data analysis in Chapter 3, the research question differs from the primary study. Participants could have provided more information regarding the outcomes patients perceive as important to measure after LSFS, perhaps affording greater richness of data and insights.

4.6. Implications and future recommendations

Overall, understanding the important outcomes to measure following LSFS would help in effective clinical evaluation. The variation of outcomes reported in this thesis may reflect the heterogeneity of the LSFS population. Although the findings from the systematic review reflect the COS, insights gained directly from patients in the qualitative study challenge this COS due to the variation and differences in outcomes. This implies that we might not be effectively assessing what is important to patients.

The insights that are challenging the concepts of the COS were from a secondary analysis of UK-based patients; therefore, it cannot be assured that this translates to the Canadian population. Future recommendation entails conducting a primary qualitative study that explicitly explores the outcomes important to patients who underwent LSFS and are based in Canada. This thesis recommends developing open-ended questions about outcomes within each ICF component for patients. The findings from the primary study

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will then question whether the current outcome measures in use capture patients' information on important outcomes to measure.

This thesis further recommends the engagement of patient-partners in research to participate as collaborators ensuring that the patients' perspectives are taken into consideration in the development of relevant open-ended research questions and research designs. This improves confidence in the research findings thus increases the likelihood of implementing the findings in clinical practice and encourages a patient-centered approach.

Further research also recommends exploring whether the outcome measures available for the LSFS population are co-developed with patients and whether they assess the important outcomes to measure. This research also recommends exploring if these outcome measures can be adaptable due to the heterogeneity of the LSFS population.

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Chapter 5

5 Conclusion of the thesis

This thesis provides insight into the outcomes to measure following LSFS, highlighting the variability of outcomes that have been measured for patients and those patients perceive as important to measure. Following synthesis across both studies, there is a difference in the pattern within each ICF component as what has been chosen to be measured in research studies is sometimes the same but also can vary from what patients perceive as important to measure. This was evident in the different components of the ICF. We learned that within the ICF component of body functions, the sensory function and pain chapter reflected outcomes from the systematic review and qualitative study. Pain was frequently measured by researchers and reflected as important to measure for patients within this component. The ICF component of activities and participation reflected a large breadth of outcomes that mapped various domains and chapters. This component was mostly mapped by the qualitative data studies of the systematic review and the qualitative study, thus reflecting that outcomes within this component is mainly reported by patients as important to measure. The ICF component of environmental factors consistently reflected outcomes relating to support and relationship chapter with the systematic review frequently focused on patients receiving support from others while the qualitative study focused on patients' ability to support others. Furthermore, synthesis also showed some outcomes were not reflected in this ICF and this may be attributed to the thesis's objectives which explored outcomes beyond functioning and disability which is the focus of the ICF framework. This thesis being exploratory in nature gives insights to future research which should focus on a primary qualitative study which explores patients' perspectives of important outcomes to measure following LSFS.

Appendices

Appendix 1: JBI tool for systematic review data extraction

JBI QARI Data Extraction Tool for Qualitative Research

Reviewer		Date
Author		Year
Journal		Record Number
Study Description		
Methodology		
Method		
Phenomena of interest		
Setting		
Geographical		
Cultural		
Participants		
Data analysis		
Authors conclusions		
Comments		
Complete	Yes 🗆	No 🗆
Copyright © The Jo0anna Briggs Institute 2014		

