The clinical profile and assessment of cervical spine radiculopathy

A thesis submitted for the degree of Doctor of Philosophy (PhD)

By

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Faculty of Medicine and Health Sciences: School of Health Sciences

2024

Word Count: 88,382

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Abstract

Background: Cervical spine radiculopathy (CSR) is a complex entrapment neuropathy that can result in changes in physical and mental health. Clinical practice is inconsistent in assessing CSR. This PhD research programme aimed to understand the clinical assessment practices when establishing CSR diagnosis.

Methods: Four studies were undertaken. Two systematic reviews reported CSR epidemiology and health outcomes. A mixed methods research study was grounded in a pragmatist paradigm and implemented an explanatory sequential design involving an online survey and qualitative interviews of United Kingdom (UK) physiotherapists. A case-control study assessed quantitative sensory testing and conditioned pain modulation of healthy control participants and people with CSR.

Results: CSR prevalence ranges from 1.07 to 1.76 per 1000 for males and 0.63 to 5.8 per 1000 for females. Poor health outcomes were associated with stress, depression, and anxiety symptoms. To diagnose CSR, manual muscle strength, light touch sensation, and reflex testing are most frequently used by UK physiotherapists. Pain screening tools or questionnaires and small-fibre somatosensory testing are less frequently used. Four qualitative themes contextualised the reasons underpinning the choices made when assessing CSR: perception of physiotherapist's role in practice, service constraints, minimising risk, and understanding symptoms. Large and small nerve fibre somatosensory alongside psychosocial profiles of 25 healthy participants and four people with CSR were reported in the case-control study.

Conclusion: This PhD programme has enhanced the understanding and evidence for assessing people with CSR. The incidence and prevalence of CSR have been established, and the differences in assessment methods used have been reported. The association between mental health symptoms, such as depression, anxiety, and distress, and their negative impact on health outcomes have been discussed. The physiotherapy assessment strategies used and the basis for the decisions made when determining CSR have been identified. The PhD programme of research began to examine the somatosensory profiles of people with CSR and healthy

control participants. Future studies examining prognosis indicators to develop the stratification of clinical assessment for people with CSR are recommended.

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Acknowledgements

Ní neart go cur le chéile — Find strength in unity.

This thesis would not have been possible without the support, encouragement and guidance of my supervisory team, physiotherapists, friends and family.

I owe much to my primary supervisor, Prof. Toby Smith, who gave me an opportunity to undertake this PhD project with him. I am deeply grateful for Prof. Smith's personal and professional support over the past 10 years. Prof. Smith's faith in me has enabled me to grow and develop as a researcher. His insights and knowledge know no bounds, and if I can pass on a fraction of this to future researchers, I will have succeeded. I hope this thesis goes some way to repaying Prof. Smith's faith in me.

Dr. Stephanie Jong, I also owe a deep gratitude. Dr. Jong, as my second supervisor, has supported me over the length of this thesis, providing honest and constructive insights, which have transformed my thinking, writing and positioning as a researcher. Dr. Jong's expertise in qualitative and mixed methods research has opened my horizons, and for that, I am most grateful.

Importantly, Prof. Smith and Dr. Jong, as a supervision team, have provided a pragmatism, down-to-earth nature and sense of humour throughout the length of this project. This has kept me 'on the straight and narrow'! Thank you both for your honesty and constructive feedback throughout.

I would also like to express my deep appreciation to Prof. Mick Thacker throughout this journey. Prof. Thacker is a true asset to our physiotherapy profession. But perhaps more importantly, I have learnt so much from him over the last 10 years, I feel extremely privileged to have worked and learnt (and laughed!) with Prof. Thacker – my sincere thanks.

I have developed a rich set of skills and knowledge during this thesis. I would like to thank Dr. Kirsty Bannister and the Bannister Laboratory at King's College London for developing somatosensory testing and translational pain science skills. My

thanks also go to Dr. Carolyn Roskell, Mr. Clive Liles and Mr. Rhys Hayward for their encouragement and wise words during the length of this thesis. To Prof. Lesley Haig, who enabled me to start and supported me on this journey – thank you. I acknowledge and express my gratitude for the support from the School of Sport, Exercise and Rehabilitation Sciences at the University of Birmingham and the Faculty of Medicine and Health Sciences at the University of East Anglia. I would also like to thank Ascenti for supporting patient recruitment and the Private Physiotherapy Education Foundation, which saw potential in the somatosensory profiling phase of the thesis and supported this with funding.

This project would not have been possible without my family. My mother is such a special person. Mum has provided me with unconditional love and belief in me. I will always be in debt to her – thank you. My father has provided a sense of pragmatism throughout this journey; his ability to find solutions is his superpower. My brother, his partner Julia and the Purcell family have been incredibly supportive and understanding. Anthony has an uncanny ability to see the light through the denseness of my thoughts. Anthony has provided dry-witted humour and a sense of reality in higher education (and beyond!) – thank you, Anthony.

Finally, my wife Catherina and son Aaron. Words cannot express my gratitude for both your understanding and support. Catherina's unwavering support in listening to my ramblings, sacrifices made to balance my academic and family life and enabling me to see the 'wood from the trees' will not be forgotten. Aaron is the shining light in our family. His laugh, smile, thoughts, enthusiasm and encouragement are an absolute joy and have provided a sense of perspective throughout. I am one lucky dad to have him in my world.

This thesis is dedicated to Catherina and Aaron.

Publications and presentations

Peer review scientific article publications.

Mansfield, M., Smith, T., Spahr, N. and Thacker, M., 2020. Cervical spine radiculopathy epidemiology: a systematic review. *Musculoskeletal Care*, *18*(4), pp.555-567.

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Mansfield, M., Jong, S.T. and Smith T.O. 2023. Cervical spine radiculopathy: A physiotherapist mixed methods assessment approach. Allied Health Professions Musculoskeletal Symposium

Abbreviations

Abbreviation	Meaning
AANEM	American Association for Electrodiagnostic Medicine
ADL	Activities of Daily Living
AROM	Active Range of Motion
ATOCP	Association of Trauma and Orthopaedic Chartered Physiotherapists
AUC	Area Under the Curve
AS	Alexandra Stead
BMJ	British Medical Journal
BPI	Brief Pain Inventory
CDT	Cold Detection Threshold
CENTRAL	Cochrane Central Register of Controlled Trials
CI (95%)	Confidence Interval (95%)
CIG	Clinical Interest Group
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CNS	Central Nervous System
CNSLBP	Chronic Non-Specific Low Back Pain
COREQ	Consolidated Criteria for Reporting Qualitative Research
COS	Core Outcome Set
CPM	Conditioned Pain Modulation
CPD	Continuing Professional Development
CPT	Cold Pain Threshold
CROSS	Checklist for Reporting Survey Studies
CRN	Comprehensive Research Network
CSp±R	Cervical Spine Pain With or Without Radiculopathy
CSR	Cervical Spine Radiculopathy
CT	Computed Tomography
CTS	Carpal Tunnel Syndrome
CVD	Cardiovascular Disease
DALYS	Disability-Adjusted Life-Years
DASH	Disabilities of the Arm Shoulder and Hand
DFNS	German Research Network on Neuropathic Pain
DMA	Dynamic Mechanical Allodynia
DN4	Douleur Neuropathique en 4 Questions
EDX	Electrodiagnostic Examination
EMG	Electromyography
EQ-5D	European Quality of Life-5 Dimensions
ESP	Extended Scope Practitioner
ESRC	Economic and Social Research Council
FCP	First Contact Practitioner
GCP	Good Clinical Practice
GIRFT	Getting It Right First Time
GP	General Practitioner
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HADS	Hospital Anxiety and Depression Scale
HCPC	Health and Care Professions Council

HPT	Heat Pain Threshold
HR	Hazard Ratio
HRA	Health Research Authority
IASP	International Association for the Study of Pain
ICC	Intraclass Correlation Coefficient
ID-PAIN	Identification-Pain
IL-6	Interleukin Factor-6
IPA	Interpretative Phenomenological Analysis
IQR	Interquartile Range
IVD	Intervertebral Disc
LANSS	Leeds Assessment of Neuropathic Symptoms and Signs
LBP	Low Back Pain
LR	Likelihood Ratio
MacOS	Macintosh Operating System
MCID	Minimal Clinically Important Difference
MM	Michael Mansfield
mm	Millimetre
MOM	Mature Organism Model
MPA	Maximal Pain Area
MPQ	McGill Pain Questionnaire
MPS	Mechanical Pain Sensitivity
MPT	Mechanical Pain Threshold
MRC	Medical Research Council
MMP	Matrix Metalloproteinases
MRI	Magnetic Resonance Imaging
MT	Mick Thacker (External Advisor)
NDI	Neck Disability Index
NCS	Nerve Conduction Studies
NeP	Neuropathic Pain
NeuPSIG	Neuropathic Pain Special Interest Group
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NIHR	National Institute of Health Research
NNT	Numbers Needed to Treat
NOS	Newcastle-Ottawa Scale
NPQ	Neuropathic Pain Questionnaire
NPRS	Numeric Pain Rating Score
NPSI	Neuropathic Pain Symptom Inventory
ODI	Oswestry Disability Index
OR	Odds Ratio
PCS	Pain Catastrophizing Scale
PDT	Pain Detection Threshold
PEDro	Physiotherapy Evidence Database
PEO	Population or Problem, Exposure, and Outcome
PHS	Paradoxical Heat Sensation
PICO	Participant, Intervention, Comparator, and Outcome
PIS	Patient Information Sheet
PPEF	Private Physiotherapy Education Foundation
PPIE	Patient and Public Involvement and Engagement

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PRISMA-P	Preferred Reporting Items for Systematic Review and Meta-analysis Protocols
PROM	Patient Reported Outcome Measures
PROSPERO	International Prospective Register of Systematic Reviews
QST	Quantitative Sensory Testing
QUIPS	Quality In Prognosis Studies
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RFU	Rugby Football Union
RR	Relative Risk
SD	Standard Deviation
SEM	Standard Error Measurement
SF-36	Short Form-36
SJ	Stephanie Jong (Second Supervisor)
SPSS	Statistical Package for the Social Sciences
STAI	State Trait Anxiety Inventory
SWiM	Synthesis Without Meta-Analysis
TKR	Total Knee Replacement
TNF-α	Tumour Necrosis Factor-Alpha
TS	Toby Smith (Primary Supervisor)
TSL	Thermal Sensory Limen
UK	United Kingdom
ULNT	Upper Limb Neural Tension Test
ULTT	Upper Limb Tension Test
UEA	University of East Anglia
USA	United States America
VAS	Visual Analogue Scale
VDT	Vibration Detection Threshold
WAD	Whiplash Associated Disorder
WDT	Warm Detection Threshold
WHO	World Health Organisation

Chapter 1: Setting the scene

1.1. Introduction

This chapter begins by presenting a general introduction to cervical spine radiculopathy (CSR). The lead researcher's (MM) research area of interest and reasons for embarking on this PhD programme are described, followed by the aims, objectives, and outline of the PhD thesis. Following this, a detailed narrative literature review is presented, where CSR is described in greater depth, and key concepts surrounding the assessment of CSR are introduced. Finally, current knowledge regarding CSR pathophysiology and epidemiology is discussed.

1.2. General introduction to cervical spine radiculopathy and the importance of this PhD research

Cervical spine radiculopathy occurs when a nerve root in the neck (cervical spine) is compressed (Bogduk, 2011, Van Zundert et al., 2011). Degenerative changes can cause cervical spine nerve root compression by narrowing the joint space where the nerve roots pass through and/or changes in the intervertebral discs (such as disc herniation) (Bogduk, 2011, Vardeh, 2016). The term 'degenerative changes' refers to osteoarthritis of the spine, which is the most common form of arthritis (Iyer and Kim, 2016). Osteoarthritis of the cervical spine is sometimes called cervical spondylosis. Cervical spondylosis is defined by joint space narrowing, affecting all components of the cervical spine, including intervertebral discs, facet joints, joints of Luschka, ligamenta flava, and laminae, which can cause nerve root compression (Iyer and Kim, 2016, Yang et al., 2022).

Cervical spine radiculopathy can cause pain that may spread beyond the neck and into the arm, chest, shoulders, and/or upper back regions (Marco et al., 2023). People with CSR may also experience muscle weakness, sensory changes, and impaired reflexes in the arm (upper limb) (Marco et al., 2023). The clinical assessment for diagnosing CSR typically involves obtaining a detailed history of the present condition, mapping symptoms onto a body chart, determining the severity of symptoms, and identifying any associated co-morbidities that may delay full

recovery or a return to daily activities (Marco et al., 2023). When completing a physical examination of the cervical spine with the suspicion of nerve root compression, the National Institute for Health and Care Excellence (NICE) guidelines (NICE, 2023) recommends clinicians assess the neck and arms, conduct reflex and muscle strength testing, and assess any sensation changes in the upper limb.

At the time of conducting this PhD, there was no agreed clinical working definition of CSR. For the purpose of this PhD, a pragmatic decision was taken to establish a working definition of CSR informed by the International Association for the Study of Pain (IASP) and North America Spine Society (Bono et al., 2011, Scholz et al., 2019):

> *A compressed or impeded nerve root in the cervical spine leading to pain, sensory and/or motor dysfunction that can spread beyond the cervical spine into the arm, chest, shoulders, and upper back.*

At the start of this PhD programme, it was not clear what the prevalence or incidence rates of CSR were among adults globally. Although cross-sectional studies had assessed the prevalence and incidence of CSR, no study had synthesised the evidence-base (Mansfield et al., 2020). Furthermore, the global epidemiology of CSR and the diagnostic methods used to determine its prevalence and/or incidence were unknown. The first systematic review in Chapter 2 addresses questions that individual epidemiology studies may not be able to answer. The systematic review in Chapter 2 is important as it assesses the quality of research and provides recommendations for enhancing future epidemiology and CSR diagnostic research.

The association between psychosocial factors and health outcomes in people with CSR have not yet been established in the literature. While observational studies have reported how psychosocial factors and mental health diagnoses and symptoms may be associated with poorer health outcomes and neuropathic pain (NeP) pain conditions (Gormsen et al., 2010, Turk et al., 2010), the external validity of these studies to people with CSR is limited. Therefore, at the time of starting this

PhD, it was not possible to say if psychological and/or psychosocial factors are associated with health outcomes for the CSR population. As such, the second systematic review in Chapter 3 was indicated to understand whether there is an association between psychological and/or psychosocial factors in CSR populations and health outcomes.

Evidence-based decision-making in clinical practice is essential for the best possible care (Sackett et al., 1996). Evidence-based practice involves combining research findings with a healthcare professional's expertise, experiences and patient expectations to make informed decisions regarding healthcare (Haynes et al., 2003, Sackett et al., 1996). Adopting an evidence-based approach to CSR assessment can be challenging. There is no agreement on which assessment methods to use when assessing CSR. This makes it unclear how physiotherapists decide on which assessment strategies to use for CSR diagnosis. To gain a better understanding of why certain assessment strategies are used or not used, it is salient to understand physiotherapist decision-making. Therefore, the lead researcher (MM) designed and completed a mixed methods study (Chapters 4-8) to determine the assessment practices used by physiotherapists and the reasons behind their implementation in clinical practice.

Adults with CSR do not always show obvious signs of nerve damage and NeP symptoms (Schmid et al., 2020). Chapters 1 and 2 discussed how nerve root compression might impact both large and small sensory fibres, and the degree of sensory fibre damage may explain the variability of symptoms in adults with CSR. Chapter 3 reported how the association of mental health conditions and CSR could negatively impact the health outcomes of adults with CSR and, as such, are essential components of a robust clinical assessment when establishing a CSR diagnosis. Chapters 7 and 8 indicated a paucity of evidence on sensory testing (using QST) for assessing CSR was a significant reason for its limited adoption in clinical practice. The clinical utility of QST in this context is therefore unclear. To begin to address this, a case-control observational study (Chapter 9) was designed and completed to investigate whether somatosensory profiling, assessed through QST, and/or psychosocial/psychological determinants, are associated with adults with CSR compared to healthy volunteers.

1.3. Aim and objectives

The aim of the PhD thesis is to investigate the clinical assessment when establishing a CSR diagnosis. Specifically, to answer the following objectives:

1) To ascertain the epidemiology of CSR globally in adult populations.
2) To systematically review the association between psychological and psychosocial factors in CSR and health outcomes.
3) To understand the assessment practices utilised by physiotherapists in the UK for diagnosing CSR, and the underlying reasons for their approach.
4) To identify the somatosensory profile of adults with painful CSR and compare them to those of healthy control subjects.

1.4. Thesis structure

1.4.1. Chapter 1. Setting the scene.

This chapter described the lead researcher's (MM) interest in the research topic and an outline of the content of each subsequent chapter. The aims and objectives of the PhD programme are stated. This chapter also describes, with a narrative literature review, the pathophysiology, clinical assessment and diagnosis strategies of CSR, and the epidemiology of CSR. The conceptual models of pain and psychosocial factors are presented.

1.4.2. Chapter 2. Epidemiology: systematic review.

In Chapter 2, a systematic literature review establishes the prevalence and incidence of CSR. It begins by justifying the methods completed for this type of evidence synthesis methodology. The prevalence and incidence data are presented and discussed. The chapter concludes with a discussion of the strengths and limitations of the completed systematic review and how the sub-group analysis of CSR clinical diagnosis informs the subsequent thesis chapters.

1.4.3. Chapter 3. The association of mental health symptoms and health outcomes: systematic review.

In Chapter 3, a systematic literature review establishes the association between mental health symptoms and diagnoses and health outcomes among adults with CSR. The chapter progresses by discussing protocol development and methods. It concludes by discussing how mental health symptoms and diagnoses can negatively impact the health outcomes of adults with CSR.

1.4.4. Chapter 4. Mixed methodology: methodological principles.

In Chapter 4, the use of mixed methods research to investigate the assessment strategies of UK physiotherapists when diagnosing CSR are discussed. To begin, a critical review of mixed methods research and common criticisms directed towards this research approach are discussed. An explanation of why mixed methods research was chosen for this research is presented. Two studies that make up this research, which are further explored in subsequent chapters, are discussed. To conclude this chapter, a plan to integrate the different studies to achieve the aim of this thesis is presented and justified.

1.4.5. Chapter 5. Cervical spine radiculopathy assessment practices: quantitative survey.

In Chapter 5, a quantitative survey conducted on the clinical assessment practices of physiotherapists in diagnosing CSR is discussed. A review of the survey's purpose, development, and analysis is presented. Following this, an examination of the key findings of the survey and its strengths and weaknesses are discussed. To conclude, an explanation is given of how combining the survey results with qualitative interview data will provide a better understanding of what UK physiotherapists use CSR assessment to diagnose their patients and the reasons underpinning.

1.4.6. Chapter 6. Cervical spine radiculopathy assessment practices: qualitative interviews.

Chapter 6 presents the second component of the mixed methods research, namely qualitative interviews, exploring the reasons why UK physiotherapists assess CSR in clinical practice. It will begin with a review of the qualitative interview method and an explanation of the rationale for using it to understand physiotherapist decision-making when establishing CSR diagnosis. It will continue with a discussion of the selection and recruitment of participants. The chapter will conclude with a description of the participants, the method used for data collection and how trustworthiness was established during the research process.

1.4.7. Chapter 7. Cervical spine radiculopathy assessment practices: mixed methods integration.

Chapter 7 discusses the demographic variables of the quantitative survey and qualitative interviews are presented. The chapter presents the results from the qualitative and quantitative phases that were integrated using visual joint displays.

1.4.8. Chapter 8. Cervical spine radiculopathy assessment practices: integrated quantitative and qualitative discussion.

In Chapter 8, the integrated results from Chapter 7 are discussed and contrasted with relevant literature to address the aim of this mixed methods research study.

1.4.9. Chapter 9. Somatosensory profiling: a case-control study.

In Chapter 9, a case-control study with the purpose of identifying the somatosensory profiles of healthy adults and adults with CSR is presented and analysed. The association between psychosocial factors and QST findings is discussed. Following this, a discussion of the strengths and weaknesses of this study with clinical implications is completed.

1.4.10. Chapter 10. Discussion and conclusion.

Chapter 10 analyses the thesis' findings and suggests that a comprehensive person-centred approach should be considered when establishing CSR diagnosis. Additionally, recommendations for future research and clinical practice are proposed based on the thesis' findings. To conclude, the strengths and weaknesses of the thesis are evaluated.

1.5. My area of interest and reasons why I embarked on this PhD

I became a qualified physiotherapist in 2006 and was awarded my MSc in Advanced Physiotherapy (Neuromusculoskeletal) in 2012. My interest in spinal conditions started during my junior National Health Service (NHS) musculoskeletal outpatient rotation. For six months, I primarily assessed people with persistent neck and lower back pain, which led me to observe differing signs, symptoms, disability, and treatment outcomes, despite receiving the same or similar clinical diagnosis. The discrepancies in clinical presentation enhanced my curiosity about people with CSR.

As I advanced in my clinical career, I secured a job in an inner-city London-based musculoskeletal spinal assessment service that had connections with academic institutions. During this time, I developed an interest in education and research while still focusing on spinal assessment strategies. I collaborated with clinicians and academic staff to create spinal assessment and management teaching and research projects for undergraduate and postgraduate physiotherapists. This experience fuelled my desire to pursue a research career that would help individuals living with CSR and positively impact the education of healthcare professionals.

I am currently a Lecturer in Physiotherapy at a higher education institution in the UK. My main responsibility is to oversee a range of postgraduate MSc programs focused on musculoskeletal physiotherapy. I develop and deliver curricula for qualified physiotherapists in this field. Additionally, I participate in outreach activities and collaborate with clinical partners in the private, public, and charity sectors. This collaboration allows me to apply my knowledge in patient care settings and industry. Furthermore, working with clinical academics in my academic role in the area of

entrapment neuropathy and NeP further fuelled my interest in CSR and motivated me to pursue a PhD research program.

1.6. Background literature review

The review of literature below discusses and evaluates studies, perspectives, theories, and bodies of work that are relevant to this PhD research. The main purpose of conducting this narrative literature review is to introduce the concept of CSR in greater depth and explain its significance by analysing the current body of literature and its relevance to this PhD research. This narrative literature review provides the reader with the necessary background and clearly outlines the specific gaps or opportunities that this PhD research aims to address.

The aim of the narrative literature review was to discuss the themes in relation to CSR as outlined below:

a) Anatomy of cervical spine nerve roots
b) Taxonomy and terminology of CSR
c) Pathophysiology of CSR
d) Explanatory pain models
e) Epidemiology and natural history of CSR
f) Psychosocial factors and their association with CSR
g) Clinical assessment strategies for CSR
h) The role of imaging and electrodiagnostic testing
i) Psychophysics and somatosensory profiling

1.6.1. Sources of literature

To begin, a computerised search strategy was used to gather information from relevant electronic databases and presented in **Table 1.1**. These subject-based electronic databases used were appropriate as they are relevant to orthopaedic, neuroscience and physiotherapy clinical practices (Moseley et al., 2009, Zlowodzki et al., 2006). Additionally, to prevent publication bias, unpublished or grey literature databases were also searched, including OpenGrey (System for Information on Grey Literature in Europe), Zetoc, World Health Organization (WHO) International

Clinical Trials Registry Platform, Current Controlled Trials, and the UK Comprehensive Research Network (CRN) Portfolio Database.

Table 1.1 Electronic database search strategy

Database (Platform)	Date range
Allied and Complementary Medicine Database (AMED)	1985 to December 2023
Cumulative Index to Nursing and Allied Health Literature (CINAHL)	1982 to December 2023
Excerpta Medica Database (EMBASE)	1974 to December 2023
Medical Literature Analysis and Retrieval System Online (MEDLINE) (Via OVID)	1950 to December 2023
PsycINFO (via OVID)	1906 to December 2023
Physiotherapy Evidence-base Database (PEDro)	December 2023
Cochrane Library	Inception to December 2023

Conference proceedings from the British Orthopaedic Association Annual Congress, European Pain Federation, International Association for the Study of Pain conference proceedings, Chartered Society of Physiotherapy congress and the World Confederation for Physical Therapy were also searched. This ensured identification of studies presented as abstracts at conferences.

Specific search terms were developed for each database and adapted according to the theme being investigated. The search terms adopted for the MEDLINE databases for each theme are presented in **Appendix 1.1**. To synthesise information about people who have CSR, the lead researcher (MM) looked at various research that covered topics such as anatomy, aetiology, pathophysiology, epidemiology, psychosocial factors, somatosensory assessment and clinical assessment. The lead researcher (MM) also included papers that focused on childhood, adult or cadaver cohorts, to ensure a comprehensive representation of the CSR lifecycle. Each paper was evaluated based on the aforementioned themes,

and the lead researcher (MM) reviewed and assessed all literature before narratively synthesising findings.

1.7. Anatomy of the cervical spine nerve root and associated neuroaxis

The cervical nerves start from the spinal cord as rootlets, small bundles of neurons that combine to form roots (Lee et al., 2017, Leijnse and D'Herde, 2016). The anterior and posterior roots of each spinal nerve come together to create a complete nerve.

Spinal nerves consist of both sensory and motor fibres. Sensory fibres are termed the dorsal root and their cell bodies can be found in the dorsal root ganglion (Bogduk et al., 1981, Yabuki and Kikuchi, 1996). The motor fibres make up the ventral or anterior root (Yabuki and Kikuchi, 1996). When the dorsal and ventral roots unite, a typical spinal nerve is formed, just below the dorsal root ganglion (Yabuki and Kikuchi, 1996). The upper limb muscles and skin receive their sensory and motor innervation from multiple nerve roots due to the intricate anatomy of the cervical and brachial plexus (Johnson, 2004).

The term “dermatome” comes from the Greek words *derma*, meaning “skin”, and *tome*, meaning “cutting” or “thin segment” (Lee et al., 2008). A dermatome refers to the specific cutaneous area that is supplied by a single spinal nerve root (Lee et al., 2008). The distribution of spinal nerve roots is based on their association with spinal cord segments. Each spinal cord level (such as C3, C4) gives rise to nerve roots, which can combine in a plexus (such as brachial, lumbar, or lumbosacral) to form various peripheral nerves (Leinberry and Wehbé, 2004). A single nerve root can supply multiple peripheral nerves, for example the median nerve originates from C6, C7, C8, and T1 nerve roots, while the ulnar nerve comes from C7, C8, and T1 (Gilcrease-Garcia et al., 2020, Leinberry and Wehbé, 2004).

1.8. Important taxonomy considerations

To comprehend CSR, and support clinical diagnosis formation, it is essential to understand and distinguish between the signs, symptoms and clinical features of neck pain, somatic referred neck pain, radicular pain and radiculopathy.

1.8.1. Nociceptive neck pain

Nociceptive neck pain is defined as pain that is triggered by noxious stimulation of structures in the cervical spine (Bogduk, 2003, Bogduk, 2009). Neck pain is felt as pain in the region between the superior nuchal line, the lateral margins of the neck, and a transverse line through T1 spinous process (Fandim et al., 2021). This boundary does not necessarily mean that the pain's cause is in this area, but rather it indicates where the person feels or perceives their pain (Fandim et al., 2021). Noxious stimuli to certain cervical spine structures, such as zygapophyseal (facet) joints, intervertebral discs (IVDs), muscles of the neck or interspinous ligaments, can cause pain (Bogduk, 2009, Vardeh et al., 2016). The noxious stimulation causes a dull, aching pain in the neck. Therefore, when this type of pain occurs clinically, it can be inferred to be nociceptive neck pain.

Several proposed classification strategies for people with neck pain, mainly based on specific clinical features, have been developed (Dewitte et al., 2016). Werneke et al., (1999) ground their categorisation on changes in pain location with repeated or sustained cervical spine movements. Wang et al., (2003) categorise patients into one of four main categories (i.e., radicular arm or neck pain, referred arm or neck pain, cervicogenic headaches, or neck pain only). Whereas Childs et al., (2004) propose a treatment-based classification that places people into one of five subgroups (i.e., mobility, centralisation, exercise and conditioning, pain control, or headache). Dewitte et al., (2016) completed a Delphi study involving 21 musculoskeletal physical therapists from Belgium and the Netherlands who were experienced in assessing and treating people with neck pain (without radiculopathy). The clinical indicators suggestive of a clinical dominance of 'articular', 'myofascial', 'neural', 'central', and 'sensorimotor control' dysfunction patterns may help clinicians assess and diagnose people with nociceptive neck pain.

1.8.2. Somatic referred pain

Pain in the neck can sometimes spread to the upper limbs and scapular region due to noxious stimulation of structures in the cervical spine. This type of pain is known as referred pain, as it is perceived in areas innervated by nerves other than those that innervate the site of noxious stimulation (Jin et al., 2023, Vecchiet et al., 1999). Somatic referred pain is caused by noxious stimulation of spinal structures such as the IVDs or zygapophysial joints (Bogduk, 2009). Unlike radicular pain or visceral referred pain, somatic referred pain does not involve stimulation of nerve roots (Bogduk, 2009). The proposed referral mechanism is the convergence of nociceptive afferents on second-order neurons in the spinal cord that subtend regions of the upper limb (Graven-Nielsen, 2006, Jin et al., 2023). Since somatic referred pain is not caused by nerve root compression, there are no neurological signs associated with it (Graven-Nielsen, 2006, Jin et al., 2023).

1.8.3. Radicular pain

Radicular pain differs from somatic referred pain in both mechanism and clinical features (Bogduk, 2009, Milette, 1994). It is caused by the ectopic discharge of nerves from a dorsal root or its ganglion (Patel and Perloff, 2018). The most common cause is disc herniation. Inflammation of the affected nerve is the primary pathophysiological process (Patel and Perloff, 2018). Studies on people who have undergone surgery for disc herniation have established clinical features of radicular pain (Govind, 2004, Mahn et al., 2011). These studies involved stimulating the affected nerves and adjacent nerves by squeezing them with forceps or placing sutures around them during surgery (Govind, 2004). The resulting pain is distinct, with a lancinating quality that travels along the length of the limb (Mahn et al., 2011). This type of pain is only produced by stimulating nerve roots and should be interpreted as radicular pain.

1.8.4. Radiculopathy

Radiculopathy is a distinct neurological condition that occurs when there is a ‘blockage’ of conduction along a spinal nerve or its roots (Caridi et al., 2011). Radiculopathy usually leads to weakness in motor fibres and decreased reflexes

(Van Zundert et al., 2011). Sensation changes are usually present, although the sensory changes may not always be dermatomal in distribution. It is important to acknowledge that radiculopathy is not defined by pain in isolation. While radiculopathy and radicular pain often occur together, it is possible for radiculopathy to occur without pain and for radicular pain to occur without radiculopathy (Van Zundert et al., 2011). Furthermore, Lam et al's (2022) Delphi study from 12 physiotherapists agreed a cluster criterion consisting of radicular pain with arm pain worse than neck pain; paraesthesia or numbness and/or weakness and/or altered reflex; MRI confirmed nerve root compression compatible with clinical findings. The complex pathophysiology of radiculopathy in relation to clinical signs and symptoms will be further discussed in the subsequent subsections of this chapter.

1.9. Cervical spine pain and symptom referral patterns

Individuals with suspected CSR may experience varying pain patterns. These can be attributed to underlying pathomechanisms. Tanaka et al., (2006) observed that people experiencing isolated C5 and C6 radiculopathy could feel pain in the suprascapular shoulder region, while those with C8 nerve root compression could experience pain in the scapular region (Tanaka et al., 2006). However, these referral patterns shared similar innervations with other structures in the cervical spine (Dwyer et al., 1990, Tanaka et al., 2006). Grubb and Kelly (2000) conducted cervical discograms and reported that the pain referred from the IVDs to the shoulder was similar to that caused by the facet joints (Grubb and Kelly, 2000). In a cross-sectional study of 98 people with a CSR (mean age 48 years; Standard Deviation (SD) 8.0 years), only 54% of the cohort with CSR had a typical 'dermatomal distribution' (Marco et al., 2023). People with CSR symptoms with more dominant neuropathic (NeP) than nociceptive pain presentations had higher pain intensity and symptoms spread (extra dermatomal distribution) (Marco et al., 2023). The wide variance and overlap in pain distribution should provide caution when identifying specific nerve roots based on the spread of symptoms, and the absence of clearly defined symptom referral patterns does not rule out a diagnosis of CSR.

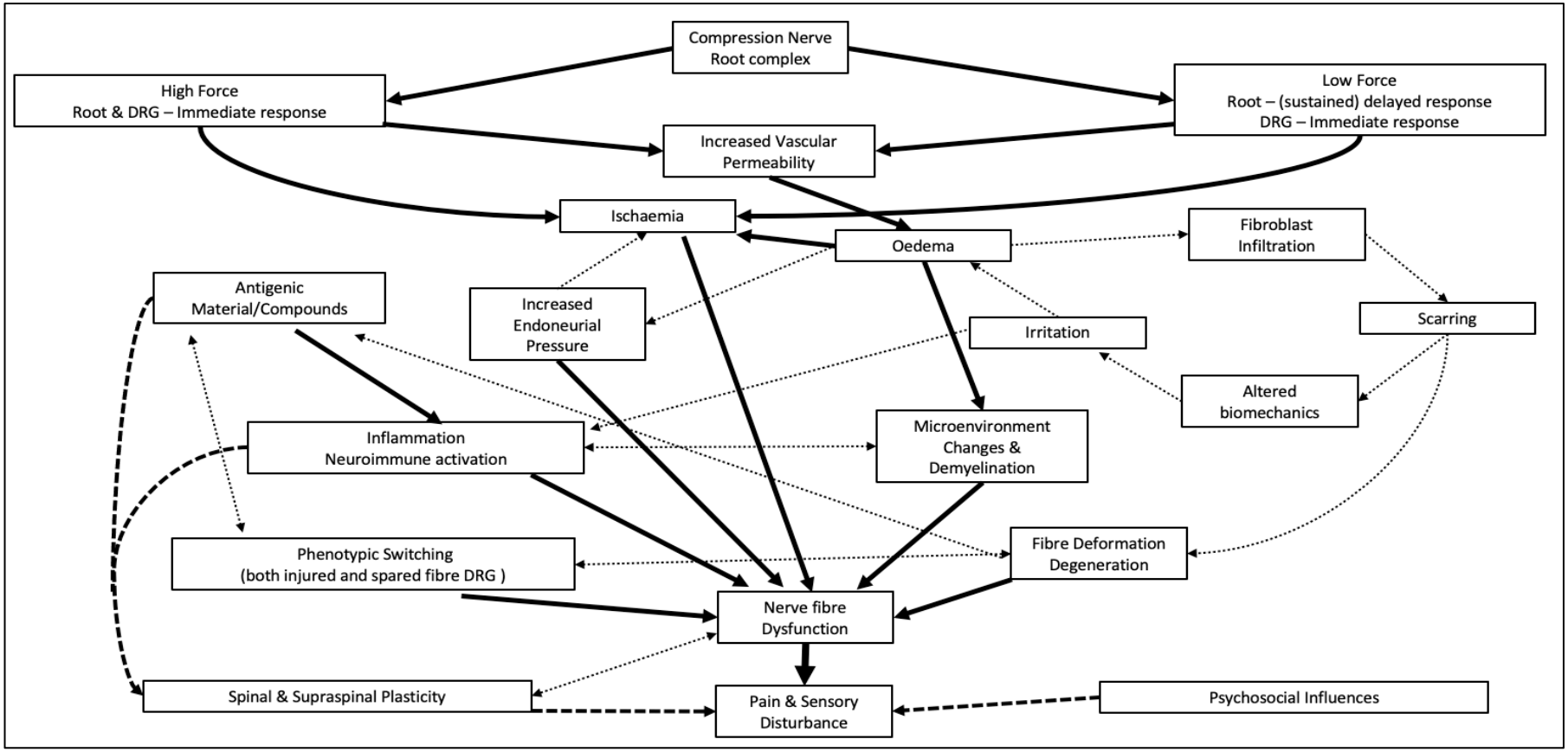
The overlapping of referral patterns may be attributed to nerve injury or inflammation that causes spontaneous activity in neurons that innervate muscle or deep tissues (Rainville et al., 2016). This activity can contribute to referred limb pain that does

not follow a specific dermatome. Additionally, there may be overlap between dermatomes, with one dermatome covering one or two adjacent segments, which can cause nerve root pain to have a dermatomal distribution that does not precisely match classic dermatome maps (Rainville et al., 2016). Persistent nociceptive input can also expand the size of receptive fields in dorsal horn cells, leading to pain referral in a wider area (Neziri et al., 2010). Identifying this complex and overlapping picture of nerve innervation from the cervical plexus supports the importance of multi-component evaluation of people with suspected CSR.

1.10. Pathophysiology of cervical spine radiculopathy

Radiculopathy can be linked to various pathophysiological mechanisms (Rempel and Diao, 2004). It is often defined as a condition where the complex of nerve roots is compressed by material from the disc (Danielsen et al., 2023). The C7 root (C6-7 herniation) is the most commonly affected, followed by the C6 (C5-6 herniation) and C8 (C7-T1 herniation) nerve roots (Iyer and Kim, 2016, Yoon and Koch, 2021). When the nerve root is compressed by disc material, it can cause nerve damage through both mechanical and chemical pathways (Iyer and Kim, 2016). The nucleus pulposus initiates a pro-inflammatory cascade mediated by tumour necrosis factor-alpha (TNF-α), interleukin factor-6 (IL-6), and matrix metalloproteinases (MMPs) (Cunha et al., 2018). However, most cases of CSR are not due to ‘soft’ disc herniation but rather to cervical spondylosis (Iyer and Kim, 2016, Yang et al., 2022). Disc herniation is responsible for only 22% of reported CSR (Luyao et al., 2022). The compression process is intricate and involves an interplay between the root’s anatomy and pathophysiological mechanisms (Figure 1.1). A response profile to compressive forces across the nerve root’s fibre types has been proposed in animal models (Lundborg, 2004, Rydevik et al., 1984). Rydevik et al., (1984) and Lundborg (2004) have demonstrated that when lumbar nerve roots are compressed through ligation, it results in consistent and predictable behaviours related to radiculopathy and radicular pain. However, this concept has been questioned recently; Schmid et al., (2020) outlined potential implications for clinical testing and management. This will be further discussed in **Chapter 8**.

Figure 1.1 A spatiotemporal model of the pathophysiological mechanisms in radiculopathy



*A number of parallel converging cascades are involved in the production and maintenance of the symptoms of radiculopathy. The main cascades are indicated using **bold** arrows. It is important to note that there is no requirement for all elements of this causative cascade to be present and that these mechanisms are unlikely to be isolated to the root complex once established*. Reproduced with permission (Mansfield and Thacker, 2023).

1.11. The explanatory pain models

Pain and its related behaviours, such as withdrawal, increased alertness and focusing on symptoms, serve as a critical biological signal that alerts an individual to potential harm, and prompts protective actions (Gifford, 2014). There are notable variations in how individuals react to identical nociceptive stimuli, and this can result in different pain-related behaviours (Gifford, 2014). As a physiotherapist developing knowledge in practice for over 17 years, the lead researcher's (MM) positioning is that an individual's CSR symptoms can present physical symptoms as the dynamic interaction between biological, psychological and social factors. It is acknowledged that these factors often overlap and interact with one another (Gifford, 2014). **Table 1.2** below summarises the historical models of painful experiences and offers a contextual explanation of a person's pain experience and its dynamic interactions.

Table 1.2 The historical models of painful experiences

Pain experience model	Description summary
Line Labelling –'Pain Pathways'	The traditional biomedical approach to pain prioritises finding the root cause of the pain, rather than comprehending the various dimensions of the painful experience itself (Moayedi and Davis, 2013). Pain is transmitted through specific 'pain pathways' to a centre in the brain (Cartesian perspective). This reductionism resulted in the belief that all symptoms and signs arise from an underlying abnormality within the body (Moayedi and Davis, 2013).
The Gate-Control Theory	Proposed by Melzack and Wall (1965). The model suggested that a 'gating mechanism' was controlled by 'large fibres' that inhibited the gate and small nerve sensory fibres that activated it (Melzack and Wall, 1965). Descending fibres from the supraspinal region that project into the dorsal horn could also modulate the gating system (Melzack and Wall, 1965). The original theory was later expanded into a three-dimensional model that includes sensory-discriminative components like intensity, location, quality, and duration, affective-motivational components (Melzack and Casey, 1968).
Neuromatrix Theory	Pain is a multi-dimensional experience that results from specific neuro-signatures (Melzack, 2001). These neuro-signatures are patterns of nerve signals produced by a neural network in the brain (Melzack, 2001, Moseley, 2003). Melzack (2001) suggested that networks of 'neuromodules' in the sensory, affective, and cognitive areas of the brain work together to create the collective experience of pain. This process is considered cyclical, with input and output processes synthesising the experience (Moseley, 2003).

Fear-Avoidance Model	This model has been used to explain individual variation in response to injury (Leeuw et al., 2007, Vlaeyen and Linton 2000). This model proposes that avoiding activities of daily living (such as physical activity) can lead to multiple symptoms such as disability, negative mental health symptoms, and a cycle of persistent pain (Vlaeyen and Linton, 2000). It is related to the 'onion skin' model of pain (Loeser, 2006), which suggests that to effectively manage and assess pain, the different layers of pain (nociception, pain, suffering, and expressed behaviour) must be recognised and understood.
Mature Organism Model	The model proposes that the organism plays a crucial role in examining the environment to either achieve a reward or avoid a threat (Gifford, 2014, Gifford, 1998). This theory suggests that the body aims to maintain a state of balance by analysing past experiences, beliefs, knowledge, and success in relation to nociceptive input and the surrounding environment.
Mechanisms-Based Approach	The development of a mechanistically based model to classify a pain presentation can, broadly, be based on four pain states: nociceptive, inflammatory, neuropathic (NeP) and centralised or nociplastic (Vardeh, 2016). Nociceptive pain reflects the activation of nociceptors (usually high threshold primary sensory neurons) by mechanical stimulus (Vardeh, 2016). Hypersensitivity to pain in the presence of a pathogen or sterile-driven inflammation is categorised as an inflammatory pain mechanism (Vardeh, 2016). Neuropathic (NeP) pain is defined as pain caused by a lesion or disease affecting the somatosensory system can be classified as NeP pain (Jensen et al., 2011). Central sensitisation is a term used to describe an increase in neural signalling within the central nervous system that can lead to heightened sensitivity to pain (Nijs et al., 2021). In 2017, the IASP added "nociplastic pain" to its previous classifications of nociceptive and NeP pain. Nociplastic pain is pain that occurs despite no clear evidence of tissue damage or disease of the somatosensory system (IASP, 2023).

1.12. Cervical spine radiculopathy – epidemiology and natural history

Globally, there were approximately 288.7 million cases of neck pain (± CSR) in 2017 (Beckworth et al., 2021). The number of years lived with disability globally was 28.6 million (Beckworth et al., 2021, Wong et al., 2014). The number of neck pain cases (± CSR) and years lived with disability did not change from 1990 to 2017 (Beckworth et al., 2021). The recovery time for people with CSR can be long; 83% of people with CSR take up to two to three years to fully recover, and 22% of people will have a moderate pain recurrence within two to three years following recovery (Wong et al., 2014). Over five years, 32% of people with CSR have symptom recurrence and 26% require surgical intervention for muscle weakness, worsening pain or sensory disturbances (Radhakrishnan et al., 1994).

Radhakrishnan et al., (1994) reported that the annual age-adjusted incidence rate for CSR was 83.2 per 100,000 individuals. Radhakrishnan et al., (1994) found that males were more commonly diagnosed with the condition, with a mean age of 47.9 years. This study was based on a large retrospective population analysis; however, it should be recognised that the data may be underestimated as some people with mild or transient symptoms may not have sought medical attention, resulting in underreporting. It is unclear if all participants had a neurological deficit or if only people with radicular pain were included in the analysis. In a survey conducted in Sicily, 7,653 individuals were interviewed door-to-door (Salemi et al., 1996). The survey found a prevalence of 3.5 per 1000, with a similar age distribution to Radhakrishnan et al., (1994). However, it should be noted that these findings did not necessarily indicate the presence of radiculopathy alone. A systematic review that assessed neck pain in the general population reported that disc herniation with radiculopathy has an incidence rate of 0.055 per 1000 persons per year (Hogg-Johnson et al., 2009). **Chapter 2** will provide a detailed discussion of the epidemiology of cervical radiculopathy in adult populations.

The available evidence reporting the natural course of CSR is sparse. A systematic review reported three studies that people with untreated CSR experienced significant improvement within four to six months, which tends to last for two to three years (Luyao et al., 2022). Luyao et al., (2022) reported that, two studies (one Phase I study and one cohort within a randomised trial) described the course of

symptomatic cervical disc herniations. Overall, the results suggested that the course of symptomatic cervical disc herniation with CSR across the three studies was favourable (Luyao et al., 2022). However, these studies had a high risk of bias on assessment; the reasons for this include lack of blinding of assessors. In contrast, Radhakrishnan et al., (1994) reported that 90% of people with CSR showed little to no symptoms after a four-year follow-up. These findings suggest that CSR is self-limiting.

1.13. Psychosocial factors and their interaction with radiculopathy

1.13.1. Psychosocial factors – development

Social factors impact social structure and processes, while psychological factors influence mental states (Nahit 2003, Thomas 2020, Upton 2013). Psychosocial factors combine both, implying that social processes can be mediated through psychological understanding. These two words are sometimes combined to form the term ‘psychosocial’, which implies that social processes can be mediated through psychological understanding (Upton, 2013). These factors include social situations, relationships, competition, technological change, work deadlines and changes in social roles. They describe an individual in relation to their social environment and can include protective resources and risk factors. Erikson’s stages of psychosocial development expanded on Freud’s theory by adding social dynamics and extending the stages into adulthood (Maree, 2022). It includes eight sequential stages of development influenced by biological, psychological, and social factors (**Appendix 1.2**).

Fordyce et al., (1968) were the first to apply the behaviour model to pain. It was reported that there was a causal relationship between pain and external factors (environment). Acute pain is initially a response to tissue damage, but if the environment reinforces it, the pain can become operant and persistent (Fordyce et al., 1968). Operant pain can continue because of the actions of others, including family, friends and healthcare providers, who unintentionally reinforce the pain’s return during the acute pain stage. This reinforcement may lead to secondary gains, such as being excused from daily tasks or receiving attention and care that may not have been available otherwise (Fordyce et al., 1968). Cognitive approaches were

partly inspired by Melzack and Wall's (1965) gate control theory, established a role for the cognitive-evaluative process in the modulation of pain. The cognitive approach analyses various factors that impact on pain perception, including attributions, expectations, beliefs, self-efficacy, personal control, attention to pain stimuli, problem-solving, coping self-statements and imagery (Melzack and Wall, 1965). However, it does not provide the solution in isolation from other aspects of the multidimensional problem of pain.

When someone experiences pain, they may also suffer from psychological distress. A cross-sectional study found that up to one-third of people seeking care from physical therapists have high levels of distress (Cairns et al., 2003). This may be attributed to catastrophic thinking processes and is broadly described as an exaggerated orientation towards nociceptive stimuli and pain experience (Turner et al., 2000). People who consider pain as a serious threat to their health, are more likely to become fearful as compared with those who approach pain as a trivial annoyance (Turner et al., 2000). The establishment of a framework to identify psychosocial factors in a clinical assessment will now be discussed.

'Yellow flags' refer to psychological, social, and environmental factors that increase the risk of prolonged disability and failure to return to work due to musculoskeletal symptoms (Nicholas et al., 2011, Watson and Kendall, 2013). This provided guidance on the clinical assessments to incorporate cognitive-behavioural change principles into early management (Kendall et al., 1998). The development of this system progressed, with a more specific focus on occupational contexts and perceptions of work (Kendall et al., 1998), leading to an integration into a workplace management system for musculoskeletal symptoms.

Main and Spanswick (2000) contend that 'yellow flags' should only refer to the more overtly psychosocial risk factors, such as fears and unhelpful beliefs. The development of 'blue' and 'black' psychosocial factors (or flags) has been proposed (Main and Spanswick, 2000). 'Blue flags' incorporate issues related to the perception of job characteristics, such as job demand, and the perception of social interactions (with management or fellow workers) (Gray and Howe, 2013). In terms of retaining or rehabilitating workers, there are two types of occupational risk factors: 'blue flags' which pertain to the perception of work and 'black flags' which refer to

organisational obstacles to recovery such as objective work characteristics and employment conditions (Gray and Howe, 2013, Nicholas et al., 2011). ‘Black flags’ affect all workers equally, regardless of role, and include both national policies and specific organisational working conditions (Gray and Howe, 2013, Nicholas et al., 2011). The differentiation between psychological risk factors may be considered ‘normal’ but unhelpful reactions to musculoskeletal symptoms, such as the belief that pain always indicates damage, and more clearly ‘abnormal’ psychological or psychiatric factors and disorders, like post-traumatic stress disorder or major depression, which may suggest diagnosable psychopathology (Gray and Howe, 2013). These abnormal factors are also known as ‘orange flags’ (Gray and Howe, 2013, Nicholas et al., 2011). The primary significance of this distinction is to differentiate ‘yellow flag’ factors, which might be amenable to change by suitably trained healthcare providers such as general practitioners (GPs) and physiotherapists, from ‘orange flag’ factors that probably require specialist mental health referral.

1.13.2. Psychosocial factors and radiculopathy

Research investigating people’s beliefs about CSR and its impact on their lives is limited. In a meta-synthesis of nine studies with a total of 103 participants (73 women), individuals described commonly experiencing three dimensions related to neck pain and nerve-related arm symptoms (Falsiroli Maistrello et al., 2022). These were: a physical dimension (symptoms experienced – “My neck has gone wrong”), a social dimension (employment and activities of daily living limitations – “Pain limits my life”) and a psychological dimension (feelings of worry – “I am worried about my recovery”) (Falsiroli Maistrello et al., 2022). The categories with the highest frequency in the physical theme were symptoms (67%) and body perception (44%). In the psychological theme, the frequencies from highest to lowest were psychological consequences (100%), coping strategies (100%), mindset (67%), expectations from healthcare professionals (44%), and gender influence (22%). The social theme had frequencies from highest to lowest in social relationships (56%), work, activities of daily living, and physical activity (44% each) (Falsiroli Maistrello et al., 2022). This provides evidence of how physical, psychological, and social dimensions can influence each other in nerve-related neck and arm symptoms such as CSR.

People with radicular symptoms report worsening pain severity and disability compared to non-radicular pain presentations (Lin et al., 2020, Ng et al., 2015, Ryan and Roberts, 2019, Shi et al., 2023). A qualitative interview study sampling 14 people with radicular pain found that this condition had a negative impact on almost all aspects of life (Ryan and Roberts, 2019). Participants faced challenges in maintaining their physical and functional independence, as well as their important relationships, social networks and joyful activities (Ryan and Roberts, 2019). The impact of radicular symptoms was a “life on hold”, and an uncertain future, and three participants reported suicidal thoughts (Ryan and Roberts, 2019). Furthermore, in a cross-sectional survey evaluating the beliefs of 211 people awaiting surgery with CSR across Norway, 50% of participants indicated they would undergo surgery even if they were only experiencing mild symptoms (Danielsen et al., 2022). These impactful implications strengthen the argument of how some psychosocial factors can have a negative impact on the overall presentation and association with CSR symptoms.

The exact connections between mental health conditions, pain and self-evaluated function are not completely understood (Bondesson et al., 2018). However, it is likely that these pathways work bidirectionally (Bondesson et al., 2018, Yao et al., 2023). Impairment of mental health can adversely affect an individual’s cognitive and social functioning, making it challenging to handle daily life demands, including productivity at work, and can often lead to long-term anxiety and depression (Michaelides and Zis, 2019, Yao et al., 2023). Mental health problems can range from minor distress to long-term clinical illness, such as depression, which may require psychological therapy or medication (Michaelides and Zis, 2019). The biopsychosocial paradigm suggests that psychological symptoms like low mood can significantly affect pain conditions such as low back pain (Fisker et al., 2018), osteoarthritis (Wise et al., 2010) and Carpal Tunnel Syndrome (CTS) (Mansfield et al., 2018), thus influencing their development risk and prognosis related to pain and disability.

Studies have found that people who suffer from musculoskeletal pain may also experience poor mental health. A systematic review of five moderate-quality studies, measured by a modified QUIPS tool, reported that psychological factors are associated with the development of musculoskeletal pain (Martinez-Calderon et al.,

2020). Fear-avoidance beliefs were longitudinally associated with the risk of developing low back pain (Odd Ratio (OR): 2.04, 95% confidence intervals (CI): 1.19– 3.48) and disability (OR: 1.70, 95% CI: 1.12–2.59) at 12 months (Martinez-Calderon et al., 2020). Fear-avoidance beliefs were longitudinally associated with the risk of developing disabling low back pain at six months (OR: 3.1, 95% CI: 1.1–8.7) (Martinez-Calderon et al., 2020). Whereas a different systematic review by Wertli et al., (2014), including two low-quality cohort studies, reported inconsistent results about the longitudinal association between fear-avoidance beliefs and changes in pain intensity at 12 months (significant results: 95% CI: 0.10 to 0.23, $p<0.001$; non-significant results: fear-avoidance beliefs physical activity subscale $p=0.716$; fear-avoidance beliefs work subscale $p=0.546$). There were inconsistent results on the longitudinal association between fear-avoidance beliefs and changes in disability at 12 months (significant results: 95% CI: 1.61-3.00, $p<0.001$; non-significant results: fear-avoidance beliefs physical activity subscale, $p=0.347$; fear-avoidance beliefs work subscale, $p=0.741$) (Wertli et al., 2014). The difference in findings between the two systematic reviews may be attributed to the different inclusion criteria of low back pain with Martinez-Calderon et al., (2020) including persistent pain, and Wertli et al., (2014) including all non-specific low back pain regardless of time. Hence, although the reviews can provide useful insights, it is important to interpret them cautiously. Nonetheless, how people with spinal pain perceive their own symptoms and their engagement in daily activities, is associated with the risk of developing pain and ongoing disability.

There has been limited research on the effects of psychological factors on entrapment neuropathies. In a systematic review of six moderate high-quality included studies, five studies reported a positive association between psychosocial factors and CTS, where psychosocial factors were more in those who reported CTS (Mansfield et al., 2018). One study reported no positive or negative association with CTS development (Mansfield et al., 2018). Four studies reported a negative association between psychosocial factors and CTS, where psychosocial factors were less in those who reported CTS (Mansfield et al., 2018). Anxiety can also decrease pain thresholds (Skeppholm et al., 2017). In their study, Skeppholm et al. (2017) evaluated the impact of potential pre-operative risk factors, specifically mental distress, on 136 people with CSR. Anxiety can inhibit pain-inhibiting mechanisms, resulting in a more painful experience of a similar stimulus. Generally,

anxiety and depression decrease as pain does, but people with higher anxiety and depression may not benefit as much from surgery or other treatments. Despite these associations being reported, prior to this PhD, no studies had investigated the impact of psychological factors on health outcomes in CSR. In **Chapter 3**, this is undertaken.

1.14. Clinical assessment principles

An essential part of the clinical assessment is listening to the person's description of their symptoms and how this impacts daily activities (Cohen, 2015). Although outside the scope of this thesis, clinicians should formulate whether symptoms are of 'sinister' origin (referred to as red flags) (Cohen, 2015). If this suspicion is confirmed, prompt medical attention should be sought. In the UK, unlike lumbar spine radiculopathy (Bernstein et al., 2017), there is no NICE guideline supporting diagnostic or management clinical decision-making of CSR. There are, however, Danish management guidelines for acute CSR to support clinical decisions (Kjaer et al., 2017). The clinical guidelines (Kjaer et al., 2017) were based on systematic reviews of the scientific literature and subsequent meta-analyses. The guidelines advocate various supervised exercise and manual therapy options for treatment (Kjaer et al., 2017). It is suggested to try combinations of exercise and manual therapy before resorting to medication, and mechanical traction is recommended for CSR (Kjaer et al., 2017). There were no recommendations on optimal diagnostic strategies for CSR in clinical practice.

1.15. Psychophysics and somatosensory assessment

Psychophysics is a field of study within psychology and neuroscience that explores the connection between physical stimuli and how people behave or perceive things (Price and Barrell, 2012). If a researcher touches a specific area of a participant's skin, they can draw conclusions about neural activity and function along the neuroaxis based on how the participant perceives the stimulus. However, this hypothetical scenario is quite complex. Both the participant and researcher need to carefully interpret the sensory experience from first-person and third-person perspectives (Price and Barrell, 2012).

To conduct psychophysical testing, a participant's response is necessary to detect and distinguish differences in stimuli and provide meaning to the sensory experience (Price and Barrell, 2012). Quantitative sensory testing (QST), which uses a group of non-invasive, quantifiable sensory stimuli procedures, can provide insight into a person's somatosensory nerve system function (Backonja et al., 2009). This testing is conducted systematically and characterises a participant's somatosensory nervous system (Rolke et al., 2006). During QST, the participant is asked to quantify and interpret a calibrated stimulus applied by a researcher, typically in the form of a thermal or mechanical stimulus (Yarnitsky, 1997). Depending on the test parameters of the selected stimulus, the participant will reflect immediately on their experience and verbally communicate to the researcher whether the stimulus can be detected or perceived as painful (Zaslansky and Yarnitsky, 1998). This process requires the participant to scrutinise their own experience through a simple form of introspection (Price et al., 2002, Price and Barrell, 2012).

Introspection in relation to QST refers to how a person directly notices what an experience is and then quantifies this through a description of the experience, or usually through a quantifiable scale (for example, rating a mechanical stimulus such as blunt pressure, using a numeric pain rating score) (Price et al., 2002, Price and Barrell, 2012). After a stimulus is applied, a numeric pain rating score describes the immediate experience. This description includes the person's thoughts, beliefs, stress, anxiety, and motivation, which are all part of their ongoing nervous system processes (Bustan et al., 2015).

Quantitative sensory testing evaluates the sensory function, including sensory loss (hypoesthesia), and the increase in sensory function (hyperalgesia and allodynia) of the afferent myelinated A-beta and unmyelinated C- and thinly myelinated A-delta fibres (Reimer et al., 2020). A standardised test protocol is completed by trained researchers, which includes precise oral instructions given to the test participants for each test procedure (Rolke et al., 2006). A total of 13 individual parameters are assessed in the testing protocol (Rolke et al., 2006). Testing procedures can be divided into two categories, static and dynamic. Static testing includes stimulus rating or pain intensity rating (usually through a numeric pain rating score) (Rolke et al., 2006). Dynamic testing involves temporal and spatial summation and tests of descending control (Rolke et al., 2006). The interpretation of QST results may also

be affected by discrepancies between the outcomes of QST and neurological testing conducted at the bedside (Devigili et al., 2008, Hansson et al., 2007). This difference can occur because QST measurements are limited to a small area of the painful region, whereas bedside examinations offer a larger assessment of the affected nervous system's entire innervation territory (Bouhassira and Attal, 2023). In addition, QST is helpful in determining if a nerve lesion exists, but it cannot determine where the lesion is located (Schmelz, 2018). Even with these limitations, identifying sub-groups of somatosensory phenotypes can assist in achieving personalised care in clinical practice (Schmelz, 2021).

1.16. Quantitative sensory testing and somatosensory profiling in clinical practice

Cervical spine radiculopathy diagnosis relies on clinical signs and symptoms, which may be supported by imaging or electrophysical testing. However, different underlying pathophysiological mechanisms cause various clinical signs and symptoms (Bannister et al., 2020, Schmid et al., 2020). It is recognised that various underlying mechanisms can cause a single symptom. A combination of positive and negative sensory experiences, or a symptom profile, could help predict the underlying pain mechanism (Reimer et al., 2020). However, this approach should not be used alone and should be part of a comprehensive examination (Schmid et al., 2020).

The German Neuropathic Pain Network (DFNS) QST protocol tests all sub-modalities of the somatosensory system (Rolke et al., 2006) (**See Chapter 8 – Methods**). Through the implementation of this protocol, comprehensive somatosensory profiles have been created for individuals experiencing NeP pain. A cohort study of 1,236 people with different types of NeP pain syndromes, including polyneuropathy, peripheral nerve lesions and trigeminal neuralgia, reported significant differences in their sensory profiles, even within the same type of NeP pain or disease (Maier et al., 2010). People experienced varying combinations of sensory loss and gain for different QST modalities (Maier et al., 2010). Ninety-two percent of this cohort presented at least one abnormality across all QST testing parameters (Maier et al., 2010). Hypoesthesia in thermosensory or mechanical modalities (41% of the cohort) was more prevalent than hypoalgesia (18% of the

cohort for mechanical stimuli) (Maier et al., 2010). Mechanical hyperalgesia occurred more frequently (blunt pressure and pinprick were 36% and 29% of the cohort respectively) than thermal hyperalgesia (cold: 19%, heat: 24%), dynamic mechanical allodynia (20%) or paradoxical heat sensations (18%) (Maier et al., 2010). This illustrates the heterogeneity of people within one aetiology.

As previously discussed, the clinical expression of sensory and motor symptoms of CSR may not always conform to standard 'textbook' descriptions. To assess somatosensory integrity and function, both large and small sensory nerve fibres should be evaluated since both may be impaired in radiculopathy presentations (Schmid et al., 2020). It is not only the causes that differ, but also the clinical expression of CSR symptoms. This can be achieved through somatosensory bedside examination, patient-reported outcomes, and QST. However, it is unclear which somatosensory testing methods are commonly used by clinicians to support diagnosis formulation and identify underlying pain mechanisms. Furthermore, it remains unclear if CSR presentations always exhibit predominantly NeP components, as they can be classified as mixed-pain syndromes but can also be categorised as a NeP condition. The definition and diagnostic criteria for radiculopathy vary across publications, which creates challenges for study comparisons and generalisation.

Whilst acknowledging that these NeP pain conditions are classified according to underlying aetiology, it is, however, recognised that the underlying mechanisms and pain phenotypes differ within each diagnosis and, at the same time, may be shared across diagnoses. Few studies have examined this in CSR. Chien et al., (2008) reported that individuals with CSR tend to have lower pain thresholds for both pressure and cold stimuli in all areas compared to those without the condition ($p<0.01$). Additionally, among those with radiculopathy, the limbs that were experiencing symptoms showed significantly higher detection thresholds for all stimuli compared to the unaffected limbs within the same group and the control groups ($p<0.01$) (Chien et al., 2008). However, it is unclear where the sensory testing occurred in relation to the participant's maximum pain area. In a case-control study comparing CTS (n=103) and people with CSR (n=23) (Tampin et al., 2018), both groups presented with loss of mechanical and thermal function in the main pain area compared to healthy reference data ($p<0.001$). People with CSR self-reported

higher pain intensities (p=0.008) and more severe pain attacks (p=0.009) than people with CTS (Tampin et al., 2018). This suggests an underlying NeP pain mechanism dominance with CSR compared to CTS.

A case-control study investigating NeP pain with 23 patients with C6 nerve root CSR, reported a localised loss of function measured by QST (thermal, mechanical, vibration detection (p<0.009)) in the maximal pain area and dermatome (thermal detection, vibration detection, pressure pain sensitivity p<0.04) compared to those with non-specific arm pain (Tampin et al., 2012). However, these findings only apply to people with C6 nerve root entrapment that were diagnosed without the use of clinical judgement (Tampin et al., 2012). For instance, if a person presented with C6 radicular pain and a sensory dermatomal deficit, no motor impairment, heightened nerve mechanosensitivity, and no clinically significant abnormality on cervical imaging, they would be classified as having non-specific arm pain, not CSR (Tampin et al., 2013). **Chapter 8** aims to address this gap in knowledge for this research area.

1.17. Somatosensory Profiling. Pain screening and assessment questionnaires

There are two types of pain questionnaires available: screening questionnaires and assessment questionnaires. Screening questionnaires are used to identify NeP pain mechanisms in clinical populations, while assessment questionnaires are designed to measure NeP pain symptoms and complement screening questionnaires (Bennett et al., 2007). They can also be utilised in clinical practice to monitor treatment response (Bennett et al., 2007). In research settings, assessment questionnaires have been utilised to create phenotypic profiles of NeP symptoms or their combination (such as spontaneous burning pain) in people who experience NeP pain (Attal et al., 2018, Jones and Backonja, 2013).

The Leeds Assessment of Neuropathic Symptoms and Signs (Bennett, 2001), the Neuropathic Pain Questionnaire (Krause and Backonja, 2003), the Douleur Neuropathique en 4 Questions (DN4) (Bouhassira et al., 2005), painDETECT (Freynhagen et al., 2006), and Identification-Pain (ID-Pain) (Portenoy and Committee, 2006) are validated NeP pain screening tools largely based on verbal

pain descriptors such as burning pain, electric shocks, or pins and needles. **Table 1.3** presents a summary of NeP pain-screening tools.

Despite the potential usefulness in identifying NeP pain, there are possible limitations to consider. For example, the person's clinical history of pain and the sensory examination are usually brief or not present (Attal et al., 2018). Furthermore, pain-screening questionnaires are not designed in isolation to diagnose underlying pain mechanisms (Attal et al., 2018). Therefore, questionnaires are not a substitute for an in-depth clinical assessment, but positive findings in conjunction with clinical assessment may prove beneficial to identify a nerve lesion and support the questionnaires' usefulness in clinical practice (Attal et al., 2018).

Table 1.3 Neuropathic pain screening tools

Questionnaire	Number of items	Cut-off score for neuropathic pain	Sensitivity	Specificity	Revalidated in	Languages validated in
Self-administered Leeds Assessment of Neuropathic Symptoms and Signs Bennett (2001)	Seven descriptors (yes or no)	≥12 means that neuropathic pain is likely (total score 24)	74%	83% (interview), 76% (self-report)	Not done	English (original), Arabic, Greek, Malayalam, Spanish, Turkish
Neuropathic Pain Questionnaire Krause and Backonja (2003)	12 descriptors with distinct scoring coefficients per descriptor rated on visual analogue scales (from 0 to 100)	≥0 means that neuropathic pain is likely (total discriminant function score from 0 to 3·37 for neuropathic pain)	67%	74%	Not done	English (original), Mandarin, Turkish
Douleur Neuropathique en 4 Questions (interview, self-report) Bouhassira et al., (2005)	Seven descriptors (yes or no)	≥3 means that neuropathic pain is likely (total score 7)	78% (interview), 81·6% (self-report)	81·2% (interview), 85·7% (self-report)	Painful diabetic neuropathy	French (original), Arabic, Dutch, Hindi
painDETECT Freynhagen et al., (2006)	Seven descriptors (categorical scales from 0 to 5), two spatiotemporal items (yes or no), one item related to radiating pain (yes or no)	≥19 means that neuropathic pain is likely, 12–18 means that neuropathic pain is uncertain, <12 means that neuropathic pain is unlikely (total score 35)	85%	80%	Postherpetic neuralgia, spinal cord injury, lower back pain	German (original), Arabic, Dutch, English, Hindi, Japanese, Korean, Spanish, Swedish, Turkish
ID Pain Portenoy et al., (2006)	Five descriptors (yes or no), one item related to negative symptoms (yes or no)	≥3 means that neuropathic pain is likely, scores of 0 or −1 mean that neuropathic pain is unlikely (total score 5)	Not reported	Not reported	Breast cancer surgery	English (original), Mandarin, Thai

There are four validated questionnaires for assessing NeP pain. The Neuropathic Pain Scale (Galer and Jensen, 1997) and the Neuropathic Pain Symptom Inventory (Bouhassira et al., 2004) both use self-assessment and numerical or categorical scales to quantify symptoms. The McGill Short-Form Questionnaire (Dworkin et al., 2009) is a generic questionnaire that can be used for any type of pain, while the Pain Quality Assessment Scale (Jensen et al., 2006) is derived from the Neuropathic Pain Scale (Galer and Jensen, 1997) and can be used for both NeP and non-NeP pain. Additionally, the painDETECT questionnaire (Freynhagen et al., 2006) was originally validated as a screening tool, but there is evidence to suggest it is also reliable as an assessment questionnaire. **Table 1.4** presents a summary of NeP pain assessment tools.

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Table 1.4 Neuropathic pain assessment tools

Questionnaire	Number of items	Original validation	Languages validated in
Neuropathic Pain Scale Galer and Jensen (1997)	Ten descriptors scored on a numerical scale (0–10), one temporal item scored on a categorical scale (0–2); scores per descriptor to measure individual symptoms	The study examined the effect of intravenous lidocaine or phentolamine treatment on 288 patients with peripheral neuropathic pain and 78 patients with complex regional pain syndrome. The goal was to determine the sensitivity to change before and after treatment.	English
Neuropathic Pain Symptom Inventory Bouhassira et al., (2004)	A total of ten descriptors are rated on a scale of 0 to 10, along with two temporal items - pain duration and number of paroxysms - that are scored on categorical scales. The factorial structure is composed of five dimensions: burning pain, deep pain, paroxysmal pain, evoked pain, and paraesthesia or dysesthesia. Scores are assigned for each descriptor or dimension used to measure individual symptoms or their combination.	176 patients with peripheral or central neuropathic pain	French (original), German, Italian, Japanese, Portuguese, Spanish, and Thai Face and content validation in English, Chinese, Finnish, Japanese, Portuguese, and Spanish
Revision of Short-form McGill Questionnaire Dworkin et al., (2009)	15 descriptors from the Short-form McGill Questionnaire plus seven new descriptors to assess neuropathic pain (all scored 0–10 on numerical scales), factorial structure with four subscales (continuous pain, intermittent pain, predominantly neuropathic pain, and affective pain)	Web survey of 882 patients with chronic pain and 226 patients with diabetic neuropathic pain	English, Chinese, Japanese
Pain Quality Assessment Scale Jensen et al., (2006)	Ten descriptors of the Neuropathic Pain Scale plus ten additional descriptors to assess nociceptive pain, all scored on numerical scales (0–10)	40 patients with carpal tunnel syndrome	English (original)

Assessment questionnaires are similar to screening questionnaires, as they rely on sensory descriptors like burning, squeezing, shooting, electric shock pain, or pain that occurs when brushing (Attal et al., 2018). These descriptors can be organised into various dimensions or combinations of symptoms, such as deep pain, paroxysmal pain, dysaesthesia or evoked pain. For example, the Neuropathic Pain Symptom Inventory's (Bouhassira et al., 2004) dimension 'paroxysmal pain' is the mean of two descriptors: 'stabbing' and 'electric shocks'. Assessment questionnaires do not include information obtained from clinical or sensory examination, or negative symptoms like feelings of sensory loss. Therefore, using these assessment tools in isolation may lead to inaccurate diagnosis formulation.

1.18. The role of physical assessment

When assessing people with CSR, clinicians rely on information collected during their medical history and physical examination to create a management plan. Physical tests may involve checking reflexes, manual muscle strength, sensory assessments, range of motion, and tests that provoke symptoms, such as Spurling's test, Upper Limb Neural Tension Test (ULNT), or a combination of these (Thoomes et al., 2018). After examining five studies of low quality, a systematic review assessed the ability of physical examination tests to diagnose CSR (Thoomes et al., 2018). Among the three studies (n=350) that evaluated the Spurling test, the movements performed before adding downward axial compression to the cervical spine varied slightly. The review reported moderate sensitivity and high specificity (Sensitivity (Se) 0.65, 95% CI: 0.49–0.79; Specificity (Sp) 1.00, 95% CI: 0.56–1.00) and (Se 0.38, 95% CI: 0.22–0.56; Sp 0.94, 95% CI: 0.83–0.99), respectively (Thoomes et al., 2018). The variance of sequencing of the Spurling's test also demonstrated a variance in accuracy. However, these findings should be cautiously interpreted as the reference test description was not adequately described by included studies, thus potentially compromising internal validity.

When four ULNTs were used together, they were found to be 0.97 sensitive (95% CI: 0.83-1.00) and had a specificity of 0.69 (95% CI: 0.41-0.88). Among the individual tests, ULNT3 (ulnar) had the highest specificity at 0.88 (95% CI: 0.60-0.98), while ULNT1 (median) had the highest sensitivity at 0.83 (95% CI: 0.66-0.93) (Thoomes et al., 2018). In a diagnostic accuracy study of 85 participants with CSR,

single ULNTs tests were better at ruling in CSR versus ruling out (Grondin et al., 2021). Three of four ULNTs test combinations demonstrated the highest clinical utility for changing the post-test probability with a positive finding at 83.29% (Likelihood Ratio (LR)+ = 12.89 95% CI: 3.10–53.62) (Grondin et al., 2021). No positive test could rule out CSR (LR-=0.08 95% CI: 0.01–0.56) (Grondin et al., 2021). Clinicians may, therefore, benefit from clustering physical tests when diagnosing CSR (Grondin et al., 2021).