QuADS Criteria	0	1	2	3
 Theoretical or conceptual underpinning to the research Statement of research aim/s 	No mention at all.	General reference to broad theories or concepts that frame the study. e.g. key concepts were identified in the introduction section.	Identification of specific theories or concepts that frame the study and how these informed the work undertaken. e.g. key concepts were identified in the introduction section and applied to the study.	Explicit discussion of the theories or concepts that inform the study, with application of the theory or concept evident through the design, materials and outcomes explored. e.g. key concepts were identified in the introduction section and the application apparent in each element of the study design. Explicit and detailed statement of
		achieve embedded within the report but no explicit aims statement.	appear in the abstract or be lacking detail.	aim/s in the main body of report.
3. Clear description of research setting and target population	No mention at all.	General description of research area but not of the specific research environment e.g. 'in primary care.'	Description of research setting is made but is lacking detail e.g. 'in primary care practices in region [x]'.	Specific description of the research setting and target population of study e.g. 'nurses and doctors from GP practices in [x] part of [x] city in [x] country.'
4. The study design is appropriate to address the stated research aim/s	No research aim/s stated or the design is entirely unsuitable e.g. a Y/N item survey for a study seeking to undertake exploratory work of lived experiences	The study design can only address some aspects of the stated research aim/s e.g. use of focus groups to capture data regarding the frequency and experience of a disease.	The study design can address the stated research aim/s but there is a more suitable alternative that could have been used or used in addition e.g. addition of a qualitative or	The study design selected appears to be the most suitable approach to attempt to answer the stated research aim/s.
			quantitative component could strengthen the design.	
5. Appropriate sampling to address the research aim/s	No mention of the sampling approach.	Evidence of consideration of the sample required e.g. the sample characteristics are described and appear appropriate to address the research aim/s.	Evidence of consideration of sample required to address the aim. e.g. the sample characteristics are described with reference to the aim/s.	Detailed evidence of consideration of the sample required to address the research aim/s. e.g. sample size calculation or discussion of an iterative sampling process with reference to the research aims or the case selected for study.
6. Rationale for choice of data collection tool/s	No mention of rationale for data collection tool used.	Very limited explanation for choice of data collection tool/s. e.g. based on availability of tool.	Basic explanation of rationale for choice of data collection tool/s. e.g. based on use in a prior similar study.	Detailed explanation of rationale for choice of data collection tool/s. e.g. relevance to the study aim/s, co- designed with the target population or assessments of tool quality.
7. The format and content of data collection tool is appropriate to address the stated research aim/s	No research aim/s stated and/or data collection tool not detailed.	Structure and/or content of tool/s suitable to address some aspects of the research aim/s or to address the aim/s superficially e.g. single item response that is very general or an open-response item to capture content which requires probing.	Structure and/or content of tool/s allow for data to be gathered broadly addressing the stated aim/s but could benefit from refinement. e.g. the framing of survey or interview questions are too broad or focused to one element of the research aim/s.	Structure and content of tool/s allow for detailed data to be gathered around all relevant issues required to address the stated research aim/s.
8. Description of data collection procedure	No mention of the data collection procedure.	Basic and brief outline of data collection procedure e.g. 'using a questionnaire distributed to staff'.	States each stage of data collection procedure but with limited detail or states some stages in detail but	Detailed description of each stage of the data collection procedure, including when, where and how

Appendix 2: QuADS tool for data extraction

			omits others e.g. the recruitment	data was gathered such that the
			process is mentioned but lacks	procedure could be replicated.
			important details.	
9. Recruitment data provided	No mention of recruitment data.	Minimal and basic recruitment data	Some recruitment data but not a	Complete data allowing for full
		e.g. number of people invited who	complete account e.g. number of	picture of recruitment outcomes
		agreed to take part.	people who were invited and	e.g. number of people approached,
			agreed.	recruited, and who completed with
				attrition data explained where
				relevant.
10. Justification for analytic	No mention of the rationale for the	Very limited justification for choice	Basic justification for choice of	Detailed justification for choice of
method selected	analytic method chosen.	of analytic method selected. e.g.	analytic method selected e.g.	analytic method selected e.g.
		previous use by the research team.	method used in prior similar	relevance to the study aim/s or
			research.	comment around of the strengths of
				the method selected.
11. The method of analysis was	No mention at all.	Method of analysis can only	Method of analysis can address the	Method of analysis selected is the
appropriate to answer the		address the research aim/s	research aim/s but there is a more	most suitable approach to attempt
research aim/s		basically or broadly.	suitable alternative that could have	answer the research aim/s in detail
			been used or used in addition to	e.g. for qualitative interpretative
			offer a stronger analysis.	phenomenological analysis might
				be considered preferable for
				experiences vs. content analysis to
				elicit frequency of occurrence of
				events.
12. Evidence that the research	No mention at all.	Consideration of some the research	Evidence of stakeholder input	Substantial consultation with
stakeholders have been		stakeholders e.g. use of pilot study	informing the research. e.g. use of	stakeholders identifiable in planning
considered in research design or		with target sample but no	pilot study with feedback	of study design and in preliminary
conduct.			influencing the study	work e.g. consultation in the
		stakeholder involvement in	design/conduct or reference to a	concentualisation of the research
		planning stages of study design	project reference group established	project advisory group or evidence
		planning stages of stady design.	to quide the research	of stakeholder input informing the
			to guide the recourds.	work.
13. Strengths and limitations	No mention at all.	Very limited mention of strengths	Discussion of some of the key	Thorough discussion of strengths
critically discussed		and limitations with omissions of	strengths and weaknesses of the	and limitations of all aspects of
		many key issues. e.g. one or two	study but not complete. e.g. several	study including design, methods,
		strengths/limitations mentioned with	strengths/limitations explored but	data collection tools, sample &
		limited detail.	with notable omissions or lack of	analytic approach.
			depth of explanation.	