There are no systematic reviews investigating the accuracy of muscle strength, tendon reflexes, and sensory impairments in CSR populations. However, a systematic literature review has been conducted synthesising 12 studies assessing the sensitivity and specificity of sensory, motor, and tendon reflex in lumbosacral radiculopathy (Tawa et al., 2017). Some motor tests have poor to moderate sensitivity, including those measuring heel walk, heel raise, sit-to-stand and isometric contractions for hip flexion, knee extension, great toe extension, ankle dorsi- and plantar flexion (Tawa et al., 2017). Sensitivity ranged from 0.13 (95% CI: 0.04-0.31) to 0.61 (95% CI: 0.36-0.83) (Tawa et al., 2017). The clinical implication is that motor tests, in isolation, are not useful for ruling out the diagnosis of lumbosacral radiculopathy. Diagnostic performance of reflex tests across the studies was ‘good’ with specificity ranging from 0.60 (95% CI: 0.51-0.69) to 0.93 (95% CI: 0.87-0.97) (Tawa et al., 2017). However, the sensitivity was moderate with the highest being 0.67 (95% CI: 0.21-0.94) (Tawa et al., 2017). The diagnostic performance of sensory testing using MRI imaging as a reference standard demonstrated a sensitivity 0.61 (95% CI: 0.47-0.73) and a specificity of 0.63 (95% CI: 0.38-0.84) (Tawa et al., 2017). The low number of low-quality studies limits the application of these findings to clinical practice. Furthermore, the external validity of these finds from lumbosacral radiculopathy to CSR populations is also limited.

A retrospective cohort study of 227 people who underwent surgery for CSR at a single vertebral level reported that 63% had upper limb symptoms in the distribution of the nerve root that was consistent with the level of surgery (Hong and Nam, 2022). Additionally, 67% had muscle weakness at the level of operation or one adjacent level (Hong and Nam, 2022). Among those who experienced motor weakness, only two out of six people with C5/6 radiculopathy fit the dermatomal distribution and muscle weakness at the level of surgery (Hong and Nam, 2022). Caution should be

taken with these findings as the examiner was not blinded to the MRI report, which may have created assessor bias in the execution and interpretation of findings. It is important to acknowledge that various factors can affect the accuracy of a physical examination when diagnosing CSR, such as the medical setting (primary or secondary care), participant characteristics, the consistency of the tests (inter-observer variation), and the reference standard used for comparison (imaging or surgical findings). Using MRI as a reference standard requires a meaningful predefined definition of a positive result indicating the relevant presence of a herniated disc or foraminal encroachment with clear nerve root impingement. This clear definition in the included studies was not achieved. This lack of transparency may negatively impact the internal validity and reliability of these clinical tests.

1.19. The role of imaging and electrodiagnostic examination

When diagnosing CSR, imaging techniques include plain radiograph and MRI, which are often supplemented by electrodiagnostic examination (EDX) such as nerve conduction studies (NCS) (Woods and Hilibrand, 2015). Cervical spine radiculopathy can be diagnosed without routinely requiring cervical radiographs, which are mainly useful for diagnosing spondylosis, degenerative disc disease, malalignment or spinal canal stenosis. Radiographic findings rarely alter treatment in the absence of suspicion of serious spinal pathology. Spondylotic changes are commonly seen on radiographs in people over 30 years of age, even in the absence of neck pain. Furthermore, regardless of radiculopathy symptoms, 65% of asymptomatic people aged 45 to 59 years demonstrated show significant cervical spine degeneration on radiograph. The Bone and Joint Decade 2000-2010 Task Force on Neck Pain (Haldeman et al., 2008) recommended considering radiographic imaging for neck pain (±CSR) when suspecting serious spinal pathology (known as ‘red flags’). Red flags may include trauma, malignancy, prior neck surgery, spinal cord injury, systemic diseases or intractable pain despite conservative treatment.

If a person has complex CSR (such as motor weakness across two or more muscle groups), MRI may be recommended (Haldeman et al., 2008). This could be the case if there is suspicion of myelopathy or abscess, if there are persistent or worsening neurological symptoms, or if conservative treatment has not improved symptoms

after four to six weeks (NICE, 2023). An MRI can detect changes to the anatomy of the spine, such as disc herniations and spinal canal stenosis, as well as changes to tissue properties like disc desiccation and reactive marrow changes (Farrell et al., 2019). However, it is important to note that MRI of the cervical spine can reveal incidental findings that may be morphologically abnormal, but not necessarily related to an individual's symptoms (Farrell et al., 2019). Kato et al., (2012) conducted a cohort study using MRI data from 1,211 adults to establish the standard values for the cervical spinal canal, dural tube and spinal cord for healthy individuals of each gender and age group. The study also looked at how these parameters change with age. Fifty-eight percent (58% SD: 7.0%) of healthy subjects over 40 years of age demonstrated abnormal MRI findings of the cervical spine including foraminal canal narrowing and disc degeneration (Kato et al., 2012). These findings highlight the difficulty in making management decisions based solely on diagnostic tests without considering clinical signs and symptoms.

The association between MRI and surgical findings has questionable reliability, as false positive and negative findings can be influenced by the experience of the interpreting clinician (McAnany et al., 2019). Conversely, abnormal neurological assessment findings (such as manual muscle strength deficits and hyporeflexia) were associated with the presence of nerve root compression on MRI in 67% of people (n=20/30) (p=0.033) (Yousif et al., 2020). However, this study was from a lumbosacral radiculopathy population that was undergoing surgical intervention, and not CSR. Therefore, MRI findings should be interpreted cautiously and used in conjunction with symptoms to guide management decisions, as they may not always be relevant.

Electromyography (EMG) is a diagnostic tool that can determine the location of lesions in a specific root level and provide insight into the severity of the disease process (Chichkova and Katzin, 2010). The aim is to detect a consistent pattern of motor unit changes, whether they are spontaneous or chronic. However, it can only detect changes in the motor nervous system and primarily identifies damage to the axonal component of the nerve, rather than myelin (Chichkova and Katzin, 2010). A narrative review conducted by the American Association for Electrodiagnostic Medicine (AANEM) (Cho et al., 2010) reported that the sensitivity of needle EMG in diagnosing CSR was found to be 50% to 71%, offering moderate diagnostic

sensitivity based on nine studies. To date, no systematic reviews have investigated the diagnostic accuracy of NCS related to radiculopathy presentations.

1.20. Assessment of cervical spine radiculopathy – unanswered questions

It is necessary to understand current assessment practices before evaluating their effectiveness or making changes to meet CSR requirements. At present, it is not clear what the current prevalence and incidence rates of CSR are among adults globally. Although cross-sectional studies have been conducted assessing the prevalence and incidence of CSR, no study has synthesised evidence. Furthermore, it is not known what the global epidemiology of CSR is, and the diagnostic methods used to determine the prevalence and/or incidence.

Observational studies have reported how psychosocial factors and mental health diagnoses and symptoms may be associated with the health outcomes NeP pain conditions (Gormsen et al., 2010, Turk et al., 2010). However, the external validity of these studies limits generalisability to CSR populations. Therefore, it is not possible to say if psychological and/or psychosocial factors are associated with health outcomes for CSR populations. As such, research is required to understand whether there is an association between psychological and/or psychosocial factors in CSR populations and health outcomes.

It is crucial to understand how effective assessment strategies are for diagnosing CSR in adults, especially since current healthcare practices prioritise using the most reliable, up-to-date, and relevant evidence to inform healthcare decisions. This approach, known as evidence-based practice, involves combining research findings with the healthcare professional's expertise and the patient's preferences to make informed decisions regarding healthcare (Sackett et al., 1996). Assessing people with CSR using evidence-based practice can be difficult due to two reasons. Firstly, there is no agreement on which assessment methods to use when determining CSR. This makes it unclear how physiotherapists decide on assessment strategies for CSR diagnosis. To gain a better understanding of why certain assessment strategies are used or not used, it is important to understand therapist decision-

making. Further research is needed to determine the assessment practices used by physiotherapists and the reasons behind their implementation in clinical practice.

Assuming some of the somatosensory, physical testing and psychological/psychosocial assessment practices used in practice to diagnose CSR, it should be possible to determine if these assessment strategies can sub-group people with CSR and stratify management options accordingly. It is uncertain whether CSR presentations are always characterised by predominantly NeP pain components, as they are frequently referred to as mixed-pain syndromes and can also be classified as a NeP condition. Additionally, the definition of CSR and the diagnostic criteria for it vary between publications, which makes it difficult to compare studies and draw general conclusions. Therefore, it is unclear whether current assessment practices are effective in identifying sub-groups of people with CSR. As such, research is required to investigate whether there are sub-groups (based on somatosensory profiling and/or psychosocial/psychological determinants) across adults with CSR.

1.21. Next steps

Chapter 1 has provided a background to the key concepts of CSR, presented unanswered questions from the current literature, and the subsequent direction of travel for this PhD programme. The next chapter (Chapter 2) will report a systematic review of the incidence and prevalence of CSR globally in adult populations.

Chapter 2: Cervical spine radiculopathy epidemiology. Systematic review

2.1. Introduction

This chapter presents a systematic review of research on the incidence and prevalence of CSR in adults who are 18 years or older. A critical review of the use of systematic reviews and justification for the methodological approaches of this epidemiology systematic review is discussed. Following this, the results using a narrative synthesis are given. The chapter concludes with practical recommendations and a discussion of the limitations of this systematic review. This chapter is an update of the published systematic review in which the lead researcher (MM) led the team (Mansfield et al., 2020). The published paper can be accessed at: https://doi.org/10.1002/msc.1498.

2.2. Background

As discussed in **Chapter 1**, CSR is a disabling condition which has negative impacts on a person's mental health, physical functioning and social participation (Iyer and Kim, 2016). Cervical spine radiculopathy is a complex presentation associated with increased dependence on healthcare systems (Hogg-Johnson et al., 2009, Iyer and Kim, 2016). Currently, there is no definitive index or reference test to diagnose CSR. A systematic review of five included clinical diagnostic test accuracy studies reported that a diagnosis of CSR should be made through a detailed patient interview, physical assessment and imaging studies (Thoomes et al., 2018). Subjective complaints of paraesthesia, hyperaesthesia, dysaesthesia, and/or allodynia, substantiated by neurological examination, sensory testing and/or electrodiagnostic testing, are typical findings (Treede et al., 2008). Moreover, a systematic review of 13 randomised controlled trials (RCTs) found that the presence of neck and/or arm pain was the only consistent selection criteria in RCTs that evaluated conservative interventions for CSR (Thoomes et al., 2012). Five studies used sensory symptoms in the arm as an inclusion criterion. Four studies used cervical range of motion and motor disturbances as inclusion criteria, while reflex

changes were used in two studies (Thoomes et al., 2012). This variability may result in over- or under-reporting of CSR in observational studies.

As outlined in **Chapter 1**, CSR is associated with disability, work absenteeism, reduced quality of life and high treatment costs. To decrease this burden, it is essential to focus on prevention and optimise management. Understanding the incidence estimates is necessary to allocate resources effectively towards prevention, assessment, and treatment of CSR. However, the lack of standardisation in diagnosis of CSR and the different treatment processes used to manage it have created uncertainty on its natural variations and treatment course

To understand the existence of a disease, two measures are used in epidemiology studies: incidence and prevalence. These measures require determining the number of new or existing cases in a population (numerator) and the number of people at risk in the population (denominator) (Bruce et al., 2018). Incidence is a rate that considers the time frame, while prevalence is a proportion measured at a single point in time (Bruce et al., 2018, Noordzij et al., 2010). While neither measure directly reflects the need for healthcare, understanding them is essential for assessing it (Bruce et al., 2018). The prevalence increases if the rate of new cases or relapses increases, or if mortality or remission decrease (Hinneburg, 2017). However, some cases of the disease may go unnoticed, which means only a proportion of the total prevalence may be visible at any given time (Noordzij et al., 2010). In health needs assessment, it is necessary to determine both the incidence and prevalence of a disease (Noordzij et al., 2010). Incidence is particularly significant for short-term illnesses, such as communicable diseases, or when significant healthcare is required immediately following diagnosis, as in the case of myocardial infarction (Hinneburg, 2017, Webb et al., 2003). Conversely, prevalence is important for chronic illnesses such as asthma, diabetes, or chronic spinal pain which have longer durations. By conducting a systematic review of primary epidemiology studies, it is possible to combine prevalence and/or incidence data across multiple populations. This type of evidence synthesis can also provide valuable insights into case definitions, reporting criteria, age, gender and geographical regions used in primary research studies.

2.3. The rationale for a systematic review

Various methods can be used to synthesise research, including conducting a literature review, scoping review, realist review, systematic review or meta-analysis as part of a systematic review (Cumpston et al., 2023). Scoping reviews aim to discover gaps in research and possibilities for evidence synthesis rather than synthesising the evidence itself (Peters et al., 2015). In contrast, a realist review seeks to understand how an intervention succeeds or fails, rather than simply passing judgement on its effectiveness (Hunter et al., 2022). By examining the mechanisms behind an intervention, the realist approach aims to develop and refine theories that consider the specific context of each situation (Hunter et al., 2022, Pawson et al., 2005).

Systematic reviews (with or without meta-analyses) that are robustly conducted are acknowledged as the highest quality of research evidence for evidence-based healthcare (Cumpston et al., 2023). Where there are uncertainties about the strongest approaches in diagnosis, assessment or management of a particular health issue or condition, systematic reviews can help by collating, appraising and synthesising research (Boland et al., 2017). Furthermore, where there are gaps in knowledge or uncertainty in the disease or health issue burden, systematic reviews can help to address this problem (Gough et al., 2017). Systematic reviews are used to answer questions that individual studies may not be able to address by assessing the quality of research, evaluating theories or practices and provide recommendations for enhancing future research (Page et al., 2021).

Although systematic reviews are considered unbiased and objective scientific processes, bias can still be introduced into the evidence base. This bias can come from various sources, such as the reporting or quality of the primary research (Drucker et al., 2016). Researchers make subjective decisions at every stage of the review process, from setting the research question to interpreting the findings. This can lead to major challenges and threats to the validity and interpretation of systematic reviews, such as a lack of transparency in conduct and reporting, poor quality of included studies, and unaccounted-for statistical and clinical differences (Moher, 2013, Uttley et al., 2023). These issues can increase the risk of systematic errors and result in an overestimation of benefits or an underestimation of harm

(Moher, 2013). Additionally, some systematic reviews may have a narrow focus that does not represent clinical practice or under-represented groups (Tawfik et al., 2020, Uttley et al., 2023). When conducting systematic reviews, researchers must address these potential limitations by ensuring that their methods are transparent, objective, rigorous and comprehensive (Tawfik et al., 2020).

At the time of planning this study, there were no systematic reviews investigating the incidence or prevalence of CSR in adults over the age of 18 years. In response, this systematic review aimed to overcome this.

The systematic review was registered with PROSPERO review database (Ref: CRD42019138903 - https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=138903). Publishing the review protocol on PROSPERO ensures transparency and helps avoid bias (Pieper and Rombey, 2022). The PRISMA statement (Moher et al., 2009) provides a checklist of 27 items for reporting in systematic reviews. Since the statement's publication, there have been innovations in conducting systematic reviews, such as methods for synthesising and presenting findings without meta-analysis and new approaches to assessing the risk of bias in included studies (Page et al., 2021). To capture systematic review reporting advances, the PRISMA 2009 statement has been updated (Page et al., 2021).

The PRISMA 2020 statement (Page et al., 2021) is primarily designed for systematic reviews that analyse the impact of health interventions, regardless of the type of studies included. However, the checklist items can also be applied to systematic reviews that assess aetiology, prevalence, or prognosis. This systematic review adhered to the PRISMA guidelines for reporting (Page et al., 2021).

2.4. Aim and objectives

The aim of this study was to conduct a systematic review to investigate the incidence and prevalence of CSR globally.

The review's objectives were to:

i. Identify the prevalence and incidence in CSR across adult populations globally.
ii. Assess the quality of included studies' design and methodology.
iii. Compare and contrast the clinical diagnosis definitions of CSR of the included studies with practice recommendations.

2.5. Methods

The search strategy employed in the published review (Mansfield et al., 2020) was updated for this chapter using the same databases and the same search terms for the period from February 2020 to June 2023. To structure the research question and outline the inclusion and exclusion criteria, the Population or Problem, Exposure, and Outcome (PEO) (Stern et al., 2014a) approach was utilised.

2.5.1. The systematic review team

The research team, led by MM, had experience and expertise across research and clinical settings. The lead researcher's (MM) background and expertise are discussed in **Chapter 1**. At the time of forming the systematic review team, Toby Smith (TS) was an Associate Professor and senior physiotherapist at the Norfolk and Norwich University Hospital. TS has extensive expertise and successfully produced evidence synthesis projects and trial research in musculoskeletal patient populations. Mick Thacker (MT) was a Professor of physiotherapy, pain and rehabilitation and has vast experience of translating experimental/laboratory pain models and sensory testing in humans to clinical settings. MT has successfully led several research projects utilising sensory testing paradigms in persistent NeP. Nicolas Spahr (NS) was a clinical academic working as a consultant physiotherapist. NS has expertise in the clinical assessment and management of complex pain presentations. The team was formed to support the necessary governance aspects for a successful systematic review (such as search strategy development and independent quality assessment) and subject matter expertise with neuropathic and musculoskeletal pain presentations. In particular, the lead researcher (MM) utilised this expertise when consulting the group with CSR diagnosis classification.

2.5.2. Eligibility criteria – population and exposure

To ensure a robust review, the study population should attempt to capture a 'fair' representation of the general adult population with CSR (Higgins et al., 2019). At the time of writing this systematic review, there was no consensus on CSR diagnosis. From the group's prior knowledge and evidence available when writing the review protocol, it is acknowledged that there were inconsistencies in CSR diagnostic criteria across geographical locations and from a historical standpoint. Cervical spine radiculopathy may not always be associated with pain (i.e., painless radiculopathy) (Siller et al., 2018). As explained in **Chapter 1**, there is often a combination of clinical findings or outcomes which can be attributed to adopted clinical examination techniques (Thoomes et al., 2018). The inclusion criteria of CSR diagnosis reflected this anticipated variation and were purposively kept broad. A modified version of the IASP radiculopathy and radicular pain classification (Scholz et al., 2019) was used (**Table 2.1**) in adults aged 18 years and over.

Table 2.1 Modified radiculopathy diagnostic criteria

CSR category	Signs and symptoms domains		
Definite CSR Either (i) or (ii)	(i) Acute denervation with EMG studies or sensory changes in a dermatomal distribution. AND Weakness, atrophy or fasciculation in a myotomal distribution and Unilateral diminished deep tendon reflexes.	(ii) Abnormal myelography, CT or MRI correlating with radiculopathy with neck pain or combined neck and arm pain. OR Paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy.	
Probable CSR Either (iii), (iv) or (v)	(iii) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy. With Sensory changes in dermatomal distribution or muscle weakness in a myotomal distribution or atrophy or fasciculation in a myotomal distribution or unilateral diminished deep tendon reflexes.	(iv) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy. With Abnormal myelography, CT or MRI correlating with radiculopathy.	(v) Neck pain or neck and arm pain with two from: (v-i) Sensory changes in dermatomal distribution. (v-ii) Muscle weakness in a myotomal distribution or atrophy. (v-iii) Fasciculation in a myotomal distribution. (v-iv) Unilateral diminished deep tendon reflexes.

Table abbreviations. CSR: Cervical spine radiculopathy; CT: Computed Tomography; EMG: Electromyography; MRI: Magnetic Resonance Imaging

2.5.3. Eligibility criteria – outcome

Studies were included if incidence or prevalence data were reported. Studies were considered if they recruited from a general population, primary, secondary or tertiary healthcare sectors. All studies were required to be published in English. In health-related systematic reviews, it is acknowledged that including or excluding non-English studies may impact on external validity (Jackson and Kuriyama, 2019, Neimann Rasmussen and Montgomery, 2018, Rockliffe, 2022). Notwithstanding this, there are challenges in locating and evaluating relevant non-English studies (Jackson and Kuriyama, 2019). The Cochrane Handbook recognises that reviews that only include English language studies can exhibit publication bias. It advises that decisions about including non-English studies should be made on a case-by-case basis (Higgins et al., 2019). To ensure that relevant studies are included in a review, researchers can search specialised non-English language databases using the appropriate search terms (Morrison et al., 2012, Rockliffe, 2022). However, language barriers and the cost of professional translation services can limit access to these studies (Rockliffe, 2022). For these reasons, this review only included studies in English, but the existence of any non-English studies found were reported. Additionally, if a search is limited to publications after 2005, a study that started in 2003 but was completed in 2007 may be excluded if the database records the start date of the trial as the publication date (Aali and Shokraneh, 2021). Therefore, for this reason, no publication date limitation was set for this systematic review. The definitions for publication types differ across the world. For instance, electronic databases categorise both conference abstracts and conference papers as conference proceedings without distinguishing between the two (Higgins et al., 2019). Cochrane guidelines recommend against restricting publication type in the search strategy (Higgins et al., 2019). To ensure that all possible eligible studies are captured, publication type was not limited in the search strategy.

2.5.4. Eligibility criteria – exclusion criteria

It is recognised that CSR may exhibit similar symptoms to certain neurological, metabolic or spinal cord compression conditions. Metabolic syndrome (MetS) combines disrupted glucose and insulin metabolism, overweight and abdominal fat distribution, mild dyslipidaemia and hypertension. It is considered a risk factor for

chronic diseases like cardiovascular disease (CVD), including myocardial infarction and stroke. Additionally, the individual risk factors that constitute MetS (central obesity, diabetes, high blood pressure and dyslipidaemia) have been found to be independently associated with degenerative joint disease and radiculopathy (Gandhi et al., 2014, Kalita et al., 2018). For this systematic review, the aim was not to investigate CSR in patient populations with confirmed MetS.

Cervical myelopathy is a medical condition where the spinal cord at the cervical level of the spinal column is compressed. This leads to sustained muscle contractions, hyperreflexia, clumsiness in the hands or fingers, changes in sensation (such as paraesthesia or hyperaesthesia), and difficulty in walking (Kane et al., 2020). For this systematic review, CSR in people with myelopathy were excluded as the objectives of this study did not include spinal cord compression.

Inflammatory conditions can reduce the space between the intervertebral discs, the vertebral body and/or inflame the nerve root or trunk (known as radiculitis). This can cause neck pain and somatosensory dysfunction, mimicking CSR (Araghi et al., 2023, Manifold and McCann, 1999). This pain and paraesthesia are caused by inflammation of the nerve root or trunk. Intradural infectious diseases can cause symptoms similar to those of a mass lesion within the spinal cord or radiculopathy (Na et al., 2011). Cervical spine radiculopathy may result from specific trauma such as fracture or post-surgery when the osseous components of the vertebral body encroach on the nerve root, resulting in radiculopathy (McCartney et al., 2018). These specific trauma cases attributed to CSR were excluded from this systematic review.

The aim of this systematic review was to investigate the prevalence and incidence of CSR in adult human populations. Therefore, studies were excluded if they investigated animal or cadaveric studies. Furthermore, to retrieve prevalence and incidence data from population-based studies, commentaries, editorials, single-case studies, reports or laboratory data, books or book chapters and letters were excluded as these forms of outputs would not meet the inclusion criteria. Education material such as lecture slides, study protocols, social media postings (including blogs) or online learning material (e.g., massive online learning sites, videos) were also excluded.

2.5.5. Search strategy – information sources

The lead researcher (MM) developed and collated the search terms. The lead researcher (MM) was familiar with a primary research study conducted by Radhakrishnan et al., (1994) investigating the incidence of CSR. This study was cited in the clinical knowledge summary developed by NICE (2023) and was therefore regarded as a key publication in this field. One method to verify the electronic data searches conducted by the lead researcher (MM) was to establish whether Radhakrishnan et al's study (1994) was retrieved. This was used to develop the search strategy and provide reassurance on its robustness. The search terms were agreed with the review team. The search strategy for MEDLINE (PUBMED) is documented in **Appendix 2.1**.

During the development of the search strategy, four essential factors were focused on: relevance, resources, recall, and reproducibility. To ensure that a search strategy is effective and relevant, it is important for reviewers to specify queries that produce accurate and relevant results. The recall and precision factors are crucial in measuring the percentage of relevant records in the result set. For maximum recall, systematic reviews should search multiple databases. MEDLINE (via OVID) and EMBASE (via OVID) were selected as they are recognised major electronic databases for biomedical research (Higgins et al., 2019). CINAHL (Via EBSCO) was selected as a specialist database of nursing and allied health (Higgins et al., 2019). Both MEDLINE and EMBASE are databases that specialise in biomedical research publications (Bramer et al., 2018). While EMBASE includes MEDLINE, it does not index every article from MEDLINE (Bramer et al., 2018, Frandsen et al., 2021). It is reported that MEDLINE's indexing and MESH search capabilities may help to uncover unique references that are not available in EMBASE (Frandsen et al., 2021). Furthermore, searching MEDLINE and EMBASE can increase the number of epidemiologic publications indexed to approximately 85%. Additionally, hand searching and using specialised databases (such as CINAHL) can retrieve a further 14% of publications that are not indexed in bibliographic databases (Bramer et al., 2016, Wright et al., 2015).

A systematic search of electronic databases PubMed (MEDLINE), EMBASE and CINAHL from inception to 25th February 2020 was completed by the lead researcher

(MM). For this chapter, the systematic search has been updated from February 2020 to June 2023.

In systematic reviews, it is essential to identify all relevant evidence to answer the research question. Grey literature, which refers to evidence that is not published in commercial publications, can be valuable in providing a comprehensive review (Paez, 2017). Examples of grey literature include theses, dissertations, research and committee reports, government reports, conference papers, and ongoing research (Paez, 2017). Grey literature may contain data unavailable in commercially published literature, which is especially important in disseminating studies with null or negative results (Mahood et al., 2014, Paez, 2017). Including grey literature may reduce publication bias, increase the timeliness and comprehensiveness of reviews, and provide a more balanced understanding of available evidence (Godin et al., 2015, Mahood et al., 2014). It is essential to include grey literature in systematic reviews to provide a more accurate effect size and a balanced understanding of the evidence (Adams et al., 2016, Gusenbauer and Haddaway, 2020).

A ‘grey search’ plan was formed to include various search strategies. For this systematic review, the OpenGrey grey literature database was searched (Paez, 2017). OpenGrey provides free access to over 700,000 bibliographical references from a wide range of sources including technical reports, theses, conference papers, and other unpublished materials (Paez, 2017). OpenGrey covers various subject areas and is a valuable resource for researchers in different health and allied health disciplines (Rogers et al., 2022). In addition, clinicaltrials.gov (ClinicalTrials, 2023) was searched. This is a freely accessible database of ongoing and registered research trials. To ensure the thoroughness of the search strategy, the World Health Organization trial registry platform (WHO, 2023) and National Institute for Health and Care Research (NIHR) portal (NIHR, 2023) were also searched. This is because clinicaltrails.gov is biased towards the United States of America-registered trials.

To ensure a thorough search for relevant articles in systematic reviews, the Cochrane guidelines suggest using alternative methods in addition to traditional database searches (Higgins et al., 2019). One such method is reference checking, which involves searching for studies that text-based searches in bibliographic

records may have missed (Bramer et al., 2016, Horsley et al., 2011). A study of 215 systematic reviews found that 81% used reference checking alongside database searches (Briscoe et al., 2020). One Cochrane review analysed 12 studies and reported that manually checking reference lists can be helpful to complement traditional electronic database searching (Horsley et al., 2011). By reviewing reference lists, additional unique yield was identified and calculated by dividing it with the total number of eligible studies within the research, and the range of relevant studies' additional yield was found to be between 2.5% to 42.7% (Horsley et al., 2011). However, reference checking can result in duplicate records, which require careful management. This issue will be discussed further below.

When completing a systematic review, the Cochrane Handbook advises using reference management software to store and organise records for inclusion and exclusion and accurately cite (Higgins et al., 2019). Platforms such as EndNote, RefWorks, Zotero, and Mendeley share similar features that allow users to import, organise, and manage citations along with their full texts (Ivey and Crum, 2018, Yamakawa et al., 2014). These platforms enable users to import references from online databases, create in-text citations and bibliographies and import bibliographic information from web pages (Ivey and Crum, 2018, Yamakawa et al., 2014). Additionally, they offer a collection of citation styles and the option to edit existing ones or create new ones (Yamakawa et al., 2014). After careful consideration, EndNote desktop (X20 for MacOS) was chosen for citation management due to its unique features that best matched the lead researcher's historical experience of this platform to inform the management of this systematic review.

In this search strategy section of the chapter, a discussion of searching multiple databases was important because each database contains different records, which widens the coverage. Moreover, searching multiple databases uses differences in indexing to increase the chances of identifying relevant citations that are listed in multiple databases. However, this practice may also retrieve overlapping content, resulting in duplicates. To address this issue, EndNote has an auto-deduplication function that removes duplicate records (Butros and Taylor, 2010, Ivey and Crum, 2018, Rogers et al., 2022). However, this function may not be entirely successful, and it is acknowledged that reviewers may need to manually sift through and remove the remaining duplicates (Yamakawa et al., 2014). To address this, a two-stage

process was employed, where auto-deduplication was performed in EndNote followed by manual hand screening to identify remaining duplicates. Additionally, incomplete citations were updated using the 'Find References Update' feature in EndNote. This process is recommended to address the problem of undetected duplicates (Butros and Taylor, 2010, Yamakawa et al., 2014).

To enhance the process of identifying studies for systematic reviews, it is recommended to incorporate supplementary search methods. The Cochrane Handbook advises review authors to contact the original investigators by locating their contact details from study reports, recent publications, staff listings or by conducting an online search (Cooper et al., 2019). However, it should be noted that contacting authors or experts does not guarantee obtaining relevant information (Cooper et al., 2019). Selph et al., (2014) discovered that it is possible to find additional studies or study data through email contact with the corresponding author (Selph et al., 2014). Of the 66 authors, 68% were successfully contacted and 42% provided additional data for 29 out of 77 studies (38%) (Selph et al., 2014). Therefore, contacting study authors is challenging and missing data is still likely (Selph et al., 2014). In this CSR systematic review, nine authors from the nine included studies were contacted by email (**Appendix 2.2**). After 15 working days, there were no responses. Five email addresses were automatically returned, suggesting the contact details no longer exist. In addition, when formal study inclusion had taken place, hand searches of reference lists were completed. There were no additional articles retrieved.

2.5.6. Data collection – study selection

When conducting a systematic review, there are important decisions that need to be made at different points from inception to synthesis, which can be subjective. It is essential to provide information on how inclusion and exclusion decisions were made and any disagreements that were resolved among the research team (Bramer et al., 2018). To address this, an abstract screening tool (**Appendix 2.3**) and guidance was created by MM and verified by MT. MM and MT then independently piloted the screening tool on 10 titles and abstracts (**Supplementary file 2**). MM and MT agreed on all 10 titles and abstracts with no disagreements. Based on the eligibility criteria, all remaining titles and abstracts from the search results were

independently screened by the same two reviewers (MM, MT). One of the most significant decisions during a review process is which studies to include from the full text. Whilst it is recognised that having two independent reviewers can help reduce errors due to unclear or misunderstood eligibility criteria, it is still possible for random errors to occur. Nevertheless, Cochrane recommends having a second reviewer at the full-text stage supporting the final selection of studies. Therefore, when full-text studies from potentially eligible studies were retrieved, the same two reviewers completed an independent assessment. Final eligibility was based on a full-text assessment. To establish the reliability in the full-text inclusion/exclusion decision-making process, the assessment of reliability (between-reviewer) for the eligibility criteria was performed for a random sample of 20 (11% of 177 full-text papers retrieved) of potentially eligible papers using a weighted Kappa statistic (Cohen, 1968). The between-reviewer agreement ranged from 90 to 100% across the criteria (Kappa: 0.92, 95% CI: 0.84-1.00) (**Supplementary file 3**).

2.5.7. Data extraction

It is essential to have a thorough process for extracting data, not just for outcome data. Systematic review users require detailed information on non-outcome data to understand the primary studies and evaluate their relevance (Uttley et al., 2023). However, many systematic reviews fail to provide sufficient data on non-outcome information. In a cross-sectional study investigating the outcome reporting of systematic reviews, 43% of included studies had discrepancies in outcome reporting to protocol. When reviews were further scrutinised, 23% (35 of 150) of reviews had changes in outcomes after acknowledging the results (Shah et al., 2020). While poor reporting quality is one reason for this, inadequate data collection methods could also be a contributing factor (Büchter et al., 2020, Shah et al., 2020).

To ensure complete and accurate reporting, reviewers are advised to a priori determine which data are to be extracted (Büchter et al., 2020). In conducting this systematic review, MM consulted two previous systematic reviews on the epidemiology of neck (Fejer et al., 2006) and low back pain (Hoy et al., 2010). These two studies investigated outcomes and populations similar to those in this systematic review. **Table 2.2** lists the data extraction items used in these two studies. Using this information as a guide, MM customised a data extraction form to

meet the specific needs of the review. This form was reviewed and discussed with all members of the systematic review team, and consensus was reached that it adequately met this review's aims.

To support decision-making, MM created one data extraction table (**Appendix 2.4**). For each data item, there was a clear description and expectations for what should be extracted. Cochrane guidelines (Higgins et al., 2019) and the Centre for Reviews and Dissemination (CRD) (Akers et al., 2009) recommend having a coding document that outlines what to extract from included papers, and this also supported the second reviewer in verifying the extracted data. MM conducted the data-extraction process for the included studies with independent verification from TS to ensure the accuracy of data extracted. TS was invited due to their in-depth understanding of the topic and extensive experience in study design, data analysis, and statistics, thus meeting Cochrane's recommendations for a second reviewer. MM and TS thoroughly discussed all data extracted from the included studies and reached a consensus without any disagreements. In case of any disagreements, a plan was in place to consult with a third researcher (MT).

Table 2.2 Data extraction items across two epidemiology systematic reviews

Data extraction items: Fejer et al., (2006)	**Data extraction items: Hoy et al., (2010)**
Name of authors	Citation (authors)
Country	Country
Title	Age of participants
Source	Low back pain definition
Objective of study (and if neck pain was the primary objective)	Outcome data
Study design (cross-sectional or longitudinal)	
Method of data collection (questionnaire, interview, or examination)	
Sampling method and sample data (age, sex, target and final sample, and response rate)	
Description of neck pain (definition, type and validation of questionnaire)	
Outcome data	

2.5.8. Methodological quality

When conducting a systematic review, the accuracy of the results is reliant on the quality of the included studies (Shea et al., 2007). Therefore, it is important to assess the validity of each study. Bias or systematic error can lead to over- or under-estimating the effects of an intervention or exposure (Boland et al., 2017, Owens, 2021). Typically, four types of systematic error are considered when evaluating studies: selection bias, performance bias, attrition bias, and detection bias (Ahmed et al., 2012, Drucker et al., 2016). It is important to clarify the meaning of 'methodological quality' in this context. According to the Cochrane guidelines for systematic reviews (Higgins et al., 2019), it refers to how well a study's design, conduct, and analysis have reduced biases related to selection, measurement, and confounding factors (Shekelle et al., 2001).

There is no consensus regarding the most appropriate critical appraisal tool for allied health research. Katrak et al., (2004) carried out a narrative review of critical appraisal tools that were published. Their aim was to identify common elements, assess their relevance to allied health research, and evaluate the content, intent, construction, and psychometric properties of these tools. Katrak et al., (2004) reported considerable variability in items contained in the critical appraisal tools. Out of the 121 appraisal tools that were found, only 12% were developed based on empirical research. Forty-nine percent provided a numeric summary score to assess the quality. Face validity was confirmed in nine critical appraisal tools, with seven designed for experimental studies and the remaining two for systematic reviews (Katrak et al., 2004).

It was anticipated that for this systematic review, the retrieved studies would be cross-sectional in study design. The Newcastle-Ottawa Scale (NOS) (Wells et al., 2000), created to evaluate the quality of non-randomised studies, was initially considered for use. It uses a 'star system' to assess a study based on three main aspects: the selection of study groups, the comparability of those groups, and the ascertainment of either the exposure or outcome of interest (depending on whether it is a case-control or cohort study) (Wells et al., 2000). The NOS has been shown to have content validity and intra-rater reliability (Stang, 2010). However, for cross-sectional studies, the inter-rater reliability is only moderate to poor (Kappa-value

<0.50) (Hartling et al., 2013). An alternative critical appraisal tool was therefore sought.

Since there is no 'gold standard' critical appraisal tool (Buccheri and Sharifi, 2017, Katrak et al., 2004), a quality appraisal tool by Hayden et al., (2006) was used for this systematic review. This tool was originally developed for prognosis studies using epidemiology to inform the quality items including representation of target population, case definition, information on responses rate and non-responders. The inter-rater reliability of the Hayden et al., (2006) tool is higher compared with NOS and Downs and Black, inter-rater agreement scores for individual bias domains: study participation (Kappa=0.73), study attrition (Kappa=1.0), prognostic factor measurement (Kappa=1.0), confounding measurement and account (Kappa=0.4), outcome measurement (Kappa=0.73), and analysis and reporting (Kappa=0.73) (Hayden et al., 2006).

Two reviewers (MM, TS) independently assessed the quality of each included study. Any disagreement between reviewers was firstly discussed between the two reviewers (MM, TS). Consensus was reached through discussion between the two reviewers. A third reviewer (MT) was available to act as adjudicator but was not required. The quality appraisal assessed the appropriateness and reporting of the study population, CSR definition, response rate, information about non-responders and data precision. Scoring between the two reviewers had an agreement of 91% (42 out of 45). Disagreements were around the item "If appropriate, was information about non-responders described?", which were resolved through discussion and consensus was achieved. Individual completed quality appraisal tables are presented in **Supplementary file 1.**

2.5.9. Synthesis planning

When conducting a systematic review, the synthesis of findings is an essential element. It involves bringing together the results from a collection of studies to draw conclusions based on the body of evidence. There are two main approaches to synthesis: quantitative (using statistical pooling, also known as meta-analysis) and narrative (Campbell et al., 2020a). In some cases, both methods can be used to synthesise the same set of data. 'Narrative synthesis' refers to a systematic review

method that combines results from multiple studies primarily using a textual approach to synthesising the included studies' results (Campbell et al., 2020a).

During a systematic review, it is normal for the included studies to have some differences between themselves. This is termed 'heterogeneity' (Gartlehner et al., 2012, Ruppar, 2020). Heterogeneity can take various forms, such as clinical diversity (variations in study participants, interventions, and outcomes), methodological diversity (variations in study design and risk of bias), and statistical heterogeneity (when the observed effects are more varied than what one would expect due to chance alone) (Gagnier et al., 2012). Statistical heterogeneity can be caused by clinical or methodological diversity, or both (Fletcher, 2007).

When clinical diagnosis methods are impacted by varying factors across studies, such as specific diagnostic tests or patient characteristics, they can cause heterogeneity and a lack of consistency (Lijmer et al., 2002). Meta-analysis is only appropriate when a group of studies have sufficient homogeneity regarding participants, interventions, and outcomes to provide a meaningful summary (Lijmer et al., 2002). A fixed-effect or random-effect model can be used for meta-analysis (Borenstein et al., 2010). The fixed-effect model assumes that any differences in study results are due to chance, while the random-effects model assumes that the effects being estimated in different studies are not identical but follow a similar distribution (Borenstein et al., 2010).

The lead researcher (MM) led the clinical heterogeneity assessment, with TS as a second independent reviewer. All included studies were assessed from a clinical perspective (for example, diagnosis, variability in population characteristics) and study methodology in determining whether studies could be pooled together for synthesis. Both researchers agreed on the existence of significant clinical heterogeneity with data collection methods and CSR definition, questioning the appropriateness of meta-analysis. Data were, therefore, narratively analysed.

The Synthesis Without Meta-analysis (SWiM) guideline is a tool that helps researchers clearly report on systematic reviews when they use alternative synthesis methods instead of meta-analysis for effect estimates (Campbell et al., 2020a). This can happen if the effect estimates are incomplete or if the studies'

characteristics, are too diverse to produce a meaningful summary estimate of effect. The SWiM guideline builds on the current guidance on 'synthesis of results' items in PRISMA (Items 14 and 21) and can be used in conjunction with it (Campbell et al., 2020a). SWiM includes reporting on how studies are grouped, the synthesis methods used, the presentation of data and summary text, and any synthesis limitations.

Guidance has also been developed for conducting narrative synthesis in systematic reviews as part of the Economic and Social Research Council (ESRC) Methods Programme project (Popay et al., 2006). The framework includes four elements: developing a theory of how the intervention works, why it works, and for whom; creating a preliminary synthesis of findings from included studies; exploring relationships within and between studies; and assessing the robustness of the synthesis (Popay et al., 2006). These four elements do not have to be completed in a strictly sequential manner and may not all be necessary for every narrative synthesis (Popay et al., 2006). The appropriate tools and techniques should be chosen based on the nature of the evidence being synthesised.

One of the primary objectives of this systematic review was to investigate the prevalence and incidence of CSR in adult populations. Therefore, not all elements of the ESRC guidelines were appropriate to utilise. To support the decision on the narrative synthesis, **Table 2.3** presents the reporting items of SWiM, where there is commonality between SWiM and ESRC and the tools used to meet SWiM reporting items.

Table 2.3 Reporting items for narrative synthesis

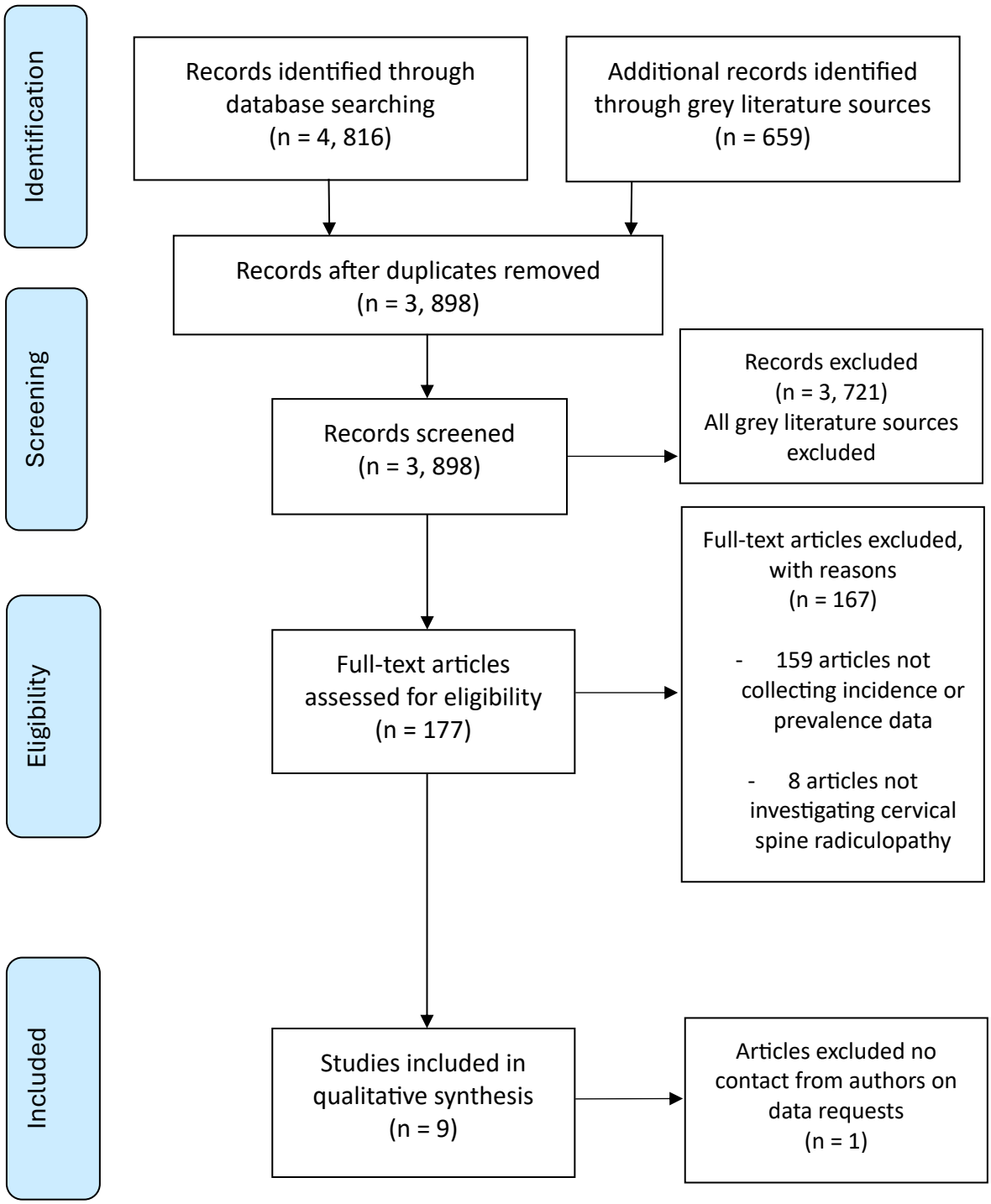
SWiM reporting item	ESRC core element	Tools/techniques to be used to support reporting
Grouping studies for synthesis	Creating a preliminary synthesis of findings	Textual description with grouping Tabulation
Describe the standardised metric and transformation methods used	No direct comparison with SWiM	Textual description
Describe the synthesis methods	No direct comparison with SWiM	Textual description
Criteria used to prioritise results for summary and synthesis	No direct comparison with SWiM	Textual description
Investigation of heterogeneity in reported effects	Exploring relationships within and between studies	Textual description
Certainty of evidence	Assessing the robustness of the synthesis	Textual description Tabulation
Data presentation methods	Creating a preliminary synthesis of findings	Textual description Tabulation
Reporting results	Creating a preliminary synthesis of findings Exploring relationships within and between studies	Textual description Tabulation
Limitations of the synthesis	Assessing the robustness of the synthesis	Textual description

Table abbreviations: ESRC: Economic and Social Research Council; SWiM: Synthesis Without Meta-analysis

2.6. Results

The search identified 5,475 records. After removing duplicates, 3,898 records remained. After reviewing the titles and abstracts, 177 records remained. Of these, 167 full-text articles were excluded as they did not meet the inclusion criteria (**Figure 2.1**). The most frequent reasons for exclusion were that the cohorts did not investigate CSR and no prevalence or incidence data were collected. Ten studies met the inclusion criteria. One study was excluded as the authors did not respond to the request for CSR data (Choi et al., 2017). Accordingly, nine studies were included in the final review.

Figure 2.1 2009 PRISMA diagram for study selection



2.6.1. Study characteristics

The characteristics of the included studies are presented in **Table 2.4**. All the studies included in this systematic review were published. There was geographical variability across the included studies. Three studies were performed within the United States of America (USA) (Braddom et al., 2009, Radhakrishnan et al., 1994, Schoenfeld et al., 2012). Two studies were conducted in Egypt (Khedr et al., 2018, Kandil et al., 2012), one from Iran (Sandoughi et al., 2013), India (Bharucha et al., 1991), UK (Brooks et al., 2005) and Italy (Salemi et al., 1996) respectively.

A total of 13,869,818 participants were recruited. Six studies analysed participants from general populations (Bharucha et al., 1991, Braddom et al., 2009, Kandil et al., 2012, Khedr et al., 2018, Radhakrishnan et al., 1994, Salemi et al., 1996, Sandoughi et al., 2013). One study analysed participants recruited from elite sport (rugby union) (Brooks et al., 2005). One study analysed participants from a neurology department in a tertiary hospital (Braddom et al., 2009) and one study analysed participants from the military (Schoenfeld et al., 2012).

Table 2.4 Study characteristics

Lead Author & Date	Population and location	Data Collection Methods	Sample Size (Age, Gender)	Definition of Cervical Spine Radiculopathy (CSR)	Prevalence/Incidence of CSR
Schoenfeld (2012)	USA Military personnel between years 2000-2009	Retrospective analysis of USA military's Defence Medical Epidemiological Database	Total sample: 13,813,333 20,806 CSR Diagnosis (Males) 3,936 CSR Diagnosis (Females) Age Range 18-40 Years	**Probable CSR criteria (iii)** "Pain (radicular pain), weakness, numbness, or difficulty controlling specific muscles related to nerve roots"	**Incidence** Males 1.76 per 1000 person-years (unadjusted incidence) Females: 1.36 per 1000 person-years (95% CI:1.30-1.42) (adjusted incidence) Total: 1.79 per 1000 person-years
Brooks (2005)	Professional UK Club Rugby Football Union (RFU). Elite Level.	Orchard Sports Injury Classification. Retrospectively analysed over 2 seasons	Total sample: 502 All Male Age: 25.4 years (SD: 4.2)	"Cervical nerve root injury" There were insufficient data presented to retrieve this detail (authors were contacted)	**Incidence** 0.02 per 1000 person-years
Radhakrishnan (1994)	General population Minnesota, USA	Retrospective population analysis of Mayo Clinic medical records	Total sample: 561 332 Male 47.6 years of age (SD: 13.1) 229 Female 48.2 years of age (SD: 13.8)	**Definite and probable CSR criteria (i)-(v) combined**	**Incidence** Female 63.5 per 100,000 person-years (Age Adjusted, 95% CI: 55.1-71.8) Male 107.3 per 100,000 person-years (Age adjusted, 95% CI: 95.4-119.2) Total – 83.2 per 100,000 person-years (age adjusted 95% CI: 77.0-91.1)

Braddom (2009)	Georgia, USA Consecutive sample through a Neurology Department at the Medical College of Georgia. Individuals following Motor Vehicle Accident	Retrospective analysis EMG reports between 1979 through to 2004.	Total sample 23,317 MVAs Mean age: 46 Years Unknown Male: Female data	**Definite CSR Criteria (i)** Acute denervation with EMG studies OR Sensory changes in dermatomal distribution AND Weakness, atrophy OR fasciculation in a myotomal distribution AND Unilateral diminished deep tendon reflexes	**Prevalence** 1,465 of 23,317 (6.28%)
Khedr (2018)	Qena area, Egypt	Prospective cross-sectional sample Interview, Questionnaire, Clinical examination and Imaging Consultant neurologist completed clinical examination and imaging interpretations at Qena University Hospital	Total sample: 9303 (1057 families) Unknown Male: Female Ages 30-80 years 32 Confirmed cases of combined Lumbar and Cervical radiculopathy 9 males CSR 2 females CSR Total – 11 (CPR: 1.2 per 1000 Lumbosacral radiculopathy (CPR: 2.3 per 1000)	**Definite CSR Criterion (i) or (ii)** Acute denervation with EMG studies OR Sensory changes in dermatomal distribution AND Weakness, atrophy OR fasciculation in a myotomal distribution AND Unilateral diminished deep tendon reflexes Abnormal myelography, CT or MRI correlating with radiculopathy WITH Neck pain or combined neck and arm pain OR Paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy	**Prevalence** Male 4.8 per 1000 Female 1.9 per 1000
Salemi (1996)	Sicilian Municipality, Italy	Door-to-door survey Stage 1: Questionnaire screening tool	Total Sample: 8792 142 evaluated for CSR 27 definite or probable CSR diagnosis	**Definite and probable CSR criteria** “Bouts of pain in the neck radiating down one or both arms. The pain had to start suddenly and could be associated with	**Prevalence** 3.5 per 1000 Both sexes 1.3 per 1000 Male 5.8 per 1000 Female

		Neurologists then completed physical assessment on suspicion of CSR	5 Male cases (50-69 Years of age) 22 Female cases (40-79 years of age)	weakness, paraesthesia or numbness in the arms. Stiffness in the neck could be present. Signs or symptoms had to persist for at least one day" Definite CSR clinical features had to relate to MRI, CT, EMG, Myelogram, X-ray Probable CSR: Reoccurring bouts without neurological signs at the visit	
Bharucha (1991)	Bombay, India	Door-to-door survey	Total sample: 14,010 334 cases of peripheral neuropathy 44% over 50 years of age	**Probable CSR criteria (vi or vii)** Pain or stiffness in the neck associated with paraesthesia, numbness, or weakness in an arm.	**Prevalence** 136 per 100,000
Kandil (2012)	Assiut Governorate, Egypt	Door-to-door survey Stage 1: Questionnaire If answers suggested of neuropathy, then Stage 2: Neurological examination at University Hospital	Total sample: 42,223 Rural and urban areas 51 total CSR cases. 35 Male and 16 Female.	**Definite CSR criteria (ii)** "Pain or stiffness in the neck associated with paraesthesia, numbness, or weakness in an arm. Both conditions were confirmed by neurophysiological data and magnetic resonance imaging of cervical regions"	**Prevalence** 121 per 100,000 (95% CI: 88-154)
Sandoughi (2013)	Zahedan, Iran	Cluster sampling method across the region COPCORD Core Questionnaire for initial data collection Where pathology suspected, subject	2100 sample size 1204 response rate (77.7%) 921 Male 1179 Female Occupation – 37.5% homemakers, 31.2%	"Cervical radiculopathy" There were insufficient data presented to retrieve this detail (authors were contacted)	**Prevalence** Male 1.14% (95% CI: 0.45-1.82) Female 1.31% (95% CI: 0.66-1.96)

		referred to hospital where a Rheumatologist completed an assessment	university or college students, 17.6% employees, 10.5% unemployed, 5.8% skilled and unskilled manual workers, 5.7% drivers.		

Table abbreviations. CI: Confidence Interval; COPCORD: Community Oriented Program for Control of Rheumatic Diseases; CSR: Cervical spine radiculopathy; CT: Computed Tomography; EMG: Electromyography; MRI: Magnetic Resonance Imaging; SD: Standard Deviation; USA: United States of America.

Key: Cervical spine radiculopathy (CSR) diagnosis criteria

Definite CSR Diagnosis – *Either (i) or (ii)*

(i) Acute denervation with EMG studies OR Sensory changes in dermatomal distribution
AND
Weakness, atrophy OR fasciculation in a myotomal distribution *AND* Unilateral diminished deep tendon reflexes

(ii) Abnormal myelography, CT or MRI correlating with radiculopathy
WITH
Neck pain or combined neck and arm pain
OR
Paraesthesia, hyperesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy

Probable CSR Diagnosis – *Either (iii), (iv) or (v)*

(iii) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy
WITH
Sensory changes in dermatomal distribution or muscle weakness in a myotomal distribution or atrophy or Fasciculation in a myotomal distribution or Unilateral diminished deep tendon reflexes

(iv) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy
WITH
Abnormal myelography, CT or MRI correlating with radiculopathy

(v) Neck pain, neck and arm pain with two from:
(v-i) Sensory changes in dermatomal distribution
(v-ii) Muscle weakness in a myotomal distribution or atrophy
(v-iii) Fasciculation in a myotomal distribution
(v-iv) Unilateral diminished deep tendon reflexes

2.6.2. Quality assessment

The quality assessment is presented in **Table 2.5**. Four studies were deemed 'high quality', four studies were deemed 'medium quality' and one 'low quality'. All studies met Criteria 1, 'The study sample represents the population of interest on key characteristics'. Following this, the most frequent criteria satisfied were 'Is the CSR diagnosis specific and reproducible?' Two studies, Brooks et al., (2005) and Sandoughi et al., (2013), lacked specific case definition details of CSR. Despite attempts to contact the authors by email for further information, no response was received. Due to the limited case definition of CSR in these studies, the clinical applicability of their findings is limited.

Brooks et al., (2005) and Khedr et al., (2018) did not report a response rate of more than 75% when collating prevalence and incidence data for their respective studies. There is a possibility of error or non-response bias in the selected sample due to some participants being unable or unwilling to participate. The extent of bias may vary depending on the incidence of non-response and how non-respondents differ from respondents in terms of variables such as CSR prevalence and incidence. The characteristics of the study population may influence selective non-response (Bruce et al., 2018). It is important to note that selective non-response can also be linked to the outcomes being studied. In health surveys, for example, respondents tend to report better health and more positive health-related behaviours than non-respondents (Bruce et al., 2018). This includes factors such as self-rated health, chronic diseases, smoking, physical activity, obesity, alcohol consumption, mental health and subjective health status. These findings suggest that people with poor health are less likely to participate in data collection related to disease or illness. Non-response can impact the accuracy of the behavioural parameters being studied, which can lead to confounding variables. Moreover, low participation rates in epidemiological studies can result in self-selection bias, which can compromise the internal validity of the findings (Campbell et al., 2020).

Of the nine studies included in this systematic review, one study (Salemi et al.,1996) described the non-response characteristics of the intended sample of participants. Describing the sociodemographic characteristics of non-responders and sub-grouping the reasons for non-response (if provided) can enhance the transparency

of data collection methods and subsequent hypotheses on the impact of non-response on prevalence estimates.

Table 2.5 Quality appraisal of included studies

Lead Author & Year	The study sample represents the population of interest on key characteristics	Was there an adequate response rate? (>75%)	If appropriate, was information about non-responders described?	Was the CSR diagnosis specified and is it reproducible?	Is it clear what was used to determined precision estimates? (E.g. CIs)
Schoenfeld (2012)	Y	Y	N	Y	Y
Brooks (2005)	Y	N	N	N	N
Radhakrishnan (1994)	Y	Y	N	Y	Y
Braddom (2009)	Y	Y	N	Y	N
Khedr (2018)	Y	N	N	Y	N
Salemi (1996)	Y	Y	Y	Y	N
Bharucha (1991)	Y	Y	N	Y	N
Kandil (2012)	Y	Y	N	Y	Y
Sandoughi (2013)	Y	Y	N	N	Y

Y = Yes
N = No

Table abbreviations. CI: Confidence Interval; CSR: Cervical spine radiculopathy

2.6.3. Cervical spine radiculopathy diagnostic criteria

In a military setting, one study used sensory (including radicular pain) and motor disturbances to confirm CSR (Schoenfeld et al., 2012). Two studies utilised a combination of sensory, diminished reflexes and/or motor disturbances with EMG, MRI or CT confirmation (Braddom et al., 2009, Khedr et al., 2018). Two studies used combined sensory and motor disturbances with imaging correlation when confirming CSR (Bharucha et al., 1991, Kandil et al., 2012). Salemi et al., (1996) confirmed CSR through combined sensory and motor disturbances with or without imaging correlation (Salemi et al., 1996). Bharucha et al., (1991) confirmed CSR with pain or stiffness in the cervical spine with sensory or motor disturbances (Bharucha et al., 1991). Sandoughi et al., (2013) relied on an 'expert' rheumatology consultant examination when confirming CSR in a study population from Iran (Sandoughi et al., 2013). Despite contacting the authors, no further details were confirmed. One study used an Orchard Sports Injury Classification retrospectively to determine CSR (Brooks et al., 2005). No further details were provided on their CSR definition, despite contacting Brooks et al., (2005).

2.6.4. Epidemiology of cervical spine radiculopathy (prevalence and/or incidence)

Incidence and prevalence data are presented in **Figures 2.2, 2.3** and **2.4**. Incidence ranged between 0.83 (converted from 83.2 per 100,000) to 1.79 per 1000 person-years from three studies (Brooks et al., 2005, Radhakrishnan et al., 1994, Schoenfeld et al., 2012). Prevalence values ranged from 1.21 to 5.8 per 1000 from four studies (Bharucha et al., 1991, Kandil et al., 2012, Khedr et al., 2018, Salemi et al., 1996). Prevalence values of 1.1% (95% CI: 0.45-1.82) and 1.3% (95% CI: 0.66-1.96) for males and females, respectively, were reported by one study (Sandoughi et al., 2013). One study reported an unadjusted prevalence value of 6.3% (Braddom et al., 2009).

Figure 2.2 The incidence of cervical spine radiculopathy

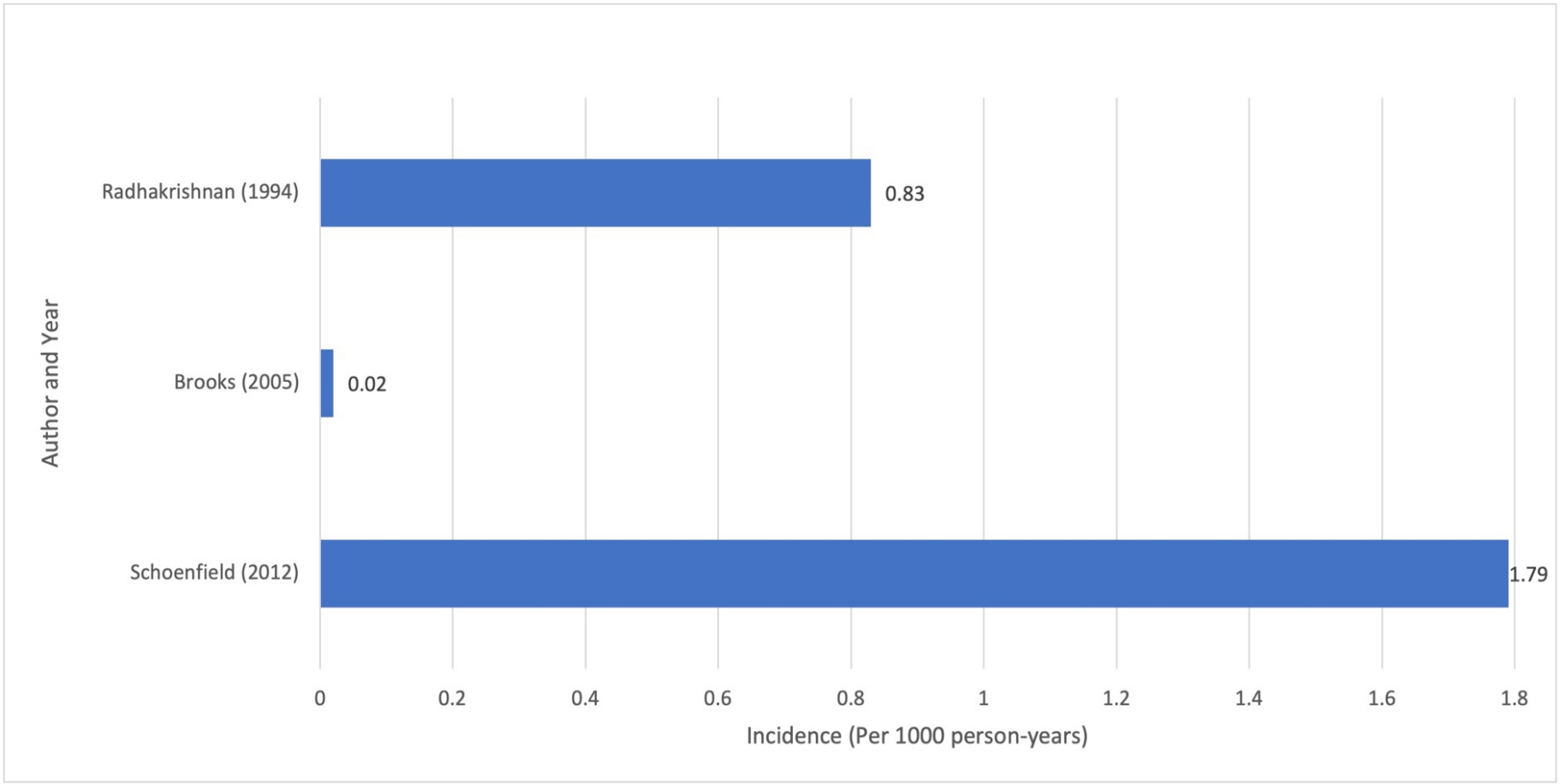


Figure 2.3 The prevalence (per 1000 people) of cervical spine radiculopathy

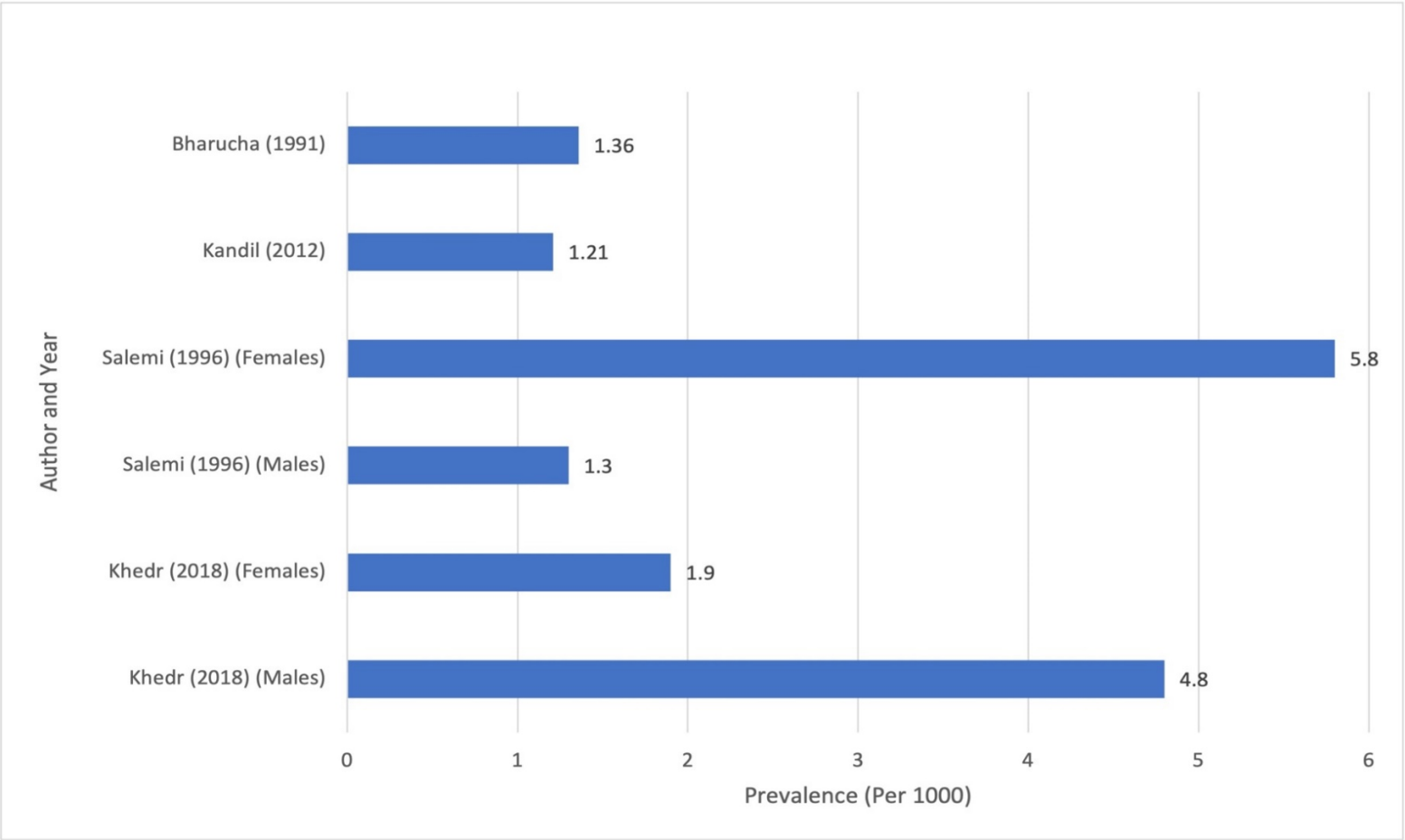
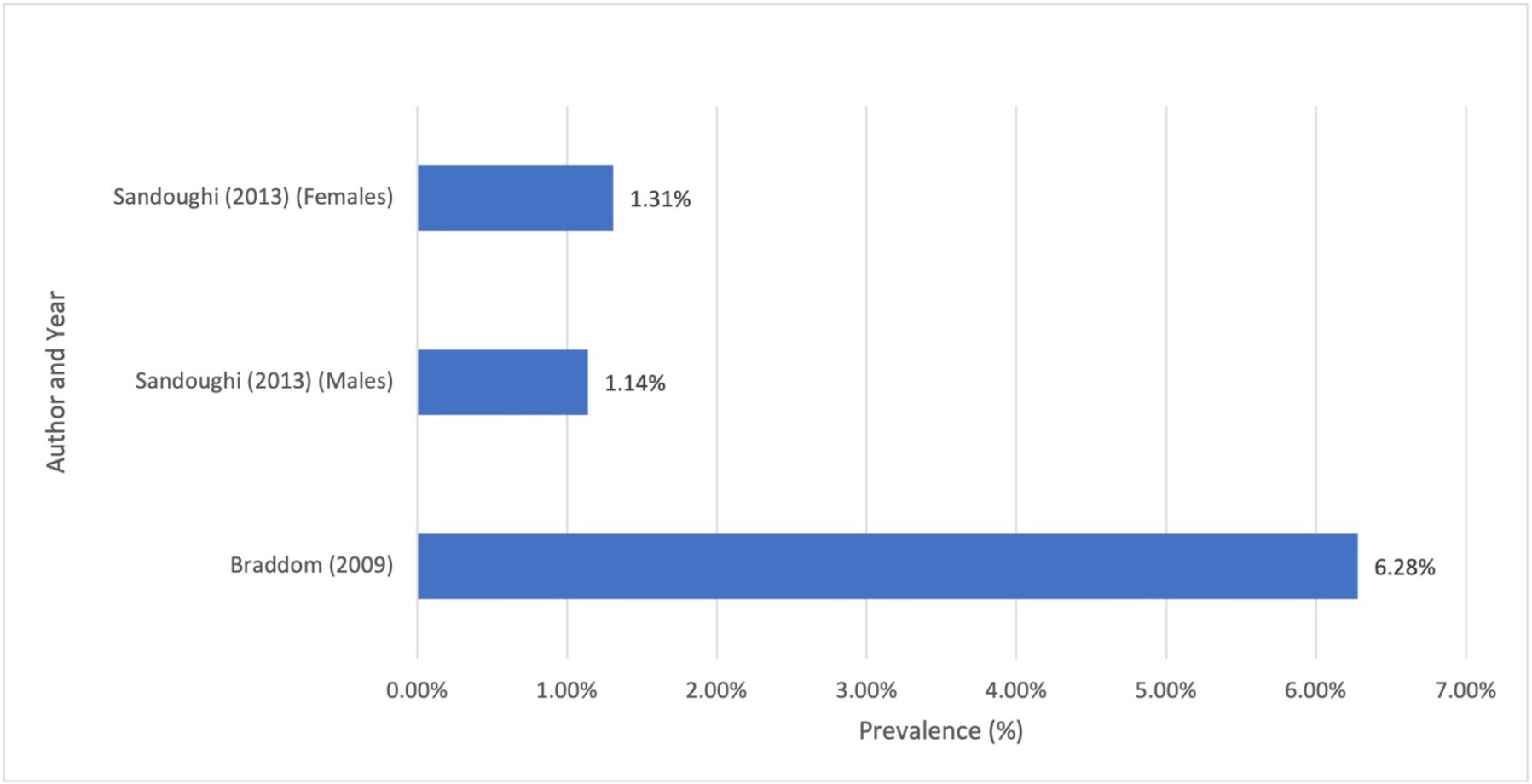


Figure 2.4 The prevalence (percentage %) of cervical spine radiculopathy



Three studies utilised a door-to-door survey to report prevalence; one in Italy (Salemi et al., 1996), one in India (Bharucha et al., 1991) and Egypt (Kandil et al., 2012). Salemi et al., (1996) reported an unadjusted prevalence of 1.3 per 1000 and 5.8 per 1000 for males and females, respectively, with a total of 3.5 per 1000 for both sexes (Salemi et al., 1996). Five male participants (50-69 years of age) and 22 female participants (40-79 years of age) were reported from a sample size of 8,782 participants (Salemi et al., 1996). Bharucha et al., (1991) recruited 14,010 participants and 334 participants with peripheral neuropathy were confirmed (Bharucha et al., 1991). The authors reported an unadjusted prevalence of 136 per 100,000. Kandil et al.'s (2012) sample size was 42,223 and 51 participants of CSR (35 male and 16 female) were confirmed. The combined prevalence for both sexes was 121 per 100,000 (95% CI: 88-154) (Kandil et al., 2012).

Two studies collected prevalence data in hospital neurology departments, one in USA (Braddom et al., 2009) and one in Egypt (Khedr et al., 2018). Braddom et al., (2009) analysed EMG reports between 1979 and 2004. In total, 23,317 participants (mean age 46 years) were consecutively recruited. The unadjusted prevalence was 6.3% (1,465 confirmed CSR cases) (Braddom et al., 2009). A cross-sectional study of 1,057 families in Egypt (total sample size 9,303) reported nine males and two females with CSR (Khedr et al., 2018), resulting in prevalence values of 4.8 and 1.9 per 1000 for male and females, respectively (Khedr et al., 2018).