Author	01	02	02	04	05	06	07	08	00	010	011	012	012	ΤΟΤΑΙ
Abott et al	3	3	3	2	2	3	3	3	1	3	3	3	1	84.62
2011. Sweden	5	5	5	2	2	5	5	5	-	5	5	5	1	04.02
Akgul et al., 2021. Turkey	1	3	2	1	2	1	2	3	0	0	2	2	3	56.41
Asher et al., 2016. USA	1	2	3	2	3	2	3	2	2	3	3	3	3	82.05
Berg et al, 2009. Sweden	1	2	2	3	2	2	3	3	3	2	3	3	3	82.05
Berjano et al., 2021. Switzerland	1	2	2	2	2	2	1	1	2	3	3	1	1	58.97
Bisson et al., 2021. USA	1	2	2	1	2	2	3	3	1	2	3	3	2	69.23
Boden et al., 2020. Georgia	1	2	3	2	1	1	3	2	1	2	3	3	3	69.23
Cho et al., 2021. South Korea	2	3	2	3	1	3	2	2	1	2	3	3	2	74.36
Coronado et al., 2020. USA	3	3	3	3	3	3	3	3	2	2	3	3	3	94.87
Divi et al., 2021. USA	2	3	2	3	3	3	2	2	3	3	3	3	3	89.74
Ganesane et al., 2017. India	2	2	2	2	2	1	3	2	2	2	3	2	2	69.23
Geoghegan et al., 2021. USA	2	3	3	3	3	2	3	3	2	2	3	3	3	89.74
Gilmore et al., 2019. Australia	3	3	3	3	3	3	3	3	2	2	3	3	3	94.87
Goh et al., 2017. Singapore	1	3	2	2	3	2	3	3	2	2	3	3	2	79.49
Goh et al., 2020. Singapore	1	3	2	2	3	2	3	2	2	2	3	3	2	76.92
Goh et al., 2020. Singapore	1	2	3	3	2	2	3	3	2	2	3	3	1	76.92

Appendix 3: Quality assessment scores using QuADS tool

Goyal et al., 2021. USA	1	2	2	1	2	1	2	3	3	2	3	2	1	64.10
Haddas et al., 2021. USA	2	2	2	3	3	2	3	3	2	3	3	3	1	82.05
Han et al., 2021. China	2	3	3	2	1	2	2	3	3	2	2	3	2	76.92
Houten et al., 2006. USA	1	3	2	2	2	3	1	2	2	2	2	2	1	64.10
Huang et al., 2021. China	2	3	2	2	2	3	3	1	2	2	2	2	2	71.79
Jacob et al., 2021. USA	3	3	3	2	2	3	3	3	1	3	3	3	1	84.62
Jakbsson et al., 2019. Sweden	1	3	2	1	2	1	2	3	0	0	2	2	3	56.41
Jekins et al., 2021. USA	1	2	3	2	3	2	3	2	2	3	3	3	3	82.05
Kaye et al., 2019. USA	1	2	2	3	2	2	3	3	3	2	3	3	3	82.05
Le et al., 2020. USA	1	2	2	2	2	2	1	1	2	3	3	1	1	58.97
Lenz et al., 2020. Germany & USA	2	3	2	2	3	2	3	3	2	1	2	3	1	74.36
Lim et al., 2020. Singapore	1	2	3	2	2	3	2	2	2	3	3	2	3	76.92
Lim et al., 2018. Singapore	1	3	3	2	2	2	3	2	1	2	2	3	2	71.79
Lin et al., 2021. China	3	3	3	2	3	3	3	3	2	2	2	3	3	89.74
Oestergaard et al., 2013. Denmark	1	2	2	2	2	2	2	1	2	2	2	1	2	58.97
Marbacher et al., 2016. Switzerland	2	3	3	2	2	2	3	2	1	1	3	3	2	74.36
Master et al., 2021. USA	2	2	2	2	2	2	2	2	2	2	2	2	2	66.67
Min & Yoo., 2012. Korea	2	3	2	2	3	2	2	3	3	3	2	3	2	82.05
Moses et al., 2021. USA	2	3	3	2	2	3	2	2	2	1	2	1	1	66.67