Sandoughi et al., (2013) conducted a cluster sampling method across multiple Iranian provinces. From a sample size of 2,100, 1,204 participants responded (74% response rate) and were included in their analysis. The male prevalence of CSR was 1.1% (95% CI: 0.45-1.82) and female 1.3% (95% CI: 0.66-1.96) (Sandoughi et al., 2013). Three studies collected incidence data, one from UK elite-level rugby (Brooks et al., 2005), one from USA military (Schoenfeld et al., 2012) and one from retrospective analysis of medical records in USA (Radhakrishnan et al., 1994). Over two sporting seasons, retrospective data were collected from 502 sportsmen (mean age of 25.4 years, SD 4.2) and the unadjusted prevalence was 2% (Brooks et al., 2005). Schoenfeld et al., (2012) included 13,813,333 participants between 2000 and 2009, with an age range of 18-40 years (Schoenfeld et al., 2012). A total of 20,806 and 3,936 males and females, respectively, were diagnosed with CSR. There was an unadjusted incidence rate of 1.76 per 1000 person-years for males and an

adjusted incidence rate of 1.36 per 1000 person-years (95% CI: 1.30-1.42) for females. The total incidence rate was reported as 1.79 per 1000 person-years.

Radhakrishnan et al., (1994) analysed 561 people, 332 being male (47.6 years of age; SD: 13.1) and 229 were female (48.2 years of age; SD: 13.8). Male incidence was 107.3 per 100,000 person-years adjusted incidence rate (age adjusted 95% CI: 95.4-119.2). Female adjusted incidence was 63.5 per 100,000 person-years (age adjusted 95% CI: 55.1-71.8). The combined male and female incidence was 83.2 per 100,000 person-years (age adjusted 95% CI: 77.0-91.1).

2.6.5. Sub-group analysis of definite cervical spine radiculopathy incidence and/or prevalence data

From the nine included studies, five studies met the modified 'definitive' CSR criteria (Braddom et al., 2009, Kandil et al., 2012, Khedr et al., 2018, Radhakrishnan et al., 1994, Salemi et al., 1996). Prevalence ranged between 1.21 (converted from 121 per 100,000) to 5.8 per 1000. One study reported a 6.28% prevalence value (Braddom et al., 2009). One study reported an incidence of 0.83 per 1000 person-years (converted from 83.2 per 100,000 person-years) (Radhakrishnan et al., 1994).

Radhakrishnan et al., (1994) utilised a combined 'definite' and 'probable' (i-v) CSR diagnostic criteria. The authors were contacted to delineate these diagnostic criteria, but there was no response. Radhakrishnan et al., (1994) reported a 107.3 per 100,000 person-years adjusted incidence rate (age adjusted 95% CI: 95.4-119.2) for males. The adjusted incidence rate for females was 63.5 per 100,000 person-years (age adjusted 95% CI: 55.1-71.8). The combined male and female incidence was 83.2 per 100,000 person-years (age adjusted 95% CI: 77.0-91.1) (Radhakrishnan et al., 1994).

Braddom et al., (2009) adopted a 'definite' CSR diagnostic criterion (i) for inclusion, which resulted in an unadjusted prevalence value of 6.28% (1,465 from 23,317 cases) (Braddom et al., 2009). Kandil et al., (2012) used a 'definite' CSR diagnostic criterion (ii) and reported a prevalence value of 1.21 per 1000 (converted from 121 per 100,000) for males and females combined (95% CI: 88-154) (Kandil et al., 2012). Khedr et al., (2018) utilised 'definite' CSR diagnostic criteria (i) and (ii) for

inclusion. The reported prevalence was 4.8 per 1000 and 1.9 per 1000 for males and females, respectively (Khedr et al., 2018).

Salemi et al., (1996) adopted a 'definite' and 'probable' CSR diagnostic criteria. Definite criteria were based on subjective sensory disturbances and motor weakness correlating with imaging findings. The authors were contacted for further details but there was no response. Salemi et al., (1996) reported an unadjusted prevalence of 1.3 per 1000 and 5.8 per 1000 for males and females respectively with a total of 3.5 per 1000 for both sexes.

2.6.6. Sub-group analysis of probable cervical spine radiculopathy incidence and/or prevalence

Four studies from the nine included studies met a 'probable' CSR diagnostic criteria (Bharucha et al., 1991, Brooks et al., 2005, Sandoughi et al., 2013, Schoenfeld et al., 2012). Two studies (Radhakrishnan et al., 1994, Salemi et al., 1996) combined definitive and probable CSR diagnosis criteria and have been described in sub-group analysis (iii) (Definite CSR criteria). Schoenfeld et al., (2012) included participants with a probable CSR diagnostic criterion (iii) and the combined incidence was 1.79 per 1000 person-years for males and females (Schoenfeld et al., 2012). Bharucha et al., (1991) adopted probable CSR diagnostic criteria of (vi) or (vii) and reported an unadjusted prevalence value of 1.36 per 1000 (converted from 136 per 100,000) (Bharucha et al., 1991). Two studies did not provide sufficient CSR diagnosis definition criteria (Brooks et al., 2005, Sandoughi et al., 2013) and were subsequently not included in either sub-group analysis. Both sets of authors were contacted for further details but did not response to requests.

2.7. Discussion

This is the first systematic review of published and unpublished studies investigating the epidemiology of CSR in an adult population. Incidence ranged between 0.83 (converted from 83.2 per 100,000) to 1.79 per 1000 person-years from three studies (Brooks et al., 2005, Radhakrishnan et al., 1994, Schoenfeld et al., 2012). Prevalence values ranged from 1.21 (converted from 121 per 100,000) to 5.8 per 1000 from four studies (Bharucha et al., 1991, Kandil et al., 2012, Khedr et al., 2018, Salemi et al., 1996). Prevalence values of 1.1% (95% CI: 0.45-1.82) and 1.3% (95%

CI: 0.66-1.96) for males and females respectively were reported from one study (Sandoughi et al., 2013). One study reported an unadjusted prevalence value of 6.3% for males and females (Braddom et al., 2009).

The sampled populations varied across military, elite sport and general populations. Three studies sampled populations from USA, two from general population and one from military personnel (Braddom et al., 2009, Radhakrishnan et al., 1994, Schoenfeld et al., 2012). Two studies sampled from urban and sub-urban districts in Egypt (Kandil et al., 2012, Khedr et al., 2018). The remaining studies recruited people from Sicily (Salemi et al., 1996), India (Bharucha et al., 1991), Iran (Sandoughi et al., 2013) and UK professional sport (rugby union) (Brooks et al., 2005). Two included studies sampled people from military (Schoenfeld et al., 2012) and sporting (Brooks et al., 2005) populations. The largest sample size was in a military population (n=13,813,333) (Schoenfeld et al., 2012). However, Schoenfeld et al.'s, (2012) findings may not be generalisable to civilian populations due to the unique stressors and experiences of military service, such as combat exposure, deployment stress, and transient geographic stability (Rhon et al., 2024). Brooks et al., (2005) sampled professional rugby players. Elite professional athletes engage in long durations of physically intense activity and subsequently are associated with an increased ability to tolerate pain (Pettersen et al., 2020). This may, therefore, in part, explain the lower CSR incidence reported. Furthermore, the diverse populations may, in part, be representative of how the different physiological, societal and/or cultural beliefs related to spinal pain symptoms impact the reporting of illness or pain behaviour.

Studies have suggested that minority groups are more sensitive to pain, which may partially explain the differences in pain reporting observed across different countries, cultures and societies (Edwards et al., 2001, Miller and Abu-Alhaija, 2019). African American people have reported greater sensitivity to various QST methods, including thermal pain, cold pressor pain, ischemic pain, electrical stimulation, and increased temporal summation, while also showing reduced pain tolerance and diffuse noxious inhibitory controls (Rahim-Williams et al., 2012, Weaver et al., 2022).

While there is less experimental data on other groups such as Hispanic Americans and Asian-Americans, recent studies suggest that Asian-Americans may also have lower pain thresholds and tolerance levels compared to non-Hispanic whites,

potentially attributed to differences in endogenous pain regulatory mechanisms (Rowell et al., 2011). People from Asia were more sensitive to cold pressor pain than non-Hispanic whites for both pain threshold and pain tolerance levels ($F(1,56) = 4.21$, $p<0.05$) (Rowell et al., 2011). Women were more sensitive to cold pressor pain than men, regardless of race (threshold: 21.40 seconds vs. 29.23 seconds; tolerance: 86.63 seconds vs. 137.7 seconds; ($p<0.05$) (Rowell et al., 2011). Furthermore, Asians rated the cold pressor task as more unpleasant than Whites, although not statistically significant ($p<0.06$) (Rowell et al., 2011). The underlying physiological aspects of processing and interpreting pain and associated symptoms are important to consider across different populations. Notwithstanding the physiological factors, culture can influence how illness behaviour or pain experiences will also affect the reporting, pain beliefs and accessing medical care.

Culture refers to the beliefs and behaviours of a social group, while recognising the unique qualities of each individual (Hernandez and Gibb, 2020, Peacock and Patel, 2008). People can identify with multiple social groups based on factors like ethnicity, gender, nationality, interests, or sexual orientation (Peacock and Patel, 2008). Culture can also influence health behaviours, such as when and where to seek help, how long to stay in care, and how to evaluate treatment success. Health itself is defined differently across cultures (Sharma et al., 2018). Since 1948 (WHO, 2023) the World Health Organization (WHO) has defined health as a state of complete physical, mental, and social well-being. It is noteworthy that other groups define health more broadly. For example, Ayurveda, a practised Indian system of medicine, views health as a harmony between the body, sense organs, mind, and soul (Sharma et al., 2018). Differences in various sociocultural factors related to patients, from family traditions and religious beliefs to patient preference and previous experiences, influence disparities in pain behaviour and reporting (Callister, 2003, Sharma et al., 2018). Ethnicity may also significantly impact the meaning of CSR and how it is evaluated and reported. In a cross-sectional survey of 127 patients with persistent pain, African Americans have been found to have a stronger connection between emotions and pain behaviour than non-Hispanic whites and report increased levels of depression, disability and pain severity due to various chronic pain conditions (Tan et al., 2005). Some populations (such as African Americans) may be more likely to rely on ‘passive’ coping strategies that can be maladaptive in relation to pain and may lead to increased depression and disability (Tan et al., 2005), such as seeking social support, praying and hoping, and diverting

attention away from pain. In a survey conducted in Australia, Italian-born men were found to be more likely to report frequent (unadjusted Odds Ratio (OR): 1.81, p=0.002), severe spinal pain (unadjusted OR: 1.93, p<0.001) compared to Australian-born men, despite no difference in the prevalence of back pain between the two groups (Stanaway et al., 2011). Therefore, ethnicity, cultural beliefs, and social interactions may offer an explanation on how CSR is reported across different geographical populations. Defining what constitutes good care is an important cultural consideration. By addressing the cultural and ethnic considerations associated with geographical variations, we can make valuable contributions to improving care pathways. Understanding the reasons for geographical variations in CSR should be a priority for future research.

As discussed in **Chapter 1**, CSR attributed to direct or indirect nerve root compression may mean people with CSR experience similar underlying pathology and symptoms as those with lumbar spine radiculopathy. Lumbar spine radiculopathy is generally characterised by somatosensory disturbances originating from the lumbar spine and radiating below the knee (Koes et al., 2007, Schmid et al., 2020). This may include power loss, radicular pain and sensory changes such as allodynia, hypoesthesia and hyperaesthesia, similar to that of CSR (Koes et al., 2007). Compared to CSR prevalence reported in this systematic review, the point prevalence is higher in lumbar spine radiculopathy compared to CSR, at 4.6% to 13.4% and a lifetime prevalence of 1.2% to 43% (Konstantinou and Dunn, 2008). The results of the study by Konstantinou and Dunn (2008) were based on a systematic review with 23 included studies. It is important to be cautious when interpreting the prevalence data for ‘sciatica’ or lumbar spine radiculopathy because there is no agreement on the definition or clinical criteria for this condition or lumbar spine radiculopathy in research, which is consistent with CSR. This lack of consensus on terminology and case definitions may have contributed to the differences in prevalence and incidence. Additionally, the inconsistent use of terminology, diagnostic criteria, and eligibility criteria has led to a heterogeneous patient population in CSR and ‘sciatica’ research studies (Bender et al., 2023). It is important to acknowledge these factors when considering diagnostic, prognosis and treatment options such as physiotherapeutic interventions and pharmaceutical management for these conditions.

The clinical diagnosis and classification of CSR can have a bias towards specific pathoanatomical classifications, for example spondylosis, spinal central or lateral stenosis (Mansfield and Thacker, 2023). Contemporary pain science recognises the complexity of biopsychosocial phenomenon in spinal conditions, with or without radiculopathy. This can present a challenge to both the assessment and treatment of this population (Finnerup et al., 2021, Vardeh et al., 2016). CSR can result in altered afferent and efferent processing at various sites along the neuroaxis, altering sensory and motor functioning, which was discussed in depth in **Chapter 1** (Baron et al., 2017). All studies in this systematic review were varied in the CSR diagnostic criteria employed (small fibre and large fibre), including a combination of sensory disturbances (with or without radicular pain) and/or motor weakness made through imaging or nerve conduction testing. As discussed in **Chapter 1**, small nerve fibre involvement can be present even without large-fibre deficits (Schmid et al., 2020). Solely relying on tests for large nerve fibre integrity may be insufficient when screening for suspected entrapment neuropathies such as CSR (Schmid et al., 2014, Schmid et al., 2020). The diagnostic criteria used by the included studies may have subsequently contributed to the variance observed in prevalence and incidence values in this systematic review.

While CSR may present with both sensory and motor dysfunction, it is important to note that there may be distinct subtypes with varying types of pain (such as nociceptive or neuropathic), as discussed in **Chapter 1**, which may respond differently to different treatment approaches. There are various drug treatments to address NeP, including antidepressants, gabapentinoids, sodium channel blockers, capsaicin, and opioids. The effectiveness of these treatments is measured by the number needed to treat (NNT), which varies from 3.6 to 6.4 (Binder and Baron, 2016). Importantly, some of the benefits of these pharmacology treatments may include improvements in mood and anxiety reduction, as people with NeP often experience depression and anxiety (Binder and Baron, 2016). The association of psychological factors and CSR are discussed further in **Chapters 1** and **3**. A study by Martini et al., (2013) have reported that people with postherpetic neuralgia or diabetic polyneuropathy who were treated with a capsaicin 8% patch responded differently from those who received a capsaicin 0.04% patch (Martini et al., 2013). There were four to five distinct groups of responders, including non-responders and those who experienced a full analgesic response. Compared to the placebo group, there were 40% fewer non-responders and 25% more full responders, indicating

that certain treatments can be highly effective for specific sub-groups of people (Martini et al., 2013). However, the absence of positive trials for effectively managing NeP may be related to limited drug efficacy (Bannister et al., 2020), heterogeneous diagnostic criteria (Scholz et al., 2019), and poor phenotyping (Attal and Bouhassira, 2019). Despite this, certain treatments can help specific sub-groups of people with NeP.

The included studies provided limited details on how 'somatosensory' assessment was completed. Using mechanical, vibration and thermal detection thresholds in maximal pain areas can accurately identify dominant nociceptive or NeP mechanisms in people with low back pain (Spahr et al., 2017). Mechanical two-touch discrimination examination scores indicated a significant increase in sensory thresholds to tactile stimulation ($p=0.029$) among people with chronic low back pain (CLBP). This suggests a loss of tactile sensitivity. Furthermore, the scores also showed a significant increase in thresholds to two-point discrimination in people with CLBP compared to controls ($p=0.002$) (Spahr et al., 2017). Additionally, the two-point examination scores indicated a significant increase in sensory thresholds to tactile stimulation in individuals with dominant neuropathic low back pain as opposed to those with dominant nociceptive low back pain ($t=-2.84$, $p=0.006$) (Spahr et al., 2017). A cross-sectional study involving 23 individuals diagnosed with cervical spine nerve root six (C6) CSR found that there was a significant reduction in vibration and mechanical detection sense on the side where they experienced the most pain compared to the other side (T-test: VDT: $p=0.003$; MDT: $p=0.021$) (Tampin et al, 2013). Identifying different types of CSR in individuals based on their specific mechanisms could improve diagnosis and further our knowledge of this complex condition, making it an important area for future research (Vardeh et al., 2016).

In **Chapter 1,** QST, a method used to support our understanding of the underlying pain mechanisms, was discussed. A consensus by IASP reported that QST can provide unique and important information about the somatosensory system (Attal et al., 2013). This information can be valuable in assessing people who experience pain and related nerve-related symptoms. Firstly, it can differentiate between people with or without pain (Attal et al., 2013). It can also help to sub-group chronic pain. Secondly, similar biopsychosocial mechanisms affect both clinical pain and QST responses. Thirdly, QST measures can predict the development or severity of clinical pain in the future. Lastly, QST measures can predict and reflect responses

to pain treatment. In a systematic review of 37 studies (n=3860), QST predicted musculoskeletal pain (mean r=0.31, 95%CI: 0.23 to 0.38) and disability (mean r=0.30, 95%CI: 0.19 to 0.40). Baseline modalities quantifying central mechanisms such as temporal summation (TS) and conditioned pain modulation (CPM) were associated with follow-up pain (TS: mean r=0.37, 95% CI: 0.17-0.54; CPM mean: r=0.36, 95% CI: 0.20 to 0.50), whereas baseline mechanical threshold modalities were predictive of follow-up disability (mean r=0.25, 95% CI: 0.03-0.45). A case-control study of 48 people with knee osteoarthritis undergoing total knee replacement surgery found that, prior to the surgery, those with osteoarthritis experienced more pain sensitivity than the healthy controls, both in the affected and unaffected areas of their body (King et al., 2013). Following surgery, the pressure pain thresholds of people with osteoarthritis increased on both sides of their body. Prior to the surgery, people with osteoarthritis did not exhibit any CPM, unlike healthy controls. However, after surgery, the CPM was normalised in people with osteoarthritis, indicating a reduction in pain (King et al., 2013). Accordingly, successful treatment has corrected the dysfunctional pain processing that causes and contributes to clinical pain.

In an entrapment neuropathy model, the sensory phenotype assessed through QST was associated with patient-reported symptoms and demonstrated statistically significant, clinically relevant change after disease-modifying intervention (surgery) (Kennedy et al., 2021, Tanigor et al., 2022). In addition, even though entrapment can be detected through electrophysical studies and imaging, the sensory characteristics found through QST were independent of the severity of the disease (Tanigor et al., 2022). Moreover, a recent systematic review, with meta-analysis surrounding the use of QST in individuals with joint pain, reports an association between depression, pain catastrophising, and physical activity level with several QST measures; therefore, such variables need to be acknowledged when evaluating the relationship between pain and somatosensory function (Weaver et al., 2022). Systematic reviews have reported central hypersensitivity (abnormal pain response) as a prognostic factor for poor outcomes in musculoskeletal pain (Lim et al., 2011, Mallen et al., 2007). Central mechanisms are reported to contribute to the development of persistent pain (pain that has lasted longer than three months) from acute pain, making early detection of such involvement critical for accurate prognosis and allocation of appropriate management strategies to mitigate the risk at an earlier stage. The potential of QST to distinguish between peripheral and

central factors that contribute to pain, and its ability to guide targeted therapies, highlights the importance of further incorporating it in research and clinical practice. Utilising components of QST in clinical assessment may facilitate clinicians to identify sensory function changes leading to increased pain, which will help enhance our understanding of the physiological mechanisms underlying conditions such as CSR.

Quantitative sensory testing may be useful in differential diagnosis and mapping of the anatomical distribution of sensory changes (for example, hypoesthesia), with QST as a means of identifying the source of the pathological findings in the peripheral nerve, plexus, root, and central (spinal or cerebral) nervous system (Schmid et al., 2020). A systematic review and meta-analysis of 34 studies has reported an association between a person's baseline QST and their musculoskeletal pain and disability (Georgopoulos et al., 2019). The meta-analysis reported an unadjusted correlation of 0.30 (95%CI: 0.19, 0.40) between baseline QST and disability (Neck Disability Index) outcome in adults with neck pain (Georgopoulos et al., 2019). Pain hypersensitivity can be a predictor of a person's prognosis across a range of musculoskeletal conditions, including osteoarthritis, LBP, neck pain, and post-operative pain (Georgopoulos et al., 2019). These findings suggest that pain hypersensitivity could play an important role in determining a patient's outcome.

Questionnaires or assessment tools can also be used (Freynhagen et al., 2006) to support the identification of underlying pain mechanisms and support diagnosis formulation (Gierthmuhlen et al., 2019). One such tool is the painDETECT questionnaire. This is a reliable tool designed to identify NeP by assigning patients a score and categorising their pain into three groups: neuropathic, unclear, or non-neuropathic (nociceptive) pain (Maier et al., 2010). From 136 individuals (mean [SD] age: 56.8 [15.2]; 54% male), there was almost perfect agreement between the total scores at first measurement and second measurement one week later (ICC 0.91; 95% CI: 0.88-0.94). Interestingly, none of the included studies in this systematic review detailed such psychophysical testing paradigms or questionnaires to support the establishment of CSR diagnosis. This will be further explored in **Chapter 4** (quantitative survey) and **Chapter 5** (qualitative interviews) to understand some of the possible reasons why clinicians may or may not select questionnaires as part of CSR diagnosis formulation.

2.8. Strengths and limitations

The systematic review has several strengths. Firstly, this was the first systematic review to investigate the epidemiology of CSR. Due to the relatively limited amount of research involving this patient population, this systematic review is important in improving our understanding of the impact of CSR and support the planning of healthcare service provision. Secondly, the CSR diagnostic criteria across the available literature were varied. Consequently, this systematic review has identified areas for future CSR assessment consensus. Thirdly, the systematic review followed a robust systematic review without a meta-analysis framework, which enhances the reporting and subsequent trustworthiness of the results.

Despite a systematic and rigorous approach to the literature searching, which included electronic databases, hand searching, grey literature and contacting authors to minimise bias, there are a number of potential limitations to this review. This systematic review has identified areas for future research related to identifying CSR in clinical practice. Furthermore, the systematic review included studies that included people with CSR at any timeline from diagnosis (i.e., acute, subacute or persistent CSR). Although most studies were conducted after three months of CSR diagnosis (persistent CSR), the inclusion of research studies across all timelines of CSR further improves our understanding of how to assess and manage people with CSR more effectively.

Ten studies met the inclusion criteria. However, one study was excluded as the authors did not respond to our request for further information on data collection methods. It is anticipated that this information would not have changed the results greatly, although it may have enhanced the reporting. Furthermore, the included studies had insufficient homogeneous data to complete a meta-analysis. Therefore, the narrative analysis was based on the small number of heterogeneous studies, which was appropriate for this study. However, if there were sufficient homogeneity, this may have facilitated a meta-analysis (Egger et al., 1997). By utilising a statistical methodological approach, outlined earlier in this chapter, a meta-analysis provides a precise estimate of the effect size. However, as heterogeneity was evident, this was not appropriate and therefore not undertaken.

The search strategy included English language (or translatable to English) studies. It is acknowledged that this may have resulted in some relevant studies being excluded and could have introduced language bias into our review. This is a frequent limitation with non-international review teams. A survey reviewing 123 systematic reviews reported that 108 reviews did not explicitly exclude, and of these 17 included non-English language studies (Neimann Rasmussen and Montgomery, 2018). One factor correlated with the number of included non-English studies across all models: the number of countries in which the members of the review teamwork (B-value: 0.56 95% CI: 0.07–1.03; p=0.02) (Neimann Rasmussen and Montgomery, 2018). This indicates that reviews which included non-English studies were more likely to be produced by international review teams. Despite this, the updated search for this systematic review did not add any further evidence to enhance the prevalence or incidence data of CSR.

2.9. Conclusion

There was considerable variability in incidence and prevalence values for CSR. This can be attributed to wide-ranging diagnostic criteria and population sampling methods. There is limited consistency showing that females are more likely to experience CSR compared to males. However, caution should be taken as the epidemiological data is based on a small number of heterogeneous studies with prevalence values ranging from 1.07 to 1.76 per 1000 and 0.63 to 5.8 per 1000 for males and females, respectively. Further research is indicated in standardising diagnosis classification criteria and analysing other populations globally to further our understanding of this debilitating condition.

2.10. Next steps

This systematic review has provided valuable insights to support the design of the next steps in this programme of research. The findings of this review supported the development and implementation of a systematic review investigating how mental health conditions may influence health outcomes in people with neck pain and CSR (**Chapter 3**). Furthermore, the variance in diagnostic criteria informed the development of a survey of current practice investigating UK physiotherapists' methods of CSR diagnosis (**Chapter 4**). The next two chapters will report the

systematic review protocol and findings of the association of mental health conditions and health outcomes among people with neck pain and CSR.

Chapter 3: Association of psychosocial factors and mental health symptoms with health outcomes in adult cervical spine pain with or without radiculopathy: systematic review

3.1. Introduction

This chapter reports the methods, results and considerations of a systematic review assessing the association between psychosocial factors or mental health symptoms in adults with cervical spine pain with or without radiculopathy (CSp±R). The background and justification for this systematic review are built upon the discussions in **Chapters 1 and 2**.

3.2. Background

Chapter 2 presented the incidence and prevalence estimates for CSR in an adult population. Incidence ranged between 0.83 to 1.79 per 1000 person-years. Prevalence values ranged from 1.21 to 5.8 per 1000 and between 1.1% (95% CI: 0.45-1.82) and 1.3% (95% CI: 0.66-1.96) for males and females, respectively. The global prevalence of neck pain and years lived with disability has increased by 18.7% and 18.6% respectively between 1990 and 2019 (Shin et al., 2022). These findings suggest that the health outcomes associated with neck pain with or without radiculopathy (CSp±R) are not improving globally.

Chapter 1 discussed how psychosocial factors encompass a wide range of characteristics such as people's beliefs, emotions, behaviours and family and workplace aspects (Martikainen et al., 2002), and that mental health symptoms or conditions are an extension of such factors. A systematic review investigating the global number of disability-adjusted life-years due to mental health conditions reported an increase between 1990 and 2019, from 80·8 million (95% CI: 59·5–105·9) to 125·3 million (95% CI: 93·0–163·2). The proportion of global disability-adjusted life-years attributed to mental health conditions increased from 3.1% (95% CI: 2·4–3·9) to 4·9% (95% CI: 3·9–6·1) (Shin et al., 2022). In an adult population survey across 17 countries in Europe, the Americas, the Middle East, Africa, Asia and the South Pacific (*N* = 85,088), people with back or neck pain were more likely

to suffer from mood, anxiety and alcohol disorders compared to those without these pain conditions (Demyttenaere et al., 2007). The pooled odds ratios (ORs) were 2.3 (95% CI: 2.1–2.4) for anxiety disorders in people with versus without chronic back/neck pain (Demyttenaere et al., 2007). However, it was unclear how these findings related to the severity of spinal pain reported by people. Furthermore, this survey was cross-sectional and therefore findings should not be interpreted as casual relationships between back and neck pain and mental disorders.

A systematic review (Wong et al., 2022), based on the guidance of the Cochrane Prognosis Group, included 62 studies (n=63,326 participants), reporting that, for acute low back pain (LBP), depressive symptoms were associated with self-reported disability (OR: 1.15, 95% CI: 0.97–1.36) and worse recovery (hazard ratio (HR): 0.94, 95% CI: 0.91–0.97). Depressive symptoms were associated with greater primary healthcare utilisation for acute LBP (rate ratio=1.04, 95% CI: 1.02–1.07). For chronic LBP, depressive symptoms were associated with higher pain intensity (β: 0.16, 95% CI: 0.04–0.29), and worse recovery (relative risk (RR): 0.91, 95% CI: 0.88–0.95). This systematic review provides prognostic factor information to guide assessment and management among patients and healthcare providers for LBP, which may improve disability and recovery in persons with LBP.

As discussed in **Chapter 1**, CSp±R has significant negative impacts on a person's physical and mental health and well-being and is an enormous burden for individuals, families and societies (Carroll et al., 2008, Cote et al., 2004, Hogg-Johnson et al., 2009). In a cross-sectional survey of 1,308 patients in primary care, depression and anxiety was present as a co-morbidity in 20% of participants, and 28% reported anxiety related to their CSp±R (Blozik et al., 2009). External validity will be limited to other populations as the findings are from Germany. **Chapter 1** also detailed how people with radicular pain report that their "life is on hold", question their "life purpose" and consider suicidal thoughts (Ryan and Roberts, 2019). The burdensome impact of CSp±R on health outcomes has not been investigated. At the time of planning this study, no systematic review had examined the association between psychosocial factors and/or mental health symptoms in adults with CSp±R on health outcomes. A systematic review will enhance our understanding and considerations for the clinical assessment of these burdensome conditions. The rationale around a systematic review methodology has been discussed in **Chapter 2**.

3.3. Aim and objectives

The aim of this study was to conduct a systematic review to assess the association between psychosocial factors and/or mental health symptoms and health outcomes in adults with CSp±R. Specifically, the objectives were to:

i. Identify which psychosocial factors and/or mental health symptoms are associated with CSp±R in adult populations.
ii. Assess the quality of included studies' design, completed methodology and reporting.
iii. Compare and contrast the clinical assessment classification of CSR in the included studies.

3.4. Methods

The registration of this systematic review was published in the PROSPERO review database (Reference: CRD42020169497). The transparency of reporting for systematic reviews was discussed in **Chapter 2**. This systematic review adhered to the PRISMA guidelines for reporting (Page et al., 2021). The review protocol was published (Mansfield et al., 2021). The systematic review team individuals and expertise have been previously outlined in **Chapter 2**.

3.4.1. Eligibility criteria – population

This systematic review retrieved studies with cohorts including adults aged 18 years and over with CSp±R. It was anticipated that there would be variance in the definition of CSp±R across geographical locations, clinical settings and from a historical standpoint. For example, IASP defines cervical spine pain as pain perceived anywhere in the posterior region of the cervical spine, from the superior nuchal line to the first thoracic spinous process (Merskey and Bogduk, 1994). The Bone and Joint Decade 2000-2010 Task Force on Neck Pain, however, describes cervical spine pain as the posterior neck region from the superior nuchal line to the spine of the scapula and the side region down to the superior border of the clavicle and the suprasternal notch (Nordin et al., 2009). All potentially eligible studies and a consensus decision were retrieved on the CSp±R diagnosis. At the time of writing

this systematic review, there was no consensus on CSR diagnosis (discussed in **Chapters 1 and 2**). Therefore, a pragmatic approach was taken to include studies with probable or definite CSR diagnosis adapted from IASP and the North American Spine Society (Bono et al., 2011, Scholz et al., 2019) (**Table 3.1**). People with CSp±R as a result of an upper motor neuron lesion, fracture, radiculitis, myelopathy, post-surgery, whiplash associated disorder (WAD), systemic pathology or metabolic diseases such as diabetes (including pre-diabetes) were excluded as discussed in **Chapter 2**.

Table 3.1 Modified cervical spine radiculopathy diagnostic criteria

CSR category	Signs and symptoms domains		
Definite CSR Either (i) or (ii)	(i) Acute denervation with EMG studies or sensory changes in a dermatomal distribution. AND Weakness, atrophy or fasciculation in a myotomal distribution and Unilateral diminished deep tendon reflexes.	(ii) Abnormal myelography, CT or MRI correlating with radiculopathy with neck pain or combined neck and arm pain. OR Paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy.	
Probable CSR Either (i i i) (iv) or (v)	(i i i) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy. With Sensory changes in dermatomal distribution or muscle weakness in a myotomal distribution or atrophy or fasciculation in a myotomal distribution or unilateral diminished deep tendon reflexes.	(iv) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy. With Abnormal myelography, CT or MRI correlating with radiculopathy.	(v) Neck pain or neck and arm pain with two from: (v-i) Sensory changes in dermatomal distribution. (v-ii) Muscle weakness in a myotomal distribution or atrophy. (v-iii) Fasciculation in a myotomal distribution . (v-iv) Unilateral diminished deep tendon reflexes.

Table abbreviations. CSR: Cervical spine radiculopathy; CT: Computed Tomography; EMG: Electromyography; MRI: Magnetic Resonance Imaging

3.4.2. Eligibility criteria – exposure

As discussed in **Chapter 1**, it was acknowledged that there is no consensus in the available literature on the definition and agreed psychosocial factors. The literature review presenting the 'flags' based psychosocial framework (NAS, 1997) was used to inform the eligibility criteria for psychosocial factors and associated mental health symptoms or illnesses. Studies were included if they assessed psychosocial factors or mental health symptoms as an exposure. Studies were required to investigate one or more psychosocial or mental health symptoms (or condition). Psychosocial factors including cognitive (neuropsychological functioning), affective (e.g., distress, mood), behavioural (e.g., coping strategies), vocational (e.g., job satisfaction, self-perceived work ability) or interpersonal processes (e.g., social support) (Upton, 2013) were considered. Mental health symptoms and conditions such as depressive symptoms, clinical depression, anxiety symptoms, perceived stress, personality, psychotic, traumatic and/or eating disorders were also potentially eligible. Self-reported, objective standardised questionnaires (e.g., Beck Depression Index, Karasek's Job Control Questionnaire, GHQ-12) and/or psychosocial factors or mental health symptoms using dichotomous data ('yes/no') were considered.

3.4.3. Eligibility criteria – outcome

To date, there are no core outcome sets for CSp±R. Therefore, health outcomes for this systematic review were informed by, but not limited to, core outcome measurements for clinical trials with non-specific low back pain (Chiarotto et al., 2018) and the Initiative on Methods Measurement and Pain Assessment in Clinical Trials for pain (Dworkin et al., 2005). These domains are not designed specifically for CSp±R, but intended to guide this review's data collection and analysis in the absence of a core health outcome set for CSp±R. The core outcomes domains for osteoarthritis, low back pain and pain are presented in **Table 3.2**.

Table 3.2 Health outcomes measurement for non-specific low back pain and pain clinical trials

Non-specific low back pain (Chiarotto et al., 2018)	**Pain trials (Dworkin et al., 2005)**
Physical functioning	Pain intensity
Pain intensity	Physical functioning
Health related quality of life	Emotional functioning
	Care utilisation
	Patient perceived quality of life

The domains encompassed for this review included: pain, using instruments such as example Visual Analogue Scale (VAS), Numeric Pain Rating Scale (NRS) (Jensen and McFarland, 1993); disability, such as Neck Disability Index (NDI) (Vernon and Mior, 1991), Disability of Arm and Shoulder Index (DASH) (Hudak et al., 1996); International Physical Activity Questionnaire (IPAQ) (Hagströmer et al., 2006); health status, for example 36-item Short Form Survey (SF-36) (Jenkinson et al., 1994), 12-item Short Form Survey (SF-12) (Ware et al., 1996). Healthcare utilisation (such as clinician visits, spinal imaging, hospital length of stay) was also reviewed. All studies were required to be published in the English language (or able to be translated into English). No publication date or study setting restriction was applied. The rationale for English studies and publication date is outlined in **Chapter 2**.

3.4.4. Eligibility criteria – exclusion criteria

People with CSp±R as a result of an upper motor neuron lesion, fracture, radiculitis, myelopathy, post-surgery, whiplash-associated disorder (WAD), systemic pathology or metabolic diseases such as diabetes (including pre-diabetes) were excluded. Studies were excluded if they were animal or cadaveric studies, commentaries, editorials, single-case study's, reports or laboratory data, books or book chapters, letters, conference posters or proceedings that did not have a full methodology and data sets available on request, lecture slides, study protocols, social media postings (including blogs) or online learning material (e.g., massive online learning sites, videos). The decision-making around the exclusion criteria is presented in **Chapter 2**.

3.4.5. Search strategy – information sources

The lead reviewer (MM) developed and collated the search terms. All corresponding authors then reviewed this to reach an agreement and consensus. A systematic search of electronic databases EMBASE, CINAHL, MEDLINE (PubMed) from inception to 1st September 2022 was led by MM. The search strategy was repeated using the same databases and search terms for the period from September 2022 to August 2023 to update for the submission of this thesis.

The MEDLINE (PubMed) search strategy is presented in **Appendix 3.1**. **Chapter 2** discusses the rationale for completing reference checking and expert author contact. All included studies underwent reference checking; there were no additional articles included in this review. When formal study inclusion has was completed, 'expert' authors in the field were contacted by email requesting any pending articles and/or missing data. In this CSR systematic review, all lead authors from the 23 included studies were contacted by email (**Appendix 3.2**). After 15 working days, there were no responses. Four email addresses were automatically returned, suggesting the contact details no longer exist. An unpublished (grey) literature search and trial registry were also completed (WHO.It, OpenGrey and NIHR). The justification for this decision is discussed in **Chapter 2**. No additional studies were included from this search.

3.4.6. Data collection – study selection

For this systematic review, we uploaded the search strategy results into the Rayann systematic review online platform (https://www.rayyan.ai). Although it is acknowledged that the sample size of survey respondents was small, we opted to utilise Rayann for this systematic review as a practical choice. This decision was made because it is a cost-zero tool and been utilised by the study selection team in the past (Mansfield et al., 2018). Two reviewers (MM, TS) independently reviewed, checked titles and abstracts and documented decisions on study eligibility using an abstract screening tool designed by MM (**Appendix 3.3**). The same two reviewers independently reviewed all potentially eligible full-text papers to determine final inclusion. A third reviewer (MT) was available to review any disagreements.

3.4.7. Data extraction

In conducting this systematic review, a previous systematic review on the patient health outcomes in spinal pain was considered (Boyle et al., 2021). This study was selected as the outcomes and populations included were similar to those of this review. Furthermore, the background literature review on health outcomes presented earlier in this chapter informed the theme generation of this data extraction. This informed the design of this systematic review's data extraction form. To support decision-making, one data extraction table was created (**Appendix 3.4**), and for each data item, there was a clear description and expectations for what should be extracted. As discussed in **Chapter 2**, the reasons for utilising two reviewers are outlined. Two reviewers (MM, JT) independently extracted data from included studies. The same two reviewers discussed the data extracted and reached a consensus through discussion. MT was available if there were any unresolvable disagreements, of which there were none. **Supplementary file 3.1** presents the independent data extraction forms. Highlighted in yellow are the areas where our independent data extraction differed. **Supplementary file 3.2** documents the discussion and agreed resolution.

3.4.8. Methodological quality

The quality assessment of studies included in systematic reviews is essential to enable a clear understanding of the evidence base, which was discussed in **Chapter 2**. The Newcastle-Ottawa Scale (NOS) was used in this systematic review. This was justified as the ICC for NOS demonstrated moderate overall inter-rater reliability with an ICC of 0.73 (Hootman et al., 2011, Oremus et al., 2012). Two reviewers (MM, TS) independently assessed the quality of each included study using NOS. Any disagreement between reviewers was discussed between the two reviewers (MM, TS). A consensus was reached through a discussion between the two reviewers. A third reviewer (MT) was available to act as adjudicator but was not required. There were five disagreements between the two reviewers. Disagreements were around the items 'population representativeness,' 'outcome of interest' and 'length of follow-up'. Each were resolved through discussion and consensus was achieved. The quality appraisals spreadsheet is presented in **Supplementary file 3.3**. The yellow highlights identify the discrepancies.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to assess the quality of evidence for a specific outcome across studies in a systematic review (Balshem et al., 2011, GRADE, 2023, Guyatt et al., 2011, Imberger and McGain, 2019). Initially, evidence from randomised control trials (RCTs) is considered high quality. However, it can be downgraded based on five factors: risk of bias, inconsistency, indirectness, imprecision and publication bias (Guyatt et al., 2016, Imberger and McGain, 2019). Conversely, evidence from non-randomised studies is initially rated as low quality, but it can be upgraded if no other limitations are identified based on the five factors mentioned above (Guyatt et al., 2008). Importantly, the certainty of evidence is evaluated for each outcome measure by combining data from all studies included, rather than on an individual study basis (GRADE, 2023, Imberger and McGain, 2019). Following this process, the quality of evidence for each outcome is rated as very low, low, moderate or high. GRADE was used in this systematic review because it enhances the transparency of certainty of outcomes of the included studies in this review. For this systematic review, the lead researcher (MM) completed the GRADE assessment, which MT subsequently verified. There were no disagreements on the ratings applied to each sub-group.

3.4.9. Synthesis

Similarly to **Chapter 2**, MM led the clinical heterogeneity assessment, with TS as a second independent reviewer of the included studies. All included studies were assessed from a clinical perspective (e.g., diagnosis, variability in population characteristics) and study methodology in determining whether studies could be pooled in a meta-analysis. Both reviewers agreed on the existence of significant clinical heterogeneity with data collection methods and CSp±R definitions, resulting in a decision that meta-analysis was inappropriate. Data were, therefore, narratively analysed using the SWiM tool (Campbell et al., 2020) as a framework for analysis.

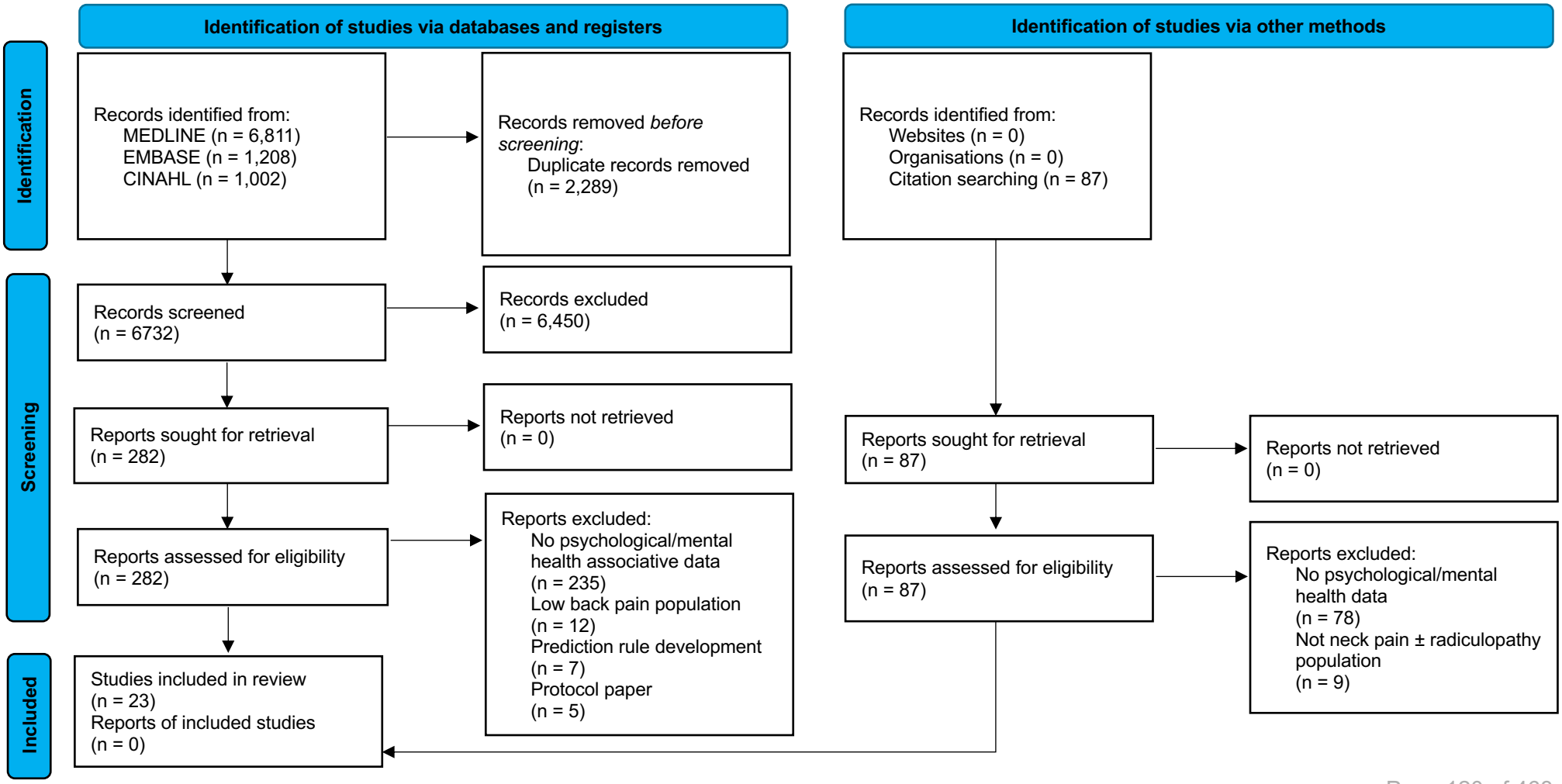
Following the literature reviews in **Chapters 1 and 2**, it was anticipated that mixed sample populations were likely to be retrieved during this systematic review. An analysis of studies with cervical spine pain and radiculopathy was completed as an additional sub-group analysis.

3.5. Results

The results of the search strategy are presented in **Figure 3.1.** A total of 6,732 studies were identified and screened. Of these, 6,450 were excluded from the title and abstract. Of the remaining 282 full-text studies reviewed, 259 were excluded. Twenty-three studies met the inclusion criteria and were included in the review (Alipour et al., 2009, Beltran-Alacreu et al., 2018, Bohman et al., 2019, Carroll et al., 2004, Diebo et al., 2018, Divi et al., 2020, Elbinoune et al., 2016, Engquist et al., 2015, Grimby-Ekman et al., 2009, van den Heuvel et al., 2005, Hoe et al., 2012, Hill et al., 2007, Hurwitz et al., 2006, Kim et al., 2018, Lee et al., 2007, MacDowall et al., 2018, Meisingset et al., 2018, Myhre et al., 2013, McLean et al., 2011, Peolsson et al., 2006, Pico-Espinosa et al., 2019, Rodriguez-Romero et al., 2016, Wibault et al., 2014).

Figure 3.1 2020 PRISMA flow diagram for new systematic reviews, which included searches of databases, registers and other sources

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement



3.5.1. Study characteristics

A total of 21,968 participants were recruited across the 23 included studies. There were 17,604 participants with non-specific neck pain and 4,364 participants with CSR. Sixteen studies included neck pain populations, five were cohort study designs (Alipour et al., 2009, Bohman et al., 2019, Grimby-Ekman et al., 2009, McLean et al., 2011, van den Heuvel et al., 2005) and 11 were cross-sectional study designs (Beltran-Alacreu et al., 2018, Carroll et al., 2004, Elbinoune et al., 2016, Hill et al., 2007, Hoe et al., 2012, Hurwitz et al., 2006, Lee et al., 2007, Meisingset et al., 2018, Myhre et al., 2013, Pico-Espinosa et al., 2019, Rodriguez-Romero et al., 2016). Of the seven studies that included CSR populations, five were observational (Diebo et al., 2018, Divi et al., 2020, Kim et al., 2018, Peolsson et al., 2006, Wibault et al., 2014) and two were secondary analyses of healthcare records (Engquist et al., 2015, MacDowall et al., 2018). The characteristics of the included studies are presented in **Table 3.3.**

Seven studies recruited participants with CSR who were identified from waiting lists for elective spinal surgery. The diagnosis of CSR was established through neurological imaging and clinical examination, indicating a deficit (Diebo et al., 2018, Divi et al., 2020, Engquist et al., 2015, Kim et al., 2018, MacDowall et al., 2018, Peolsson et al., 2006, Wibault et al., 2014).

Nine studies measured depressive symptoms (Bohman et al., 2019, Carroll et al., 2004, Elbinoune et al., 2016, Engquist et al., 2015, Kim et al., 2018, MacDowall et al., 2018, McLean et al., 2011, Pico-Espinosa et al., 2019, Wibault et al., 2014). Five studies measured anxiety symptoms (Alipour et al., 2009, McLean et al., 2011, Elbinoune et al., 2016, MacDowall et al., 2018, Wibault et al., 2014) and three studies measured job strain and stress (Grimby-Ekman et al., 2009, van den Heuvel et al., 2005, Hoe et al., 2012). Three studies used the psychological components of SF-36 (Diebo et al., 2018, Lee et al., 2007, Rodriguez-Romero et al., 2016). Two studies used the psychological components of SF-12 (Divi et al., 2020, Hoe et al., 2012). One study measured kinesiophobia (Beltran-Alacreu et al., 2018) and one study measured catastrophising (Meisingset et al., 2018). Three studies used more than one mental health symptom measurement (McLean et al., 2011, Elbinoune et al., 2016, Hoe et al., 2012). The mental health symptoms and tools to measure the

severity of mental health conditions across the 23 included studies are presented in **Table 3.3. Table 3.4** presents the associative data for each included study.

Table 3.3 Included study characteristics

Author and year	Study location	Total population number	Male (M): Female (F)	Mean age (years)	Spinal diagnosis	Mental health diagnosis or symptoms	Mental health measurement	Health outcome
Alipour (2009)	Sweden	12,184	11,562M; 581F	29	Non-specific neck pain	Anxiety symptoms	Nordic Musculoskeletal Questionnaire	Sick Leave from employment
Beltran-Alacreu (2018)	Spain	128	23M; 105F	42.7 (SD: 12.0)	Non-specific neck pain	Kinesiophobia	Tampa Scale Kinesiophobia	Presence of pain (NPRS)
Bohman (2019)	Sweden	89	89F	Median 52 (IQR: 47-59)	Neck pain for 3 months or longer	Depressive symptoms	Montgomery-Asberg Depression Rating Scale	Neck Disability Index
Carroll (2004)	Canada	781	400M; 381F	44.5 (SD: 13.5)	Non-specific neck pain	Depressive symptoms	Centre for Epidemiological Studies-Depression	Development of pain (NPRS)
Diebo (2018)	USA	375	121M; 254 F	65.4 (SD: 10.2)	Cervical spine radiculopathy	Psychological outcomes with SF-36	SF-36 Mental Health Component (MHC)	Neck Disability Index (NDI)
Divi (2020)	USA	264	123M; 141F	53	Cervical spine radiculopathy	Psychological outcomes with SF-12	SF-12 Mental Health Component (MHC)	Neck Disability Index (NDI)
Elbinoune (2016)	Morocco	80	23M; 67F	51.8 (SD: 11.8)	Neck pain for 3 months or longer	Anxiety and depressive symptoms	Hospital Anxiety and Depression Scale	Presence of Pain (NPRS)
Engquist (2015)	Sweden	60	30M; 30F	46 (SD:9)	Cervical radiculopathy	Depressive symptoms	Zung Depression Scale	Neck Disability Index
Grimby-Ekman (2009)	Sweden	1200	573M; 627F	19-25	Non-specific neck pain	Stress	Mood scale	Presence of pain (NPRS)
Hill (2007)	UK	346	127M; 219F	51 (IQR 23-84)	Non-specific neck pain	Psychological distress	SF-12 MCS	Presence of pain (NPRS)

Hoe (2012)	Australia	1111	15M; 350F	41.1 (SD: 11.8)	Non-specific neck pain	Job strain & SF-12 MCS	SF-12 Mental health component	Presence of pain (NPRS)
Hurwitz (2006)	USA	336	105M; 231 F	45.7 (SD: 12.0)	Non-specific neck pain	SF-36 Mental health	SF-36 Mental health	Neck Disability Index
Kim (2018)	USA	57	29M; 28F	60 (SD: 12.1)	Cervical spine radiculopathy	Depressive symptoms	Zung self-rated depression scale	Neck Disability Index and Numeric Pain Rating Score
Lee (2007)	Hong Kong	120	49M 71F	40.0 (SD: 10.0)	Non-specific neck pain	Psychological distress	SF-36 Mental Component Scale	Presence of pain (NPRS)
MacDowall (2018)	Sweden	153	75M; 78F	47.0 (SD:6.9)	Cervical radiculopathy	Anxiety and depressive symptoms	Hospital Anxiety Depression Scale	Neck Disability Index
McLean (2011)	UK	151	61M; 90F	53.9 (SD 14.4)	Neck pain for 3 months or longer	Anxiety and depressive symptoms	Hospital Anxiety Depression Scale	Disability of arm and shoulder (DASH)
Meisingset (2018)	Norway	70	28M; 52F	43.2 (SD: 12.6)	Non-specific neck pain	Catastrophising	Pain Catastrophising Scale	Pain (NPRS)
Myhre (2013)	Norway	373	200M; 173F	40.9 (SD: 9.8)	Non-specific neck pain	Emotional distress	Hopkins Check List-10	FABQ-W
Peolsson (2006)	Sweden	23	15M; 8F	51 (SD: 11.2)	Cervical spine radiculopathy	Distress	Distress and risk assessment method (DRAM)	Neck Disability Index
Pico-Espinosa (2019)	Sweden	617	191M; 426F	46	Non-specific neck pain	Depressive symptoms	Hospital Anxiety Depression Scale	Pain levels (NPRS)
Rodriguez-Romero (2016)	Spain	206	112M; 94F	23.5 (SD: 4.1)	Non-specific neck pain	Psychological outcomes with SF-36	SF-36	Presence of pain (NPRS)
van den Heuvel (2005)	Netherlands	787	Not reported	Not reported	Non-specific neck pain	Job strain	Self-reported	Presence of neck and upper limb pain shoulder pain (NPRS)

Wibault (2014)	Sweden	201	105M; 96F	50 (SD: 8.4)	Cervical spine radiculopathy	Depression and Anxiety	Zung self-rated depression scale and Somatic Perception Questionnaire	Neck Disability Index

Table abbreviations. CSR: Cervical spine radiculopathy; FABQ-W: Fear-Avoidance Beliefs Questionnaire-Work; IQR: Inter Quartile Range; NPRS: Numeric Pain Rating Score; SD: Standard Deviation; SF-36: Short-Form 36.

Table 3.4 Included studies associative data

Author and year	Associative data between health outcome and mental health
Alipour (2009)	OR: 1.4 (95% CI: 0.9-2.1)
Beltran-Alacreu (2018)	Association kinesiophobia and presence of pain (r= 0.566)
Bohman (2019)	OR: 0.94 (95% CI: 0.86-1.03)
Carroll (2004)	Hazard Rate Ratio 3.97 (95% CI: 1.81-8.72)
Diebo (2018)	When NDI is low MHC = 25.81 (SD: 8.85) When NDI is high MCS = 25.60 (SD: 8.87)
Divi (2020)	MHC low score 23.9 (95% CI: 21.0-26.7) vs MHC high score 31.8 (95% CI: 24.7-38.9) (p=0.04)
Elbinoune (2016)	HADS-Anxiety OR: 1.02 (95% CI: 0.98-1.05) HADS-Depression OR: 1.02 (95% CI: 0.98-1.06)
Engquist (2015)	No risk of depression 4 (95% CI: -4 to 15) At risk of depression 10 (95% CI: 1-19) (p=0.3)
Grimby-Ekman (2009)	OR 0.32 (95% CI: 0.25-0.39)
Hill (2007)	OR 0.88 (95% CI: 0.62-1.24)
Hoe (2012)	High Job Strain OR: 1.51 (95% CI: 0.88-2.59) SF-12 Mental Health Component OR: 0.98 (95% CI: 0.96-0.99)
Hurwitz (2006)	OR 1.75 (95% CI: 0.83-3.70)

Kim (2018)	NDI Depression 42.8 (SD: 19.9) vs Low-depression 20.9 (SD: 15.9) (p<0.0001) NPRS Depression 5.5 (SD: 2.2) vs Low depression 3.0 (SD: 2.4) (p<0.0001)
Lee (2007)	SF-36 MCS and Physical activity (r2: 0.12 p<0.01)
MacDowall (2018)	Regression Coefficient 0.25 (95% CI: -0.01-0.50)
McLean (2011)	Depression r: 0.245 (p=0.004) Anxiety r:0.104 (p=0.220)
Meisingset (2018)	OR: 1.03 (95% CI: 0.97-1.09)
Myhre (2013)	OR: 2.32 (95% CI: 1.20-3.43)
Peolsson (2006)	NDI r2=0.80 to DRAM (p=0.0005)
Pico-Espinosa (2019)	OR: 3.46 (95% CI: 2.01-5.95)
Rodriguez-Romero (2016)	OR: -0.3 (95% CI: -0.4-0.1)
van den Heuvel (2005)	Low job strain RR: 1.00 (95% CI: 0.76-1.92) High job strain RR: 1.79 (95% CI: 1.19-2.69)
Wibault (2014)	Depression OR: 0.71 (p=<0.001) Anxiety OR: 0.63 (p=0.006)

Table abbreviations. CI: Confidence Interval; DRAM: Distress and Risk Assessment Method; HADS: Hospital Acquired Depressions Scale; NDI: Neck Disability Index; NPRS: Neck Pain Rating Score; OR: Odds Ratio.

3.5.2. Neck pain associative outcomes: depressive symptoms

Of the 16 studies with people with non-specific neck pain, there were positive and negative associations between mental health symptoms and health outcomes. Four studies reported a positive association (Carroll et al., 2004, Elbinoune et al., 2016, McLean et al., 2011), and one study reported a negative association (Bohman et al., 2019) with depression. Using GRADE classifications, the overall strength of evidence was ‘low,’ which is attributed to a high risk of bias.

Depressive symptoms measured through Hospital Anxiety and Depression Scale (HADS) was positively associated with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (p=0.004) (McLean et al., 2011), OR: 3.46 (95% CI: 2.01-5.95) (Pico-Espinosa et al., 2019) and OR: 1.02 (95% CI: 0.98-1.06) (Elbinoune et al., 2016). When measured through the Centre for Epidemiologic Studies Depression Scale (CES-D), depressive symptoms were positively associated with pain (Hazard Ratio (HR): 3.97, 95% CI: 1.81-8.72) (Carroll et al., 2004). Depressive symptoms measured by the Montgomery-Asberg Depression Rating Scale were negatively associated with Neck Disability Index (NDI) (OR: 0.94, 95% CI: 0.86-1.03) (Bohman et al., 2019).

3.5.3. Neck pain associative outcomes: anxiety symptoms

Anxiety symptoms were positively associated with poorer health outcomes in two studies (Alipour et al., 2009, Elbinoune et al., 2016) and had no significance in one study (McLean et al., 2011). The overall strength of evidence was ‘very low’ in the GRADE assessment, which is attributed to a high risk of bias and imprecision.

Anxiety symptoms measured through the Nordic musculoskeletal questionnaire were more likely to be associated with sick leave (OR: 1.4, 95% CI: 0.9-2.1) (Alipour et al., 2009). Anxiety symptoms measured through HADS were more likely to be associated with the presence of pain (OR: 1.02, 95% CI: 0.98-1.05) (Elbinoune et al., 2016). In one study, anxiety symptoms measured through HADS had no statistical significance with DASH (p=0.220) (McLean et al., 2011).

3.5.4. Neck pain associative outcomes: kinesiophobia

Kinesiophobia was associated with poorer health and the presence of pain (r: 0.566, $p<0.05$) in one study (Beltran-Alacreu et al., 2018).

3.5.5. Neck pain associative outcomes: catastrophising

Catastrophising, measured by the catastrophising pain scale, was positively associated with pain (OR: 1.03, 95% CI: 0.97-1.09) in one study (Meisingset et al., 2018).

3.5.6. Neck pain associative outcomes: stress

Stress was positively associated with the presence of pain (OR: 0.32, 95% CI: 0.25-0.39) in one study (Grimby-Ekman et al., 2009).

3.5.7. Neck pain associative outcomes: job strain

A higher job strain was negatively associated with the presence of pain in the neck and shoulder in two studies (RR 1.79, 95% CI: 1.19-2.69) (van den Heuvel et al., 2005) and OR: 1.51 (95% CI: 0.88-2.59) (Hoe et al., 2012). This was rated as ‘low’ in the GRADE assessment, attributed to imprecision across the studies.

3.5.8. Neck pain associative outcomes: distress

Distress was positively associated with health outcomes in three studies (Hurwitz et al., 2006, Lee et al., 2007, Myhre et al., 2013) and negatively associated with health outcomes in two studies (Hill et al., 2007, Rodriguez-Romero et al., 2016). The overall strength of evidence using the GRADE approach is ‘very low,’ which is attributed to a high risk of bias and imprecision.

Psychological distress measures were positively associated with the presence of pain when measured by SF-36 ($r2: 0.12$, $p<0.01$) (Lee et al., 2007) and Hopkins Check List-10 (OR: 2.32, 95% CI: 1.20-3.43) (Myhre et al., 2013). Similarly, this was positively associated with NDI (OR: 1.75, 95% CI: 0.83-3.70) (Hurwitz et al., 2006).

Two studies reported a negative association between distress and the presence of pain (OR: 0.88, 95% CI: 0.62-1.24) (Hill et al., 2007) and OR: -0.3 (95% CI: -0.4-0.1) (Rodriguez-Romero et al., 2016).

3.5.9. Cervical spine radiculopathy associative outcomes: depressive symptoms

Of the seven studies with CSR populations, there were both positive and negative associations between depressive symptoms and health outcomes. Three studies reported a negative association (Engquist et al., 2015, MacDowall et al., 2018, Peolsson et al., 2006), whereas one study reported a positive association (Kim et al., 2018). The overall certainty of evidence using the GRADE approach was 'very low,' which was attributed to a high risk of bias and imprecision.

Depressive symptoms were positively associated with NDI when measured through the Zung Self-Reporting Scale (NDI with depression 42.8 (High) (SD: 19.9) vs 20.9 (SD: 15.9), $p<0.0001$) (Kim et al., 2018). Three studies reported negative associations (OR: 0.71, $p<0.001$) (Peolsson et al., 2006), regression coefficient 0.25 (95% CI: -0.01-0.50) (MacDowall et al., 2018) and risk of depression not being significant ($p=0.30$) (Engquist et al., 2015).

3.5.10. Cervical spine radiculopathy associative outcomes: distress

There were two studies that reported a positive association between SF-36 ($p<0.05$) (Diebo et al., 2018) and SF-12 ($p=0.04$) (Divi et al., 2020) and NDI. One study reported distress being negatively associated with NDI ($r^2=0.80$, $p<0.001$) (Peolsson et al., 2006). The overall certainty of evidence using the GRADE approach was 'very low.' This is attributed to a high risk of bias and imprecision.

3.5.11. Cervical spine radiculopathy associative outcomes: anxiety symptoms

In one study, anxiety symptoms were positively associated with NDI in CSR populations (OR: 0.63, $p=0.006$) (Wibault et al., 2014). All associative outcomes data are populated in **Table 3.4**.

3.6. Quality assessment. Neck pain populations

Five cohort studies included patients with non-specific neck pain as their exposure (Alipour et al., 2009, Bohman et al., 2019, Grimby-Ekman et al., 2009, van den Heuvel et al., 2005, McLean et al., 2011). These studies scored between five and seven out of nine on the NOS. All studies met the ‘representativeness of exposed cohort’ and ‘adequate follow-up.’ All five studies did not complete the ‘assessment of outcome’ item.

Eleven studies were cross-sectional in study design. Scores ranged from five to seven out of nine on the NOS. All studies met the ‘representativeness of exposed cohort’ and ‘adequate follow-up’. All studies did not meet the ‘assessment of outcome’ item. Three studies completed a secondary analysis of data (Hill et al., 2007, Hurwitz et al., 2006, Pico-Espinosa et al., 2019). These studies scored six to seven out of a possible nine. All studies did not meet the ‘demonstration that outcome of interest was not present at the start of study’ item and ‘assessment of outcome’. The overall certainty of evidence measured through GRADE is populated in **Table 3.5.** The quality assessment tables are populated in **Table 3.6.**

Table 3.5 Certainty of evidence. GRADE approach for health outcomes

Study design	Study lead author	Number of studies/ patients	Risk of bias	Imprecision	Inconsistency	Indirectness	Overall certainty of evidence
Observational Neck pain without CSR							
Depression	Bohman Caroll Elbinoune McClean Pico-Espinosa	5/1,718	High	Serious	Moderate	No seriousness	Low
Anxiety	Alipour Elbinoune McClean	1/12,415	High	Serious	High	No seriousness	Very low
Catastrophising	Meisingset	1/70	High	Serious	High	No seriousness	Very low
Stress	Grimby-Ekman	1/1200	High	Serious	High	No seriousness	Very low
Job strain	Van den Heuvel Hoe	2/1898	High	Serious	Moderate	No seriousness	Low
Distress	Lee Hill Hurwitz	3/802	High	Serious	Moderate	No seriousness	Very Low
Kinesiophobia	Beltran-Alacreu	1/128	High	Serious	Moderate	No seriousness	Low
Observational CSR							
Distress	Diebo Divi Peolsson	3/639	High	Serious	Moderate	No seriousness	Very Low
Depression	Kim; Peolsson Engquist MacDowall	4/471	High	Serious	Moderate	No seriousness	Very Low
Anxiety	Wilbault;	1/254	High	Serious	Moderate	No seriousness	Very Low

Through this, the certainty of the evidence was either increased (upgraded) or decreased (downgraded) against the following five criteria:
Methodological limitations using the Cochrane Risk of Bias tool (downgraded where there was a high risk of bias for three or more items; upgraded where all items demonstrated a low risk of bias);
Indirectness relating to similarity to clinical practice (downgraded where reviewers felt the study design was not generalisable to UK practice; upgraded where study design was generalisable to UK practice);
Imprecision relating to the number of participants and events (downgraded where outcomes reported less than 300 participants or five events; upgraded where effects reported in excess of 450 participants or 20 events);
Inconsistency in effect estimates across trials for a given analysis (downgraded where the CIs were four-times the magnitude of the effect estimate; upgraded where CIs were two-times the magnitude of the effect estimate);
Likelihood of publication bias (downgraded when reviewers observed asymmetry in funnel plot shape; upgraded when reviewers observed symmetry in funnel plot shape).

Table abbreviations. CSR: Cervical spine radiculopathy; GRADE: Grading of Recommendations, Assessment, Development, and Evaluations.

3.7. Quality assessment. Cervical spine radiculopathy populations

Five cohort studies included patients with CSR as their exposure population (Diebo et al., 2018, Divi et al., 2020, Kim et al., 2018, Peolsson et al., 2006, Wibault et al., 2014). These studies scored between six and seven out of a possible nine on NOS. All studies met the ‘representativeness of exposed cohort’ and ‘adequate follow-up’. All five studies did not complete the ‘assessment of outcome’ item. Two studies with a CSR study population were retrospective secondary data analyses, where each study scored five (Engquist et al., 2015) and seven (MacDowall et al., 2018), respectively. The overall certainty of evidence measured through GRADE is populated in **Table 3.5.** The quality assessment is populated in **Table 3.6.**

Table 3.6 Quality assessment scoring for all included studies

Author and year	Representativeness of the exposed cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts based on the design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts	TOTAL STARS
Alipour (2009)	1	1	0	1	2	0	1	0	7
Beltran-Alacreu (2018)	1	1	0	0	0	0	1	1	5
Bohman (2019)	1	1	0	0	0	0	1	1	5
Diebo (2018)	1	1	1	0	2	0	1	1	7
Divi (2020)	1	1	1	0	2	0	1	1	7
Carroll (2004)	1	1	0	0	2	0	1	1	7
Elbinoune (2016)	1	1	0	0	2	0	1	1	6
Engquist (2015)	1	1	1	0	0	0	1	1	5
Grimby-Ekman (2009)	1	1	0	0	2	0	1	1	7
Hill (2007)	1	1	0	0	2	0	1	0	6
Hoe (2012)	1	1	0	0	2	0	1	1	7
Hurwitz (2006)	1	1	0	0	2	0	1	0	6
Kim (2018)	1	1	0	0	2	0	1	1	6
Lee (2007)	1	1	0	0	0	0	1	1	5

MacDowall (2018)	1	1	1	0	2	0	1	1	7
McLean (2011)	1	1	0	0	1	0	1	1	6
Meisingset (2018)	1	1	0	0	2	0	0	0	5
Myhre (2013)	1	1	0	0	2	0	1	1	7
Peolsson (2006)	1	1	1	0	2	0	1	0	6
Pico-Espinosa (2019)	1	1	0	0	2	0	1	1	7
Rodriguez-Romero (2016)	1	1	0	0	2	0	1	0	6
van den Heuvel (2005)	1	1	0	1	2	0	1	0	7
Wibault (2014)	1	1	0	0	2	0	1	1	6

3.8. Discussion

This review is the first to investigate how mental health symptoms and conditions are associated with health outcomes in adults with CSp±R. It was reported from seven 'low-quality' studies that depressive symptoms were associated with poorer health outcomes. These studies included four with CSR populations and three with non-specific neck pain populations. However, in six studies (four with CSR populations and two with non-specific neck pain populations) of 'very low quality', there was no association between depressive symptoms and health outcomes. Distress and anxiety symptoms were also associated with poorer health outcomes in two studies, with 'very low-level' quality for both CSR populations and non-specific neck pain. Two studies with very low-quality sampling non-specific neck pain populations found that stress and higher job strain were negatively associated with poorer health outcomes measured by the presence of pain. There were no reported symptoms of stress and higher job strain in our included studies that sampled CSR populations.

At the time of conducting this research, there was no universal agreement on CSR diagnosis (Mansfield et al., 2020, Thoomes et al., 2018). Therefore, as discussed in **Chapters 1 and 2**, a pragmatic approach was undertaken, and studies with 'probable' or 'definite' CSR diagnoses adapted from IASP and the North American Spine Society (Bono et al., 2011, Scholz et al., 2019) were included in this systematic review. The diagnostic criteria for CSR varied between each included study. Included studies used a combination of subjectively reported symptoms, clinical assessment testing associated with imaging findings assessed by a physician, and/or sensory and motor electrophysiological testing. In line with our protocol (Mansfield et al., 2021), the included patients with CSR would have a 'definite' CSR diagnosis. All participants with CSR were on an orthopaedic surgery waiting list, which may limit the external validity to alternative healthcare settings such as primary care.

It is acknowledged that an international e-Delphi study has been published (Lam et al., 2022) with an agreement on CSR classification criteria. The 12 physiotherapists who participated in the e-Delphi study reached a consensus of radicular pain with arm pain worse than neck pain and paraesthesia or numbness and/or weakness

and/or altered reflex and MRI-confirmed nerve root compression compatible with clinical findings (Lam et al., 2022). Despite this consensus, the study recruited 12 physiotherapists who had authored two or more publications on CSR. While acknowledging the transparency of the 'expert' panel has been provided by Lam et al., (2022), there are limitations on the generalisability to other healthcare professions, such as orthopaedic surgeons. Furthermore, no classification was provided on whether numbness is related to thermal and/or mechanical stimuli. In addition, 'muscle weakness' is not defined by Lam et al., (2022), which may be interpreted in different ways when implementing these criteria into clinical practice. Future research should test the reliability and determine which tools can be used to assess these criteria (Lam et al., 2022). These classification criteria have supported the development of survey and interview questions presented later in this PhD (**Chapters 4 and 5**).

Seven studies (all classified as 'low quality') reported that depressive symptoms were associated with worse health outcomes. Out of these seven studies, four were conducted with CSR populations, while the remaining three were with non-specific neck pain populations. Conversely, six studies (classified as 'very low quality'), which included four with CSR populations and two with non-specific neck pain populations, did not show any association between depressive symptoms and health outcomes. The different assessment tools used to measure depressive symptoms may explain the mixed association between depressive symptoms and health outcomes across CSR and non-specific neck pain populations. Although each assessment tool has appropriate psychometric properties to measure mental health symptoms, the mode of delivery to collect these data may influence responses (Falla et al., 2016, Simon et al., 1993). For example, previous literature suggests people may rate their health and well-being as more favourable in telephone interviews compared to a self-reported paper-based questionnaire (Falla et al., 2016, Simon et al., 1993). Furthermore, it is unclear whether the included studies assessing CSR and non-specific neck pain populations compared participants' scores to the general population's normative values, or by using cut-off scores to indicate different levels of clinically relevant distress, anxiety and/or depressive symptoms (Breeman et al., 2015). This may provide some reasoning for the mixed association findings reported between non-specific neck pain and CSR populations.

Comparing the current review's results to other spinal pain populations may enhance our understanding of health outcomes and inform assessment and management strategies. Depressive symptoms or clinical depression are reported to have worse recovery and greater healthcare utilisation, but not pain or work-related outcomes in people with low back pain (Wong et al., 2022). Wong et al. (2022) completed a systematic review and included nine studies for CLBP without radiculopathy. Depressive symptoms were associated with higher pain intensity (three studies, 2902 participants, β: 0.11, 95% CI: 0.05-0.17), disability (five studies, 3549 participants, β=0.16, 95% CI: 0.04-0.29), and worse recovery (two studies, 13,263 participants, β: 0.91, 95% CI: 0.88-0.95). However, healthcare utilisation was based on one study and depressive symptoms were based on six highly heterogeneous studies (Wong et al., 2022). Wong et al.'s findings (2022) were similar to this systematic review's findings on the association of neck pain and depression. These findings strengthen the position that healthcare providers may assess for depressive symptoms early to identify patients potentially at risk of disability and worse recovery and guide patient-centred care. To establish the association between symptoms of depression and overall health outcomes, it is necessary to conduct confirmatory studies that account for any possible confounding.