Olivera et al., 2021. Brazil	2	3	3	2	2	3	2	2	3	2	2	2	2	76.92
Parai et al., 2017. Sweden	1	2	3	3	3	3	2	2	3	2	2	2	2	76.92
Parai et al., 2019. Sweden	2	3	3	3	3	2	3	1	1	2	2	2	2	74.36
Park et al., 2011. Korea	2	2	3	3	3	3	2	2	3	3	2	2	2	82.05
Park et al., 2021. USA	3	3	1	2	2	2	3	3	2	2	3	2	2	76.92
Saban et al., 2007. USA	2	2	1	1	2	2	3	2	3	3	3	2	2	71.79
Schiedt et al., 2019. Germany	2	3	2	2	2	3	2	1	2	2	2	2	1	66.67
Sielatycki et al., 2021. USA	2	3	2	2	2	1	3	3	3	3	2	2	2	76.92
Szadkowski et al., 2021. France	3	3	3	2	3	3	3	3	2	2	2	3	3	89.74
Takahashi et al., 2011. Japan	1	2	2	2	2	2	2	1	2	2	2	1	2	58.97
Triebel et al., 2016. Sweden	2	3	3	2	2	2	3	2	1	1	3	3	2	74.36
Tuomainen et al., 2020. Finland	2	2	2	2	2	2	2	2	2	2	2	2	2	66.67
Yang et al., 2020. China	2	3	2	2	3	2	2	3	3	3	2	3	2	82.05
Yoo et al., 2019. USA	2	3	3	2	2	3	2	2	2	1	2	1	1	66.67
Rushton et al 2020. UK	3	2	3	3	2	2	3	3	3	3	3	2	2	87.18

Appendix 4: Ethics



To: Professor Alison Rushton

Project ID: 121368

Review Reference: 2022-121368-70937

Study Title: PATIENTS' PERCEPTION OF IMPORTANT OUTCOMES TO MEASURE FOLLOWING LUMBAR SPINAL FUSION SURGERY

Application Type: HSREB Initial Application

Review Type: Delegated

Full Board Reporting Date: 11/Oct/2022

Date Approval Issued: 20/Sep/2022

REB Approval Expiry Date: 20/Sep/2023

Dear Professor Alison Rushton

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals and mandated training must also be obtained prior to the conduct of the study.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
PATIENTS' PERCEPTION OF IMPORTANT OUTCOMES TO MEASURE FOLLOWING LUMBAR SPINAL FUSION SURGERY. PROTOCOL FOR A QUALITATIVE STUDY.	Protocol	29/Jul/2022	2
Documents Acknowledged:			

Document Name	Document Type	Document Date	Document Version
Second Patient Interview	Other Data Collection Instruments	04/Dec/2017	2

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

The Westem University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Electronically signed by:

Ms. Jhananiee Subendran, Ethics Officer on behalf of Dr. Emma Duerden, HSREB Vice-Chair, 20/Sep/2022 09:46

Reason: I am approving this document

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations, See Electronic System Compliance Review)

Page 1 of 1

Appendix 5: Topic guide for primary study

Level of motivation	
Symptoms you have experienced over the past week	
Medications you have taken this week	
Healthcare appointments this week	
 Rehabilitation progress this week Your ability to exercise and do activity this week Return to work / activities / hobbies as relevant to you 	

Positive thought(s) this week	
Negative thought(s) this week	
Most significant/memorable moment this week	
(may be positive or negative)	
Please describe how this week has been	
compared to last week	

Please record any other comments you would like to make regarding how you have felt or your experiences over the past week?

Thank you for your completing the diary this week – your help is very much appreciated.

Curriculum Vitae

Name:

Onyinyechukwu Umemba

Post-secondary Education and Degrees:

University of Lagos, Lagos state, Nigeria Bachelor of Physiotherapy (Hons) 2012-2017.

The University of Western Ontario London, Ontario, Canada M.Sc HRS 2020- till present.

Honours and Awards:

2nd best graduating student, Best in clinical practice Physiotherapy Department, University of Lagos 2017

Related Work Experience:

Teaching Assistant: The University of Western Ontario PT 9525: Physical Therapy In Rehabilitation Settings (Winter 2021)

APPLHSCI 9010: Health Services, Systems And Policies (Summer 2021)

HS2711B: Health Issues In Aging (Winter 2022)