The symptoms related to CSR are likely to be NeP mechanisms compared to nociceptive mechanisms associated with non-specific neck pain (Tampin et al., 2013) (discussed in **Chapter 1**). Neuropathic pain is associated with more severe pain, higher workplace absenteeism, distress and higher medical costs (Dworkin et al., 2007, Tampin et al., 2013) compared to non-NeP, which is comparable to this review's findings. These findings, in part, may be attributed to paraesthesia symptoms which are more likely to be present in NeP presentations such as CSR. The reduction of paraesthesia in CSR is known to positively influence a patient's self-perception of recovery and return to everyday activities (Archer et al., 2020). Notwithstanding this, the expectation of recovery for patients with CSR pending operative management may reduce the psychological impact on health outcomes (Conradie et al., 2005). The mixed observations across CSR and non-specific neck pain populations may, therefore, be explained by the complex contributing biopsychosocial factors impacting health outcomes. The interactions and mechanisms underpinning mental health symptoms, conditions and health outcomes in musculoskeletal pain populations are highly complex (Colloca et al.,

2017, de Koning et al., 2018, Stubbs et al., 2016). Clinical conditions such as spinal pain with or without radiculopathy will have complex interactions and influences that will be unique to each individual (Green et al., 2018). These factors include genetic (Dario et al., 2015), pathoanatomical (Blanpied et al., 2017) and psychological and lifestyle health factors (Green et al., 2018, Kirsch Micheletti et al., 2019). The complex interactions will influence pain perceptions, levels of distress and, subsequently, health outcomes (Martinez-Borba et al., 2021, Mody and Brooks, 2012). Enhancing our knowledge and understanding of mental health symptoms on health outcomes such as disability, function and pain can guide expectations and management strategies for clinicians and patients with CSp±R. Healthcare providers should continue to assess mental health symptoms in a holistic assessment framework as part of a robust clinical reasoning process.

3.9. Strengths and limitations

The systematic review has several strengths. Firstly, this was the first systematic review to investigate the association of mental health symptoms or diagnosis and health outcomes in an adult population with CSp±R. Due to the relatively limited amount of research involving this patient population, this systematic review is important in improving understanding of effective management strategies for this cohort of the CSp±R population. Secondly, the health outcomes included known personal, community, family and employment domains. Consequently, this systematic review has identified areas for future assessment and treatment research related to reducing or managing health outcomes in adults with CSp±R. Finally, the systematic review included studies across the adult lifecycle of CSp±R and was not just confined to a particular time frame of CSp±R, such as the acute or subacute phases. Although most studies were conducted in people post-three months since onset of symptoms, the inclusion of research studies in the chronic phase further improves our understanding of how to manage CSp±R in the long-term more effectively.

Despite a systematic and rigorous approach to our literature searching, there are several potential limitations to our review. The first limitation relates to the classification of neck pain and CSR. In **Chapter 1**, it has been reported that there is no consensus on the CSR diagnosis. Furthermore, it is also acknowledged that clinical definitions of neck pain vary widely, especially for non-specific neck pain. In

this review, neck pain and CSR were defined using criteria outlined in **Table 3.1** and through the North American Spine Society (Bono et al., 2011). However, the use of an alternative definition of neck pain, such as the orthopaedic section of the American Physical Therapy Association (Blanpied et al., 2017), may have resulted in the inclusion of a study with participants with a slightly different clinical presentation than participants measured with this review's inclusion criteria. Alternatively, studies that used a classification system to diagnose CSP±R may have been excluded. These studies were discussed in detail among the researchers involved in this systematic review, led by MM, to determine suitability for inclusion. Therefore, it is likely that the number of relevant studies excluded from the review was minimal. The review encompassed all study designs, comprising both retrospective and prospective cohort studies. Consequently, low-quality studies were also included, which had poorly defined outcomes and sometimes limited information on their measurements. While this might accurately represent the research in CSp±R, the inadequate information on some outcomes may have caused errors in their classification.

The Cochrane Handbook (Higgins et al., 2019) acknowledges that systematic review authors may deviate from protocol. The original protocol (Mansfield et al., 2021) detailed how publication bias was planned to follow the meta-analysis of results. As detailed earlier in this chapter, meta-analysis was not appropriate due to the clinical heterogeneity among the included studies. The decision to deviate to a narrative review was led by MM and agreed across all the researchers involved in the review; as such, studies that reported negative or no effects for important outcomes were also included.

3.10. Conclusion

This systematic review has reported variable associations between mental health symptoms and diagnosis with health outcomes in people with CSp±R. Stress, depressive and anxiety symptoms are associated with poorer health outcomes in patients with CSp±R. However, this result is based on a small number of low-quality studies. The low quality can be attributed to wide-ranging diagnostic criteria and population sampling methods. Further research is indicated to standardise diagnosis classification criteria for CSR and develop core outcomes to further our understanding of this debilitating condition.

3.11. Next steps

This systematic review has provided valuable insights to support the development and implementation of a national online survey of current practice investigating UK physiotherapists' methods of CSR diagnosis (**Chapter 4**) and a qualitative study exploring the rationale of assessment strategies used among UK physiotherapists (**Chapter 5**). The next two chapters will report the development and implementation of the national online survey, and the follow-up qualitative study exploring the rationale of assessment strategies used in UK physiotherapy practice.

Chapter 4: Mixed methods research methodology

4.1. Introduction

This chapter will discuss the utilisation of mixed methods research design based on the pragmatist paradigm. This approach was adopted to address the research gap around which assessment approaches physiotherapists use when establishing CSR diagnosis and the rationale behind this decision-making. The chapter includes a description of the methodological concepts that support this research programme and why a sequential explanatory design was chosen. A visual overview of the mixed methods design is also provided. The methods used in each research phase are described in **Chapter 5** (quantitative online survey) and **Chapter 6** (qualitative interviews).

4.2. Research paradigm and epistemology

Philosophical assumptions shape the processes of research and the conduct of inquiry (Creswell and Plano Clark, 2017). Philosophical or paradigm worldviews are defined as a basic set of beliefs that guide action (Denzin and Lincoln, 2011). The research paradigm in which a study is situated helps determine how the research will be conducted. It guides all areas of the research plan, including the aim of the study, research question, instruments or measurements used and analysis methods. A researcher's paradigm reflects their beliefs about what reality is (ontology), i.e., what is the nature of reality? Whereas epistemology refers to what counts as knowledge, i.e., how do we know reality, how one gains knowledge (methodology), and the values one holds (axiology).

Informed by pragmatism, the lead researcher's (MM) paradigm affirms that reality is fluid and shaped by personal experiences and interpretations in relation to the assessment of CSR (Feilzer, 2010). It is acknowledged by the lead researcher (MM) that every physiotherapist's knowledge will be unique and created by their own unique experiences in clinical practice. Pragmatism supports a holistic approach to research questions that reflect the complexity and context of physiotherapy practice (Shaw et al., 2010). Furthermore, the lead researcher (MM) acknowledges that

decisions made by physiotherapists in clinical practice will have been constructed by evolving research and the expectations of healthcare services. Therefore, it is recognised that reality is constantly developing, and that knowledge cannot be removed from contingent beliefs, habits, and experiences (Creswell and Plano Clark, 2017). In this way, pragmatism is aligned with the research question of what assessment strategies UK physiotherapists use when diagnosing CSR and the objective to understand the reality that originates in human perception and understanding related to the assessment of CSR in clinical practice.

Using a mixed method methodology to understand UK physiotherapists' assessment strategies and reasons underpinning these decisions when diagnosing CSR was the best reflection of the lead researcher's pragmatic paradigm. Mixed methods research considers research questions and determines the appropriate mix of quantitative and qualitative methods to answer them (Tashakkori and Teddlie, 2010). Using both qualitative and quantitative methodologies can challenge the research programme's epistemological stance.

Quantitative research is generally associated with a positivist viewpoint that believes reality can be objectively measured and observed (Morgan, 1998). Typically, its primary purpose is to test a pre-conceived hypothesis, which makes it a 'deductive' approach (Morgan, 1998). The advantages of quantitative research include its ability to minimise confounding effects and its potential to produce generalisable findings using large and representative samples (Sale et al., 2002). However, this approach may not be ideal for understanding context, people's thoughts, feelings, or perceptions of a phenomenon (Sale et al., 2002). It may also not be the best approach for explaining complicated social or cultural occurrences. In contrast, qualitative research emphasises interpretation and acknowledges that people have varying perspectives based on their individual experiences and their environment (Fossey et al., 2002, Pope et al., 2000).

Qualitative research is generally associated with a constructivist viewpoint, where participants form an understanding of the meaning of phenomena, and social interactions and personal experiences shape their subjective views (Morgan, 1998). Typically, qualitative research can have an 'inductive' and 'deductive' approach (Creswell and Plano Clark, 2017, Morgan, 1998). Qualitative research has the potential to generate robust theory that applies to contexts outside of the study area

in question, which can support healthcare professionals' decision-making (Pope et al., 2000, Tariq and Woodman, 2013).

4.3. Mixed methods research

Quantitative research methods can be used in CSR assessment to measure assessment strategies. However, to understand the reasoning behind clinicians' decisions, qualitative research methods are best utilised. An underlying assumption of mixed methods research is that it can address some research questions more comprehensively than by using either quantitative or qualitative methods alone. Mixed methods research can balance the strengths and limitations of different approaches (Tariq and Woodman, 2013). Therefore, using mixed methods research to understand assessment practices of a complex presentation such as CSR can be a pragmatic approach to comprehending the nature of complex healthcare delivery (O'Cathain et al., 2007).

Five reasons for mixing methods when investigating the assessment strategies and rationale underpinning decisions by UK physiotherapists when diagnosing CSR were identified. These reasons, namely triangulation, complementarity, development, initiation, and expansion, are outlined in **Appendix 4.1**. Bryman (2006) complemented the descriptions provided by Greene et al., (1989), adding further detail to triangulation, offset, completeness, process, different research questions, explanation, unexpected results, instrument development, sampling, credibility, context, illustration, utility of findings, confirmation and discovery, diversity of views and enhancement. Given the aim(s) of this research, explanation, illustration and enhancement (Bryman, 2006) will be used to justify the use of mixed methods research. Each of the three concepts are discussed in relation to the current study in **Table 4.1**.

Table 4.1 Reasons for mixed methods research

Bryman's (2006) reasons for mixed methods research	Bryman's (2006) definitions	Justification in current research
Explanation	When one method is used to help explain findings generated by the other.	Providing an explanation behind the reported decisions made in the quantitative survey was appropriate to explain through qualitative interviews. Owing to the consideration of the complexity that existed in the professional working environments, decisions on CSR assessment practices are sets of belief systems, attitudes and the healthcare systems that have, in some way, impacted participants in this study. It enabled the comparison and communication of congruent and divergent interpretations and facilitated the drawing of conclusions.
Illustration	Is the use of qualitative data to explain quantitative findings.	
Enhancement	Entails a reference to making more of or augmenting either quantitative or qualitative findings by gathering data using a qualitative or quantitative research approach.	By using both qualitative and quantitative methods, specific relationships between CSR assessments and justification can be depicted and provide a deeper examination of those relationships. This pluralistic approach considers multiple viewpoints, perspectives, and positions (Johnson, Onwuegbuzie, and Turner, 2007) and allows a more complete picture to be assembled through engagement with the membership of UK physiotherapists.

Table abbreviations. CSR: Cervical spine radiculopathy; UK: United Kingdom.

Mixed methods research has faced criticism. The criticism that has implications for this research programme is an incompatibility thesis. The most common criticism of mixed methods research is that combining qualitative and quantitative methods in research is inappropriate due to the differing philosophical assumptions guiding their use, including beliefs about the nature of reality (ontological assumptions) and how reality can be understood (epistemological assumptions). This view, known as the incompatibility thesis (Sale et al., 2002), argues that combining methods violates philosophical assumptions and misrepresents the data captured but pragmatism does not perceive this problem (Molina-Azorin and Fetters, 2020). To ameliorate these concerns, Crotty (1998) suggests that knowing one's epistemological stance is crucial for researchers to comprehend the broader context of their research. According to Creswell et al., (2011), having a clear framework to follow mixed methods research is important, but not all mixed methods researchers believe that a single paradigm should guide research (Morgan, 2007). Morgan (2007) argues that paradigms are not conceptually significant and that methods can be used without considering ontological and epistemological matters (Van Griensven et al., 2014, Tashakkori and Teddlie, 2010). Additionally, Creswell and Plano Clark (2017) suggest that different phases of a research design may be related to multiple paradigms. For instance, a survey research phase may be guided by a positivist paradigm, which aims to obtain generalisable knowledge through valid and reliable observation and measurement of an objective reality (Dawadi et al., 2021). Conversely, an interpretivist paradigm may guide the qualitative interview phase, which aims to understand contextually specific phenomena (Dawadi et al., 2021).

Researchers can adopt a pragmatic approach to address research questions from both quantitative and qualitative research (Creswell et al., 2013, Rorty, 1999). Fundamentally, the selection of the correct methods to answer the research questions is what matters most. As such, this mixed methods research adopts a pragmatic paradigm through quantitative and qualitative research methods. In applying mixed methods research underpinned by pragmatism, it was essential that the lead researcher (MM) created research questions, underpinned by theory, that could be answered by combining the outcomes of quantitative and qualitative research related to the assessment of CSR in clinical practice (Creswell and Plano Clark, 2011, Tashakkori and Teddlie, 2010).

This research was anticipated to selectively reveal the micro- and meso-levels associated with establishing CSR diagnosis in clinical practice (Kelle et al., 2019). For example, the quantitative survey was used to gain insight into the frequency and use of assessment strategies, providing a more detailed understanding at a micro level. Individual interviews with clinicians were conducted to gain a deeper understanding of the reasoning behind assessment strategies used when diagnosing CSR, providing insight at a meso-level. By integrating and synthesising multiple data sources, knowledge and understanding were constructed that may not have been possible through a single method. Furthermore, it was recognised that the reasons listed for this mixed methods research are viewed as a general framework and have been used to justify mixed methods research. Bryman (2006) reported that many mixed methods studies use multiple reasons for mixing methods and that new reasons for mixing may emerge as the study is underway. Being responsive to new insights is an essential aspect of conducting mixed methods research (Bryman, 2006) and is detailed further in **Chapter 7**.

4.4. Mixed methods research designs

Various mixed methods research designs can be utilised to address a research question, such as embedded, transformative, multiphase, convergent, explanatory, and exploratory designs (Creswell et al., 2011). These are summarised in **Table 4.2**.

Table 4.2 Different mixed methods research designs. Adapted from Schoonenboom (2017)

Mixed methods design	Description
Embedded	In a traditional qualitative or quantitative design, a strand of the other type is added to enhance the overall design.
Transformative	The interaction, priority, timing, and combination of qualitative and quantitative approaches are shaped by a transformative theoretical framework.
Multiphase	A programme of study can incorporate multiple phases and strands, either sequential or concurrent, over a period of time to achieve an overall programme objective.
Convergent parallel	The research is conducted in two independent parts: quantitative and qualitative. The results from each part are then combined to form an overall interpretation.
Explanatory sequential	After collecting and analysing quantitative data in the first phase, the next step is to collect qualitative data to provide further explanation for the initial results.
Exploratory sequential	After completing the initial phase of collecting and analysing qualitative data, the next step is to gather quantitative data. This is completed to either test or generalise the findings from the qualitative data.

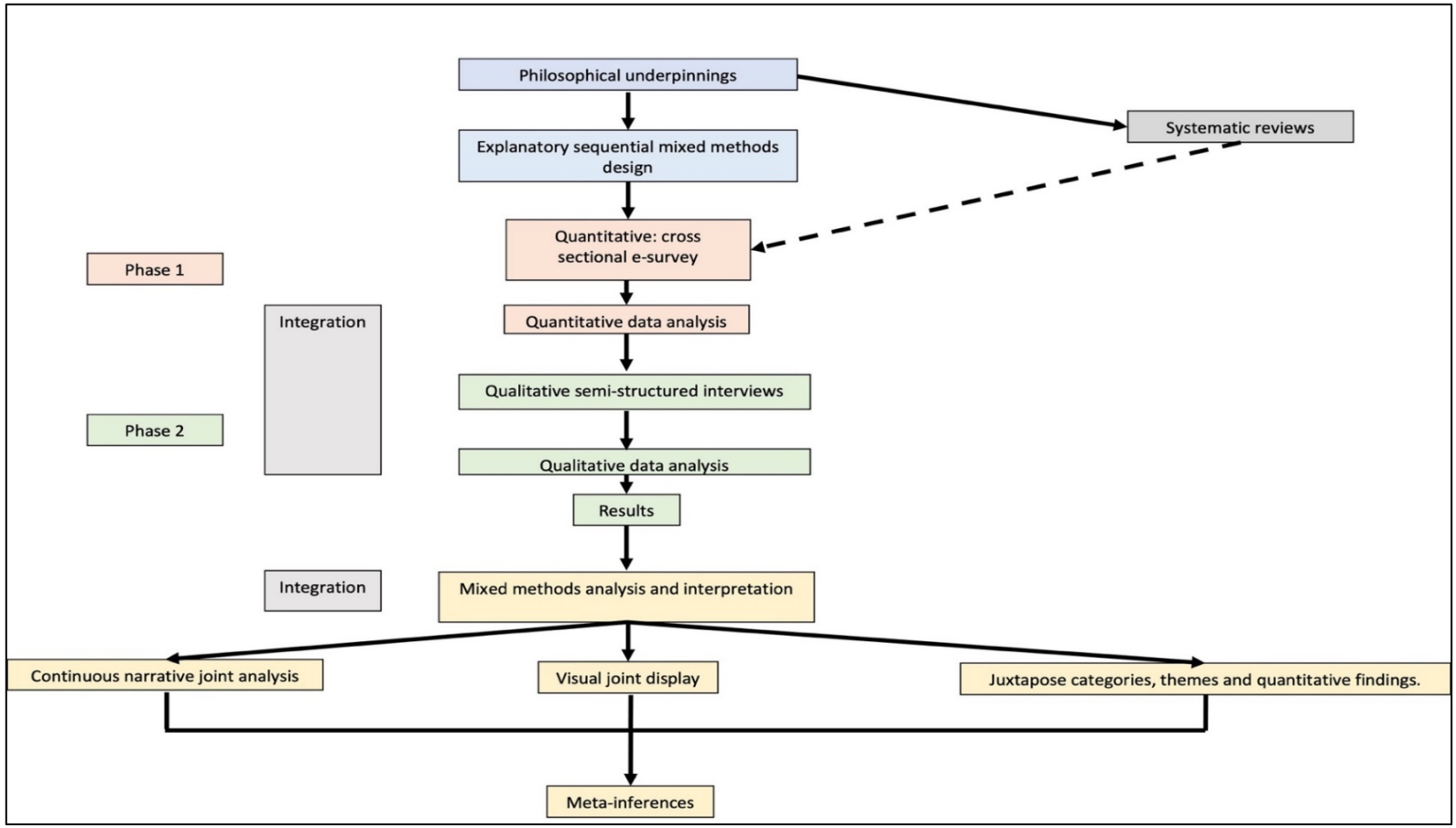
The explanatory sequential design was selected for this mixed methods phase of research. An explanatory sequential design requires collecting and analysing quantitative data to identify areas that require further explanation through qualitative research. It usually involves a purposive sampling approach to select participants (Creswell et al., 2011). Explanatory sequential design is appropriate for researchers who are more focused on quantitative methods and who have already identified a variable to measure (Creswell et al., 2011). However, it is acknowledged that sampling can be an issue with explanatory sequential design (Wilkinson and Staley, 2019). Wilkinson and Staley (2019) reported concerns about how accurately the sample for the qualitative portion of the study represented the larger group of participants whose data was analysed quantitatively (Wilkinson and Staley, 2019). Nevertheless, for this mixed methods phase, there was access to UK physiotherapists for quantitative and qualitative data collection across two phases, which supported the justification of this mixed methods research.

As an example of explanatory sequential design, Budtz et al., (2021) investigated physiotherapists' capability to make accurate management decisions for patients with musculoskeletal issues and identify associated explanatory factors. Budtz et al., (2021) conducted a quantitative questionnaire survey investigating decisions physiotherapists would make in patient scenarios, and semi-structured interviews with the same group of physiotherapists to explore the rationale behind these decisions made in the survey (Budtz et al., 2021).

Within mixed methods research, researchers are encouraged to use a classification system to assist them in selecting the most suitable method and to ensure clarity in defining the study objectives (Tashakkori and Teddlie, 2010). The mixed methods research designs can be categorised as emergent or fixed (Plano Clark et al., 2015). Fixed mixed methods involve predetermined methods at the start of the research, while emergent designs rely on the issues that develop throughout the project to determine the selection of methods (Schoonenboom and Johnson, 2017). In this research, a fixed design was selected that included pre-planning both quantitative and qualitative methods. This approach effectively addressed the study's objective, which sought to understand the rationale of UK physiotherapists' assessment approaches when diagnosing CSR. Notwithstanding this, it was acknowledged that 'fixed' and 'emergent' designs are not a dichotomy, but two ends of a continuum (Klassen et al., 2012). Therefore, although the research design was predetermined,

there were some details from the first quantitative phase that informed the semi-structured interview questions (second phase). This is further discussed in **Chapter 6**. **Figure 4.1** illustrates the mixed methods research approach adopted for this research programme and integration stages.

Figure 4.1 Overview of the explanatory sequential design



*The main sequence of mixed methods research design and implementation are indicated using **bold** arrows. The **dashed** line represents how the findings from the systematic reviews around diagnostic assessment methods have influenced the survey question design.*

4.5. Mixed methods research integration by joint display

Mixed methods research requires the integration of quantitative and qualitative methods. Integration can occur at study design, methods, and interpretation levels (Fetters et al., 2013). Integration is a dynamic and interactive process (Creamer, 2018). For this mixed methods phase, integration occurred at the qualitative interview design and the during the analysis and interpretation levels, depicted in the joint display. At the interpretation and reporting level, integration refers to combining two data sets to provide a more comprehensive understanding than either data set alone (Clark and Sanders, 2015). This type of integration can take various forms, such as presenting both quantitative and qualitative data in a report, converting one type of data to another (for example, transforming qualitative data into quantifiable data) and integrating it with non-transformed data (for example, combining quantified qualitative data with existing quantitative data), or using a joint display (Clark and Sanders, 2015). **Table 4.3** presents different mixed methods integration and reporting integration approaches.

Table 4.3 Different integration approaches with mixed methods research

Integration Approach	Description
Convergent coding matrix	Researchers compile the findings from each component of the study and look for areas where the findings from each method agree (convergence), provide additional information on the same issue (complementarity), or seem to contradict each other (discrepancy or dissonance) (Hammersley, 2008, Sandelowski, 2022). It is recommended that two researchers work together, especially where different researchers may take charge of the qualitative and quantitative aspects (Kelle et al., 2019, Paoletti et al., 2021). Planning for this triangulation method of integration should be factored into the study timetable, as it requires both time and resources (Kelle et al., 2019, Paoletti et al., 2021).
Following a thread	This method is utilised during the analysis stage of research and involves identifying significant themes and questions in both phases (Moran-Ellis et al., 2006). Researchers then select a particular theme or question and trace its connection across the other components, creating a 'thread' (Moran-Ellis et al., 2006).
Mixed methods matrix	Both qualitative and quantitative data are available from individuals, groups, organisations or geographic areas. All the data collected on a single case can be analysed together, with emphasis on cases rather than variables or themes (Teddlie and Tashakkori, 2006). Detailed examination of data on each case is possible, including a comparison of questionnaire responses and interview transcripts (O'Cathain et al., 2010).
Joint display development	Creating an effective joint display in the analysis stage involves selecting specific qualitative and quantitative data to use, choosing the appropriate format for each type of data, adjusting the organisation of the two types of data, and using creative formatting techniques to obtain a deeper understanding and meaning of the mixed data findings. It involves organising and reorganising findings into a matrix or figure to create a finalised joint display (Fetters, 2020). It can combine tables, matrices and figures to present both quantitative and qualitative results side by side (Fetters, 2020, Harrison et al., 2020). Researchers compile the findings from each component of the study and look for areas where there is convergence, complementarity, and/or discrepancy or dissonance. Joint display allows researchers to make meta-inferences and better understand their research topic. Joint displays are especially useful for mixed methods analysis and represent valuable data (Harrison et al., 2020).

While joint displays are recognised as useful for representing integration in mixed methods research, they are not widely used in health mixed methods research. A systematic review conducted by Guetterman et al., (2015) investigated the use of joint displays in the health sciences and categorised them based on their design. The most commonly used formats for reporting mixed methods research findings were side-by-side and statistics-by-themes joint displays. A systematic review published by Guetterman et al., (2021) reported that a table or matrix format was the most common way to present mixed data findings. However, despite the potential benefits of using joint displays, three systematic reviews have noted that they are still under-utilised in health (Fabregues et al., 2022, Younas et al., 2021). Furthermore, there is still a lack of research focused exclusively on the joint display of integrated mixed methods data collection. Despite recent methodological reviews of mixed methods design features, no known articles focus solely on the features and use of joint displays for integrated data collection. An example of joint display has been utilised in a study testing the acceptability and need to adapt extant digital technologies for people with musculoskeletal pain (Slater et al., 2020).

A joint display analysis method was selected to integrate the quantitative and qualitative results. Joint display is a visual representation that a researcher can use to present both quantitative and qualitative data analyses or results in a single display (Clark and Sanders, 2015, Tariq and Woodman, 2013). Joint displays have been identified as a useful tool for improving the rigour of mixed methods research (Harrison et al., 2020). Creating an effective joint display in the analysis stage involves selecting specific qualitative and quantitative data to use, choosing the appropriate format for each type of data, adjusting the organisation of the two types of data, and using creative formatting techniques to obtain a deeper understanding and meaning of the mixed data findings. This research introduced the joint display to present mixed data (quantitative and qualitative results) and an effective approach to analysing and developing meta-inferences about its suitability (Fetters et al., 2020). Integrating the survey and qualitative interview results allowed the lead researcher (MM) to make meta-inferences about the assessment practice of physiotherapists when diagnosing CSR, thereby meeting the research objectives of this mixed methods phase of research (Fetters et al., 2020).

4.6. Positionality

The concept of positionality is important for researchers as it influences their research decisions. Positionality refers to an individual's perspective and stance towards a research task and the social and political context surrounding it (Bourke, 2014, Holmes, 2020). It encompasses the researcher's beliefs about the nature of social reality and knowledge, as well as their beliefs about how humans interact with the environment (Bourke, 2014, Holmes, 2020). These factors contribute to the researcher's worldview and subsequent research paradigm. The concept of positionality emphasises its impact on the entire research process, acknowledging that researchers are part of the environment they study and have their own interpretation (Mason-Bish, 2019). Three factors normally identify positionality: locating the researcher in the subject matter being investigated, self-perception, and the researcher's presence in the research process (Folkes, 2023, Jamieson et al., 2023).

Firstly, the lead researcher (MM) examined the subject being investigated and became aware of any personal biases that could impact the research. As a UK registered physiotherapist with 17 years of clinical and academic experience, the lead researcher was conscious that experiences as a clinical practitioner, educator and subsequent PhD student may influence the topic of interest and research programme. The lead researcher's most recent clinical setting work was in the City of London in an NHS secondary and tertiary care spinal orthopaedic care service. The clinical directors were spinal orthopaedic and neurosurgeons. The role in this healthcare setting was to triage, assess and determine management pathways for adults with complex spinal pain and associated disabilities. Often, people presenting to this spinal care service had engaged in conservative forms of management for their presenting condition, which had not been successful (i.e., not significantly improved their pain or function). This often resulted in people having growing concerns, anxiety, and worry about their ongoing presentation. This service was expected to provide an expert assessment to determine the source of the symptoms and whether invasive forms of management are indicated (i.e., spinal injections or consideration of a surgical opinion). Therefore, it was acknowledged that the lead researcher's (MM) clinical experience in these specific healthcare systems will have

influenced the design and interpretation of findings from this mixed methods phase of the research.

While the lead researcher's (MM) positionality as a clinician provided some benefits, such as a deeper understanding of the intervention and pathology, these clinical experiences may have influenced the design and interpretation of the findings. As discussed in **Chapter 1,** the clinical signs and symptoms of CSR are heterogeneous. People with CSR may present with sensory and/or motor changes. Often, in specialist orthopaedic triage services that the lead researcher (MM) was employed in, people with CSR would present with varying degrees of sensory changes, including hypoalgesia, hyperalgesia and allodynia to a range of mechanical and thermal stimuli. These sensory changes observed in practice may have influenced the design of survey and qualitative interview questions relating to the somatosensory nervous system assessment practices. Furthermore, the lead researcher (MM) is currently a clinical academic in a translational pain laboratory (Bannister Laboratory, King's College London). This role enabled the lead researcher (MM) to develop translational somatosensory testing methods to assess somatosensory nervous system integrity. This exposure to enhancing understanding of pain mechanisms in nerve pathologies may have influenced the survey questions related to the somatosensory nervous systems in clinical practice. This was reflected in the lead researcher's (MM) own experiences when assessing CSR and utilised robust pilot testing and stakeholder feedback to reduce this possible bias in design.

The lead researcher (MM) has worked both as a clinician (directly interacting with patients) and an academic (non-patient facing). These past experiences as an *insider* and current experiences as an *outsider* to frontline clinical practice may have influenced the interpretation of the qualitative interview findings. This is proposed as there may have been a conflict in attempting to contextualise historical clinical practices that the lead researcher (MM) completed and the developing contemporary research knowledge of pain mechanisms in people with CSR. Furthermore, the lead researcher's (MM) position as an *insider* may have developed mutual respect between the participants, resulting in a more open and honest dialogue with the researcher embedded in clinical practice, which can lead to more genuine and deeper meaning to the collected data (Bayeck, 2022, Chhabra, 2020).

Noteworthy, the lead researcher's (MM) status as a physiotherapist may also impact a researcher's perception of the information participants provide, and the analysis of data (Bayeck, 2022, Muhammad et al., 2015). When a researcher has insider knowledge, participants may assume that they share the same perspective due to their shared profession (Muhammad et al., 2015, Wiles et al., 2006). This may lead to participants seeking to impress or agree with the researcher based on this perceived connection (Brannick and Coghlan, 2007, Muhammad et al., 2015).

The lead researcher (MM) considered self-perspective and how others potentially viewed this perspective. The lead researcher (MM) leads an advanced practice musculoskeletal physiotherapy master's programme at a UK university. This education programme's associated aims, objectives and outcomes are mapped against UK advanced practice expectations for musculoskeletal physiotherapists. These activities created public-facing, peer-reviewed research outputs in physiotherapy journals, continuing professional development training seminars and scientific conferences. Based on clinical and higher education roles, the lead researcher's (MM) self-perception of CSR is based on an advancing and/or advanced clinical setting. It was acknowledged that not every physiotherapist engaging in this mixed methods phase of research will be working in an advancing or advanced clinical practice. The lead researcher (MM) was cognisant of this when planning the semi-structured interviews as this may have influenced the interpretation of questions and answers from the sample of UK physiotherapists.

Positionality can also be discussed as a differentiation between insider (emic) and outsider (etic) viewpoints (Rowe, 2014). Insiders are viewed as part of the community being studied, while outsiders are seen as external to the community (Bukamal, 2022, Merriam et al., 2001). In this mixed methods phase of research, the lead researcher (MM) had worked both as a clinician (directly interacting with patients) and an academic (non-patient facing). This can sometimes be referred to as an 'in-betweener' (Chhabra, 2020, Bourke, 2014). The potential power dynamics of positionality will be discussed further in **Chapter 6**. The design of a reflexive approach was adopted and reflected upon throughout the qualitative interviews (through field notes and supervision mentoring sessions) and how this may have influenced data collection and analysis. Reflexivity is discussed further in **Chapter 6**.

4.7. Stakeholder engagement

Organisations such as NIHR have acknowledged the significance which patient and public involvement and engagement (PPIE) can have to enhance the relevance and quality of research (NIHR, 2023). Patient and public involvement representatives may include current and potential service users, individuals with lived experience of the condition, caregivers, and stakeholders from communities and organisations representing service users. The NIHR identifies three ways in-which PPIE can benefit research: involvement, engagement, and participation (National Institute of Health Research, 2021).

This mixed methods research consulted with PPI to administor the study and disseminate the findings. The lead researcher is an active member of two research groups at the University of Birmingham and King's College London. Each research group has long-standing members who have lived experience of spinal pain, persistent pain and/or NeP. Furthermore, each research group has stakeholder involvement from clinicians in practice (such as physiotherapists, medics and nurses) with an interest in musculoskeletal and NeP. The mixed methods research study progression and findings were presented at research group meetings, which provided an opportunity to provide feedback on survey and qualitative interview progression and scrutinise decision-making. Following the lead researcher's (MM) study presentation, there were open question and answers forums, and general observations were invited from attendees. The lead researcher (MM) used this opportunity as a chance to gather different perspectives and ideas to the research question, methods and possible analysis. Two specific comments from the PPIE research meetings included "interesting study with fascinating nerve testing methods" and "much needed research in clinicians assess in the way they do; this needs further understanding". Specific comments were made around font size of any documentation and allow for more time than expected for people to read and digest any information about the study and to ensure the font size of any reading material was large enough. As a result of this, all documentation font size was increased and additional time (up to 10 minutes) was built into the overall plan.

4.8. The current study

This chapter presented the rationale for using a mixed methods research design to investigate assessment strategies used by UK physiotherapists when diagnosing CSR. Due to the paucity of research investigating assessment strategies used by UK physiotherapists to assess CSR, a sequential explanatory research approach was used to address the mixed methods research study objectives and achieve the study's aim. **Table 4.4** presents the sequential design approach. **Figure 4.2** presents the overarching components of each stage within the mixed methods research study. The positionality discussion presented earlier in this chapter was a pertinent part of the decision-making of this mixed methods research study.

Figure 4.2 The central tenets of this mixed methods research study and features of each phase completed

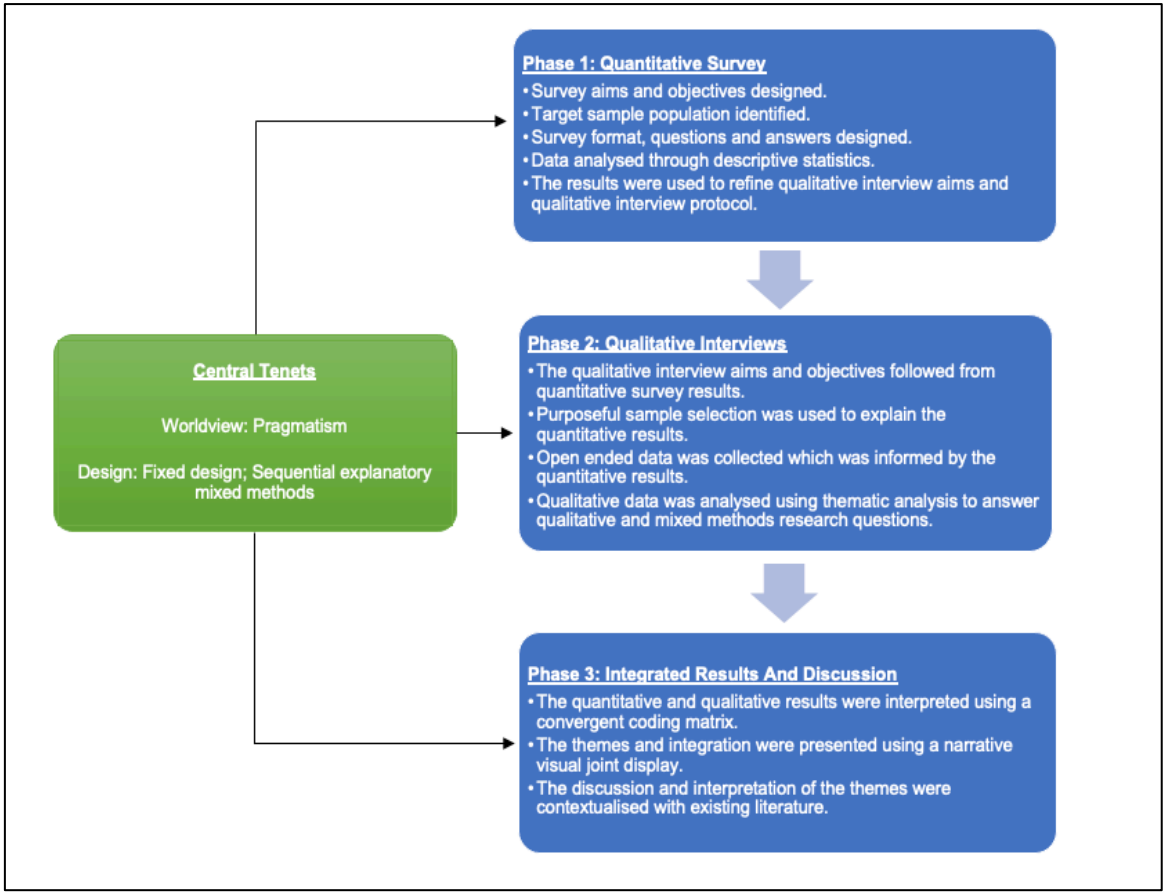


Table 4.4 Research plan outlining stages, methods and purposes

Stage	Data collection	Purpose
Quantitative	Online national survey	To establish the current assessment strategies used in UK physiotherapy practice to inform the diagnosis of CSR. To determine the barriers and facilitators in using clinical assessment strategies in practice.
Qualitative	1:1 semi-structured interviews	To explore UK physiotherapists' reasoning on assessment strategies when diagnosing CSR. To explore the use of physical assessment, somatosensory testing and screening tools when establishing a CSR diagnosis and the reasons underpinning this decision-making.
Integration of survey and interviews results		

Table abbreviations. CSR: Cervical spine radiculopathy; UK: United Kingdom.

4.9. Next steps

Chapter 5 will discuss the quantitative component implementation in terms of survey methods (for example, questions development, participant recruitment, data collection). This will lead to the discussion of the design and implementation of qualitative interviews in **Chapter 6**. **Chapter 7** will then discuss the integration of findings of the quantitative and qualitative phases of work.

Chapter 5: Understanding cervical spine radiculopathy assessment practices among United Kingdom physiotherapists. Phase 1 an online survey.

5.1. Introduction

This chapter begins by justifying the use of an online survey for data collection. The selected methods are then presented and discussed. The online survey development, recruitment and survey design are presented and justified. As discussed in **Chapter 1**, at the time of writing this survey's protocol, to the authors' knowledge, no studies had investigated how physiotherapists working in the UK assess CSR in adult populations. The integrated results of this online survey are presented in **Chapter 7** and discussed in **Chapter 8**.

When writing this chapter, the social media platform known as 'Twitter' rebranded to 'X'. However, prior to this rebrand, 'Twitter' was used throughout the development and reporting stages. For consistency, 'Twitter' will be used throughout this chapter.

5.2. Survey methods in health research

Depending on the purpose, collected survey data can be completed in different ways, including face-to-face or telephone/online. Questionnaire questions focus on specific concepts or items of interest (Schofield and Forrester-Knauss, 2010). A narrative review of surveys used in health and social science research found that the main goal is to produce summary statistics at a group (Bowling and Ebrahim, 2005). This is useful for describing information to a larger population that the group of individuals may belong to. As a result, surveying a sample of UK physiotherapists with experience assessing CSR will provide insight into physiotherapy clinical practices when assessing people with CSR.

Each survey method has its own strengths (summarised in **Table 5.1**). Questionnaires that respondents complete themselves are affordable, easy to conduct, and can be completed at the respondent's convenience (Aday and Cornelius, 2011, Bowling and Ebrahim, 2005). Online questionnaires are particularly

useful for reaching a geographically diverse group of people with common characteristics (Ball et al., 2019, Wright, 2005). As discussed in **Chapter 4**, the first phase of this mixed methods research study (**Chapter 5**) aimed to understand which assessment strategies are used in UK physiotherapy clinical practice when diagnosing CSR. Given the geographically dispersed population, and objective of this research, an online questionnaire was selected for the first phase of this mixed methods research study.

Table 5.1 Advantages and disadvantages of survey methods (Adapted from Boyer 2001, Wright 2005)

	Self-administered. Online	**Self-administered. Post**	**Interview. Face to Face**	**Interview. Telephone**
Advantages	Time efficient data collection and analysis Minimal costs Anonymity and confidentiality can be assured. Time for respondents to reflect. Returned questionnaires can be checked promptly. Transferability to electronic statistical analysis convenient	Reduced cost than face-to-face questionnaires Administration of large numbers and across large geographical areas possible Time for respondents to reflect. Anonymity assured.	Access respondents who are not literate or who are sight-impaired Appropriate for sensitive topics Allows explanation of complex or sensitive questions Low cost for the questionnaires	Minimal costs Useful when the respondents have challenges accessing e-mail or post. Possible to access respondents who are sight-impaired or have some physical disabilities.
Disadvantages	Associated with lower response rates. Administration of the questionnaire requires time and IT skill. There is no control over who completes the questionnaire. Standardised formatting does not allow further explanations	Returning the questionnaire can take more time. Increased risk of responses being lost, incomplete or the questionnaire spoiled. No control over who completes the questionnaire.	Increased time to analyse. Anonymity is compromised. Respondents are usually from a small geographical area Additional training for the interviewer to ensure standardisation. Travel costs required for the researcher and participant	Time-consuming data collection Sample size is small. Verbal communication barriers to negotiate.

5.2.1. Survey research in spinal pain with or without radiculopathy

A search investigating the use of survey research in spinal pain with or without radiculopathy was conducted on 20th August 2023. The search terms and results are presented in **Appendix 5.1 and 5.2**. Surveys exploring clinical assessment practice in spinal pain have mostly focused on understanding which treatment approaches physiotherapists use for LBP without radiculopathy (Arishy et al., 2022, Armstrong et al., 2003, Bernhardsson et al., 2015, Fidvi and May, 2010, Foster et al., 1999, Gracey et al., 2002, Hall et al., 2022, Harte et al., 2005, Husted et al., 2020, Pensri et al., 2005). Two studies have investigated physiotherapy clinical reasoning strategies when assessing spinal pain without radiculopathy (Billis et al., 2016, Ganesh et al., 2023).

Despite these surveys, the use of assessment strategies for neck pain and/or CSR has not been investigated using survey methods. The studies that have used survey research to understand how clinicians assess spinal pain have focused on how physiotherapists triage LBP in orthopaedic surgical centres (Weatherley and Hourigan, 1998), the use of biopsychosocial screening questionnaires or psychological assessment when assessing LBP (Hallegraeff et al., 2021, Hurley et al., 2000), and which serious spinal pathology indicators ('red flags') are used by physiotherapists when assessing LBP. Three studies had used survey research to explore clinical reasoning among physiotherapists (compared to clinical guidelines) when assessing LBP (Akindele et al., 2020, Billis et al., 2016, Östhols et al., 2019).

For Phase 1, an online-based survey design was selected, which is appropriate for a cross-sectional study design (Braun et al., 2021). Moreover, at the time of developing the protocol and ethics submission, the global health pandemic (COVID-19) restricted the movement of individuals, further supporting the decision to complete an online survey.

5.3. Aims and objectives

This cross-sectional online survey aimed to determine the current assessment strategies used by UK physiotherapists when establishing a CSR diagnosis.

The survey objectives were to answer three overarching research questions:

- What are the current physical assessment strategies used in UK physiotherapy practice to inform the diagnosis of CSR?
- Which questionnaire screening tools are used in current clinical practice when assessing people with potential CSR?
- What are the barriers and facilitators in using clinical assessment strategies in practice?

5.4. Methods

5.4.1. Survey development principles

The development of this survey was guided by 15 principles created by Johnson and Christensen (2020). The selection of the Johnson and Christenson (2020) development framework follows the successful use in online musculoskeletal surveys, for example Skamagki et al., (2022) and Ganesh et al., (2023). The Johnson and Christensen (2020) principles provide guidance and recommendations for formatting and detailed descriptions for creating questions for online surveys. The survey development process is divided into clear phases described below.

5.4.2. Question development

Johnson and Christensen (2020) reported the significance of choosing the right type of question for each topic to achieve accuracy. This current survey utilised ‘closed’ questions. The aim of this current survey was to understand the assessment strategies used to diagnose CSR; exploring ‘why’ these are used was not the aim of Phase 1 and will be investigated in **Chapter 6**. However, any free-text answers in the ‘other’ multiple-choice questions (Question 16,17,18, 21, 22) supported the semi-structured interview topic guide used in the qualitative interviews (**Chapter 6**). Open-ended and close-ended questions have distinct traits, particularly regarding the respondents’ role in answering them (Johnson and Christensen, 2020). Close-ended questions restrict the respondents to the given options, while open-ended questions enable them to express their opinions without any influence from the

researcher (O'Cathain and Thomas, 2004). The quality of survey data can be affected in various ways. Open-ended questions have their advantages, such as uncovering spontaneous responses and avoiding bias that may arise from suggesting responses in close-ended questions (Reja et al., 2003). However, they also have drawbacks, such as requiring extensive coding and experiencing larger item non-response compared to close-ended questions (O'Cathain and Thomas, 2004). For example, in a retrospective analysis of online survey engagement, Reja et al., (2003) reported that the higher the share of open-ended questions, presented a higher dropout rate ($p<0.05$). In a meta-analysis examining 1,071 independent online surveys response rates, open questions did not negatively impact survey completion ($p>0.05$) (Wu et al., 2022). This is based on educational research, which may limit the external validity of health-related research (Wu et al., 2022).

To enhance the reliability and relevance of the online survey to UK physiotherapists, there were multiple stages of testing and development (Braun et al., 2021, Johnson and Christensen, 2020). The systematic review from Thoomes et al., (2018) detailed the value of physical assessment and imaging modalities when diagnosing CSR. The diagnostics methods and imaging modalities retrieved from Thoomes et al., (2018), and a list of physical assessment tests collated from the lead researcher's (MM) clinical experience and previously peer-reviewed published work (Mansfield et al., 2020, Mansfield et al., 2023), were initially created to inform the questionnaire development.

When developing the survey's questions, involving subject matter or methodology experts can support designing questions, identifying any potential issues in the question-answering process, and detecting other measurement errors in the survey (Olson, 2010). In this regard, a convenience sample of five senior physiotherapists was approached to identify and categorise currently used assessment strategies for diagnosing CSR. These physiotherapists were identified through spinal orthopaedic clinical academic conferences and physiotherapy musculoskeletal professional networks. The physiotherapists had six to 23 years of experience working in public, private and corporate UK physiotherapy healthcare settings. All five senior physiotherapists had worked in musculoskeletal primary care, secondary and tertiary care settings. The rationale for using a group of senior therapists working

across spinal services was to identify a broad range of assessment strategies reflecting current clinical practice.

The five physiotherapists were initially asked to list any possible assessment strategies used in the assessment of CSR. These are detailed in **Appendix 5.3**. The lead researcher (MM) grouped the assessment strategies according to physical assessment tests, somatosensory tests and screening tools. The groupings were presented to the physiotherapists to confirm accuracy. There were no amendments made. In total, 10 grouped assessment strategies were identified. The five physiotherapists were then asked to independently explain why they may use or not use the identified assessment strategies (**Appendix 5.4**). The lead researcher (MM) reviewed the assessment strategies collated, duplicates were removed and presented back to the five physiotherapists for accuracy; no amendments were made. Based on this formative work, the lead researcher (MM) designed survey questions that sought to identify the usage and possible barriers and facilitators of common assessment procedures for CSR. The questions were split into domains across diagnostic assessment tests, screening tools (to identify dominant underlying pain mechanisms) and imaging modalities.

To determine which assessment strategies were most frequently used by physiotherapists, the questionnaire utilised a five-point Likert scale. The Likert scale facilitated participants to rate the degree to which they agree or disagree with a statement. Although responses can be rated or ranked on an ordinal scale, it is acknowledged that the distance between responses is not measurable (Taherdoost, 2019). Therefore, the differences between ‘always’, ‘often’ and ‘sometimes’ on a frequency response Likert scale are not necessarily equal. This means that questionnaire respondents may interpret the differences between responses differently. However, the convenience sample of senior physiotherapists preferred this phrasing to examples such as percentage of use or binary ‘use/not use’ answers. Likert scales had been used previously to measure the use of assessment and/or management interventions in spinal survey research (Akindele et al., 2020, Armstrong et al., 2003, Gracey et al., 2002, Hallegraeff et al., 2021, Hurley et al., 2000, Husted et al., 2020, Ostelo et al., 2003, Steen et al., 2021).

5.4.3. Length of the survey

The length of a self-administrated electronic survey can impact response rates and the quality of answers provided by respondents (Cook et al., 2000, Sheehan, 2001). A meta-analysis of 32 studies did not find a statistically significant relationship ($p>0.05$) between questionnaire length and response rates in web surveys (Sheehan, 2001). However, these reported findings were based on a high risk of biased observational studies. In an online survey study, Revilla and Hohn (2020) reported that potential online survey respondents preferred an ideal length of an online survey of between 10 to 15 minutes and a maximum length of up to 28 minutes. This was from a sample size of 4,635 participants (Revilla and Höhne, 2020). External validity of results to the UK may be limited as these findings were from a sample population in Germany. Nevertheless, the length of this survey was designed to be completed in 20 minutes.

5.4.4. Piloting the survey

Conducting a survey pilot helps to identify possible issues and shortcomings in the research instruments and protocol before implementing them in a full study (Bloomfield and Fisher, 2019, De Leeuw et al., 2012). Piloting can support the enhancement of the adequacy of the questions, ordering of the questions, comprehensiveness of the contents, and clarity of instructions (Fowler Jr and Cosenza, 2009). Moreover, piloting can review the feasibility of the technology used (such as download time) (De Leeuw et al., 2012).

The lead researcher (MM) utilised a two-stage piloting strategy. The two stages were: (1) sending a draft survey to two physiotherapists and (2) a ‘think aloud’ method. A two-stage approach to piloting has been previously used in survey health research (Eccles et al., 2017). Having two stages can provide a specific focus to each testing stage on concepts such as reliability, validity and error testing (Fowler Jr and Cosenza, 2009).

A draft survey was prepared on Microsoft Word and sent to two musculoskeletal physiotherapists for independent review. They were independent of the online survey and were asked not to complete the online survey once disseminated for

completion. This request was made to minimise the risk of previous completion of the survey influencing responses made to the final, analysed survey (Bloomfield and Fisher, 2019). The two physiotherapists were selected from a known professional interest group (Musculoskeletal Association of Chartered Physiotherapists) and worked in two central London NHS trusts. Each physiotherapist had six and 11 years of clinical experience of assessing and managing spinal pain. There is no evidence on the optimal number of people who should pilot a health-related survey. It is acknowledged a sampling bias may be present by using two physiotherapists from the same professional network and geographical region of work. This possible limitation will be discussed further in **Chapter 7 and 9**.

The physiotherapists were asked to review and pilot the survey twice, five days apart. In the first review, each physiotherapist was invited to review the order of questions and any technical question or answer errors (such as overlapping of answers, inaccurate or missing instructions, double negative or positive phrasing with questions). For the second stage of piloting, five days later, they were asked to review spelling, formatting of mandatory questions or answers that cannot be 'undone' (on mobile and desktop platforms and different web browsers), to check for possible grammar errors that may have been inadvertently introduced during the last revision process, and to ensure there was an appropriate 'exit/thank you' page (Daikeler et al., 2020). This approach to survey piloting supports the conceptualisation and re-conceptualisation of the key aims of the study and minimises errors on the implementation and analysis (Ruel et al., 2015). The feedback on the survey's wording, answers, syntax and flow can be viewed in **Appendix 5.5**.

The second stage of piloting outlined above used a 'think aloud' method (Johnson and Christensen, 2020). This promotes openness and ensures that the aims and objectives are central to the online survey question development (Braun et al., 2021). Thinking aloud is the concurrent verbalisation of thoughts while performing a task (Ericsson, 2017). The two physiotherapists were asked to verbalise their thoughts while completing the survey. The physiotherapists completed this task independently and were instructed not to interpret or analyse their thinking. This method iteratively improves the survey question wording understandability and interpretation consistency (Johnson and Christensen, 2020). However, criticisms

related to observation bias when a participant is being observed completing the task. The lead researcher (MM) wrote notes as the participants verbalised their thoughts about the survey and were able to answer any queries they had about the task. These notes can be viewed in **Appendix 5.6**.

The supervisory team (TS, SJ), with expertise in survey methodology, reviewed the final draft of the survey which met UEA research governance and good practice expectations. Their feedback primarily focused on the refinement of question formatting in Microsoft Forms. Further feedback provided insights that some of the questions may appear too technical, which may discourage people from answering. The types and formats of the questions were discussed in depth. For example, for the question about 'any other physical assessment tests', the supervisory team suggested adding a larger free-text box for people to provide additional information that could be used in the next phase of the qualitative interview. These discussions are summarised in **Appendix 5.7**. The survey questions are presented in **Appendix 5.8.**

5.4.5. Survey tool

The survey was transposed onto the Microsoft 365 cloud-based software platform, Microsoft Forms application. This application is licensed through the UEA. The platform was chosen for ease of use and known acceptability to health service organisations (Hagen et al., 2021). Furthermore, the platform allows the transfer of survey responses directly into a database (in this case, Microsoft Excel database). This direct transfer of data eliminates any survey data transcription errors and prevents survey alteration by the survey respondent (Braun et al., 2021). Several options were explored before choosing a platform to host the survey, including SurveyMonkey, Qualtrics, Google Forms and WebSurveyor. These are summarised in **Table 5.2**. Ultimately, Microsoft Forms was selected as it is fully compliant with UK data protection laws and the General Data Protection Regulations (Regulation EU 2016/679). An internet link was provided for respondents to access the survey through study advertisement. Additionally, respondents could complete the survey using any electronic device such as a laptop, tablet, or mobile phone and submit it immediately (Regmi et al., 2016).

Table 5.2 Advantages and disadvantages of survey platforms. Adapted from Wright (2005)

	Advantages	**Disadvantages**
Microsoft Forms	Integrates with UEA Office 365 software suite External participants can access Easy to set-up and use (No additional training) An email notification with responses can be set up. Unlimited number of submissions Full anonymity possible Real time responses tracking	Does not integrate with non-Microsoft products Limited visual and structure customisation Question and answer format choices are limited Templates designed for marketing products Internet-dependent (Cannot be downloaded to offline)
Qualtrics	Automated data analysis Largest database of templates and customised options Automated graph generation, which can be customised	Recommended training required Cost associated with full product Originally designed for U.S.-based users. To set up a panel you need to contact Qualtrics' support. Reports can take a time to download with large data sets
SurveyMonkey	Free to use Design and visualisation upgrades compared to Microsoft Forms Directly export surveys to SPSS Accept file uploads Create multilingual surveys	Limited design features Syncing with Microsoft word processing not always reliable Price plans for more advanced features
Google forms	No limitation on number of form designs Integration with Google services	Integration to Microsoft 365 suite is not always effective Troubleshooting usually requires payment to google

	Free to use Unlimited number of submissions	Limited design customisations Files can be uploaded – Possible information governance risk
WebSurveyor	Large database of templates Integrates with external software Can add images and videos Embed surveys to webpages	Enhanced syncing with WordPress software rather than Microsoft Downloading data is time consuming Users can upload information – possible information governance security risk Depending on software upgrades and internet access, the time can complete can be lengthy

Table abbreviations. SPSS: Statistical Package for the Social Sciences; UEA: University of East Anglia; US: United States of America.

5.4.6. Ethics and consent

Ethics approval (Ref: ETH2122-0455) was gained from the Faculty of Medicine and Health Research Ethics Sub-Committee, University of East Anglia on 24th January 2022 (see **Appendix 5.9** for approval letters). The Health Research Authority (HRA) online decision-making tool was used to support this decision. As this is a national survey, the HRA tool was used for each UK country (Wales, Scotland, England and Northern Ireland). The survey protocol development does not use past or present NHS patients, service users, prisoners, embryology or human tissue. No medical device or ionising radiation is being investigated. As a result, the survey did not require HRA approval. A screenshot of the England HRA decision-making tool is presented in **Appendix 5.10**.

In healthcare research, terms like 'patient consent', 'informed consent', 'implied consent' and 'explicit consent' refer to agreements between service users (often patients) and physicians (healthcare providers) (Vayena et al., 2013). The term 'patient consent' implies that the patient is willing to share personal health information and, where appropriate, to submit to a course of medical treatment. By extension, 'informed consent' requires that the patient is informed prior to agreement of the reasons behind the request for information, the way that information will be shared among healthcare providers and third parties, and the risks associated with the prescribed medical treatment or clinical trial (Vayena et al., 2013). The foundation of informed consent is based on three essential principles of bioethics: non-malfeasance, beneficence (non-maleficence), and autonomy (Fouka and Mantzorou, 2011, Scott, 2017).

Non-malfeasance was met by the design of the survey. The survey sought to understand physiotherapy assessment practices. Therefore, the risk of causing harm to prospective participants was very low (Aita and Richer, 2005). Regarding informed consent, all prospective participants had access to and could download a comprehensive participant information sheet (PIS). This PIS was designed by the lead researcher (MM), reviewed by the supervision team (TS, SJ) and approved by the UEA ethics committee. The PIS provided explicit information about the study and possible consequences of participation. To the lead researcher's (MM) knowledge, there was no deliberate withholding of information from a prospective

participant, which would be considered an act of malfeasance (Aita and Richer, 2005). In this way, beneficence was met in ensuring that all relevant information is available to the patient to make an informed decision (Aita and Richer, 2005, Fouka and Mantzorou, 2011). Lastly, autonomy refers to a prospective participant's right to choose, which was demonstrated by the lead researcher (MM) providing information to the prospective participant and allowing them to make their own decision about consent without any pressure or coercion (Buchanan and Hvizdak, 2009). For research such as online surveys, the virtue of participants completing and submitting the questionnaire can imply that consent for using the questionnaire data has been granted (Buchanan and Hvizdak, 2009, Vayena et al., 2013). Nevertheless, in accordance with UEA ethics submission and approval, individuals who clicked the survey hyperlink to participate were taken to an introductory page with links to the PIS (**Appendix 5.11**). The introductory information page and PIS detailed the background and aims of the study, data collection types, data storage and planned dissemination details. It also detailed that the survey was completely voluntary.

All participants were required to download the PIS before proceeding to the online consent form (**Appendix 5.12**). All data collected were completely anonymous. The potential participants were informed of this in the PIS and at the consent stages of the online survey. Information that could potentially disclose a participant's identity was not requested. Participants had the opportunity to receive the final report of the survey and/or consent to be contacted for a follow-up interview based on survey responses. This question was not mandatory. To complete this, the participant provided their email address. Participants who did not provide consent were thanked for their time and left the survey pages.

Forced answering or mandatory questions is where the survey respondent cannot finish the survey or skips items without answering all questions (Sischka et al., 2022). Forced answering is often completed to prevent incomplete data or partial completion of survey submissions (Décieux et al., 2015). Furthermore, it has been reported that this method can reduce item non-response rates, which is considered a sign of data quality (Sischka et al., 2022). However, participants who are forced to answer questions may feel that their voluntary participation is compromised (Albaum et al., 2010). When developing questions and determining whether they

should be forced answers, the lead researcher (MM) considered whether each question was a 'sensitive topic'. Sensitive topic examples can include (but are not limited to) sexual behaviour, substance use and suicidal behaviour (Lensvelt-Mulders, 2012). Furthermore, sensitive questions refer to those that trigger social desirability concerns and are viewed as intrusive or potentially harmful to the respondents (Tourangeau and Yan, 2007, p. 859). It is important to acknowledge that individuals may have varying perceptions of sensitive questions (Décieux et al., 2015). As such, forcing respondents to answer certain questions could potentially negatively affect the overall reliability of data retrieved from the survey (Décieux et al., 2015). All questions developed for this survey were discussed across the piloting and PhD supervisory team. All agreed that the likelihood of perceived question sensitivity was very low. As a result, to complete the survey, respondents were required to answer every question (except for email data collection). If they left a mandatory question unanswered, they could not proceed to the next page until it was completed. This ensured that the responses were not incomplete and those who chose not to answer a question had to exit the survey.

5.4.7. Recruitment

The programme of research, including this online survey, focused on UK physiotherapy practice. Accordingly, registered Health and Care Professions Council (HCPC) UK physiotherapists working in an acute or chronic musculoskeletal and/or orthopaedic clinical practice setting were targeted for recruitment. The number of HCPC registered physiotherapists in 2021 was 61,760. However not all these physiotherapists will have experience or work in clinical settings assessing people with CSR. At the time of writing this thesis, there were no data available on what percentage of these physiotherapists assessed and/or managed adults with CSR. The Musculoskeletal Association of Chartered Physiotherapists (MACP) is a clinical interest group (CIG) and professional network of physiotherapists in musculoskeletal physiotherapy practice-based settings. Its membership is 1,200 physiotherapists. The majority are based in the UK. However, it is acknowledged that physiotherapists may choose not to become members of this CIG but will have experience in the assessment and management of CSR. Therefore, an estimated population size of 2,000 respondents was set. The sample size calculation was made using the 'Sample Size Calculator' platform

(https://www.qualtrics.com/blog/calculating-sample-size/), considering a 95% confidence level and a margin of error of 5%. The response target was 323 respondents. This target sample size is comparable to other health research surveys, for example Ganesh et al., (2023) n=328, Husted et al., (2020) n=234.

The time available for participants to complete the survey was four weeks. This was primarily attributed to practical constraints of the lead researcher (MM), namely employment. It is noteworthy that there is no agreement on the ideal duration for an online survey to remain open (Ruel et al., 2015, Wu et al., 2022). Wu et al.'s (2022) systematic review and meta-analysis reported that the length of time a survey is kept open was not associated with higher response rates. Of note, previous, similar, musculoskeletal surveys have kept their online survey open for 12 (Ferguson et al., 2015) to 16 weeks (Hallegraeff et al., 2021).

5.4.8. Using social media as a recruitment tool

Social media was the primary recruitment tool for this online survey. By using social media to recruit participants, researchers can avoid many of the challenges associated with recruiting through healthcare organisations (such as hospital computer firewalls and time allocation to engage with research) (Edwards et al., 2014, Reagan et al., 2019, Stern et al., 2014). Potential participants can decide which surveys are salient to them, and complete the survey at a convenient time, using their preferred device (Edwards et al., 2014, Stern et al., 2014). Additionally, social media can provide access to a more diverse population, including those from rural areas who may have been under-represented in the past (Edwards et al., 2014). This can lead to enhanced generalisability of survey findings.

A search strategy was completed in MEDLINE to synthesise systematic or scoping review research evaluating the effectiveness of social media recruitment for health research. The search strategy results are presented in **Appendix 5.13 and 5.14**. Two systematic reviews have evaluated the effectiveness of the use of social media for recruitment (Brøgger-Mikkelsen et al., 2020, Whitaker et al., 2017). One systematic review included 30 studies that used any social media (Facebook, Twitter and/or Instagram) to recruit participants for health-related studies. They concluded that a single social media platform approach can recruit a mean of 32%

(IQR 0-98%) of the sample (Brøgger-Mikkelsen et al., 2020). Twelve studies had higher recruitment with social media compared to non-social media approaches, whereas 15 reported higher recruitment from other methods (such as posters, flyers and word of mouth). However, caution should be taken as these included studies which used paid advertisements to reach target populations. Another review included 35 studies that used only Facebook to recruit participants for any health-related studies. The authors concluded that Facebook advertisement was effective in recruiting participants (Whitaker et al., 2017). However, caution should be exercised as the target population was healthy participants in physical activity trials, which may limit the external validity to this survey-based research.

Using social media has been reported as effective when recruiting healthcare professionals working in a musculoskeletal healthcare setting. An observational study on recruiting participants for an international survey on shoulder pain found that using multiple social media platforms and consistent effort (defined as regularly posting and reposting study adverts) can improve completion rates (McRobert et al., 2018). Using multiple recruitment methods simultaneously and sequentially, the study received high engagement rates, with over 30% of survey data collected within the first week. This indicates that the multimodal approach effectively engaged a diverse, geographically dispersed population and directed them to the online survey (McRobert et al., 2018). This is supported by a systematic review reporting evidence that social media is best able to recruit individuals for observational survey-type studies as opposed to interventional studies; however, this finding was based on 12 high risk of bias studies. Of the 26 spinal surveys of practice presented earlier in this chapter, five used postal mail to disseminate and advertise their surveys (Topolovec-Vranic and Natarajan, 2016), the remaining 21 used single and multi-model social media strategies to advertise their respective surveys (Topolovec-Vranic and Natarajan, 2016). Of the 21 surveys, 18 used Twitter as their recruitment strategy (Topolovec-Vranic and Natarajan, 2016).

Criticism of using social media as a recruitment tool are acknowledged. Respondents recruited via social media tend to be younger than those from more traditional recruitment methods (Frandsen et al., 2016, Guillory et al., 2018). However, Topolovec-Vranic and Natarajan (2016) reported in their scoping review that observational survey participants who provided complete data had more years

of clinical experience on average (mean 16.3 (SD 9.8) years) than those who provided incomplete data (mean 13.1 (SD 10.0) years), suggesting that age may not be a disadvantage. A summary of the advantages and disadvantages of recruitment strategies for survey-based research is outlined in **Table 5.3**.

Table 5.3 Advantages and disadvantages of survey recruitment. From McRobert et al., (2018)

	Advantages	**Disadvantages**
Word of mouth	Low effort and cost.	Narrow reach. Relies on population access
Conferences and networking events	Access to relevant audience	More effort, time consuming.
Postal flyers	Personal delivery of invitation	Need access to postal addresses
Notice boards	Low cost and effort	Narrow reach
Email	Low effort and cost. Fast delivery	Easy for recipient to ignore and/or apply spam filters
Online message board	Low cost and effort	No guarantee of audience accessing notice
Society/network mailing lists	Access to large volume of respondents with possible/relevant interest	Information may be out of date. Variable costing. No guaranteed access
Social media	Low cost. Fast. Broad potential reach. Uses existing personal/ professional networks. Acceptable to approach those who are not in researcher's network. Facilitates social sharing/ snowballing. Crosses professional and geographical boundaries	Challenging to achieve good engagement. Relies on pre-existence of a diverse and functioning social network.
Internet through special interest groups	Fast. Low cost. Likely to be viewed by relevant professionals.	No control over advert impact

Social media platforms are a popular way for people to communicate and collaborate across healthcare research (Admon et al., 2016, Guillory et al., 2018). However, studies examining the usefulness of social media in recruiting participants have shown inconsistent outcomes (Admon et al., 2016, Frandsen et al., 2016). Recruiting healthcare workers for survey research can be difficult due to various internal and external factors. Examples include their busy working and personal schedules, lack of interest in the research topic, and the conflict between clinical work and participating in a study that may not accurately reflect their work (Braun et al., 2021). Therefore, when considering a survey recruitment strategy, two theories,

namely social exchange theory and leverage-saliency theory, were considered to maximise response rates (Fan and Yan, 2010).

To this author's knowledge, there are no data on the activity or engagement with social media across UK physiotherapists. Despite this, social media platforms such as Twitter should not be considered a panacea, and other internet platforms formed part of the multimodal recruitment strategy for the online survey recruitment (Ruel et al., 2015, Sanchez et al., 2020). The use of social media as part of a multi-modal strategy will now be discussed.

5.5. Using Twitter as a recruitment platform

Utilising an online survey format for data collection makes social media platforms, such as Twitter, an effective option for recruiting participants (Wilson and Usher, 2017). Twitter can support researchers find online survey participants outside of their established professional network, allowing for greater reach and distribution of the survey (McRobert et al., 2018). Social exchange theory suggests that participants are more likely to respond if they perceive the benefits of doing so outweigh the costs (Cook et al., 2013, Fan and Yan, 2010). Benefits can be tangible, such as a monetary incentive, or intangible, such as the desire to contribute to knowledge advancement. This online survey aimed to understand UK physiotherapy assessment practice of CSR. Therefore, it was hypothesised that this would be relevant and important to UK physiotherapists to participate in this online survey, which aligns with leverage-saliency theory. Leverage-saliency theory explains why someone chooses to participate or not in a survey (Groves et al., 2000). The theory states that individuals are more likely to participate if the survey is relevant or important to them (Groves et al., 2000).

By using social media platforms like Twitter, researchers can rapidly build an online network of relevant individuals who can be invited to participate in the online survey and assist in the recruitment process (Wasilewski et al., 2019). To this end, the lead researcher (MM) compiled a list of known (to the lead researcher) UK Twitter accounts of professional groups and individuals that have posted information about radiculopathy and/or neck pain. This list was then discussed with a member of the research team (MT). It is acknowledged that there may have been a sampling bias

by seeking the immediate research team to review the Twitter list and post-development. The limitations of the use of Twitter for recruitment in this programme of study will be further discussed in **Chapter 7**.

In this study, the research team's followers could share the invitation tweets, making them visible to their own followers who could also retweet them. This expanded the reach of the invitation. Additionally, some Twitter users, such as musculoskeletal and pain science professional network groups, came across the tweets and voluntarily shared the link to the research and survey on their own social media platforms, inviting others to participate. This snowballing sampling effect enhances the recruitment to online surveys, as the study advert redistribution delivers an efficient and valid approach to recruiting an unknown and large target population (McRobert et al., 2018). The specific recruitment methods using Twitter will now be discussed.

The lead researcher (MM) had a professional Twitter account for nine years before starting the research. The account name (@MM_Physio) revealed that MM was a physiotherapist with a focus on musculoskeletal health and clinical outcomes. This made it likely for people interested in these topics to follow the account (McRobert et al., 2018). Other Twitter profiles were targeted based on 'high social capital' (McRobert et al., 2018), meaning that the Twitter profile had more than 100 additional followers and posted musculoskeletal research and/or education material in the last month before online survey dissemination, demonstrating online presence and interaction (McRobert et al., 2018). These included Prof. Toby Smith (@tobyosmith), Prof. Mick Thacker (@dibbygibby), Prof. Lesley Haig (@ProfLesleyHaig) and Mr. Andrew Bennett (@andypbennett), who had a combined total number of 14,282 Twitter 'followers' at the time of the online survey study advert dissemination. The lead researcher (MM) is also a member of the Centre of Precision Rehabilitation for Spinal Pain, University of Birmingham (1,190 Twitter followers) and Bannister Laboratory Kings College London (2,014 Twitter followers). The lead researcher (MM) had agreement from the respective research groups' directors that their Twitter platforms (@CprSpine; @bannister_lab) publicised this study weekly.

The most active times for the Twitter profiles above were 10:00hrs, 13:00hrs, 16:00hrs, 19:00hrs and 21:00hrs. These times were selected based on a study by Swamy et al. (2017), which investigated the engagement of Twitter posts during March 2016. The authors report that of the total of 22,795 tweets posted, the 11,484 Twitter users' highest tweet frequency occurred between 5:00am and 9:00am Central Time (CST). This translated to 10:00hrs to 14:00hrs in London (GMT). However, this analysis was based on tuberculosis research, which may limit the external validity to this survey research (Swamy et al., 2017). When considering strategy and day of the week, it was reported that the number of retweets received during the hours of 00:00hrs to 05:59hrs and 18:00hrs to 23:59hrs (incidence rate ratio (IRR) 2.98, 95% CI: 1.88-4.71, $p<0.001$) were significantly higher than during 06:00hrs to 23:59 (IRR 1.48, 95% CI: 1.05-2.09, $p>0.05$) (Swamy et al., 2017). However, posting tweets during the hours of 12:00hrs to 1759hrs decreased the IRR for retweets by 40% compared to 06:00hrs to 11:59hrs (IRR 0.60, 95% CI: 0.46-0.79, $p<0.001$). Posting on a Monday (IRR 3.57, 95% CI: 2.50-5.09, $p<0.001$) or Wednesday (IRR 1.50, 95% CI: 1.11-1.11, $p<0.01$) compared to the other days of the week was optimal for researchers (Swamy et al., 2017). Therefore, Tweets were sent at those times during the recruitment period. This strategy, alongside 'retweets', will enhance the effectiveness of recruitment through a 'snowballing' sampling (Hendricks et al., 2016).

As part of the multi-modal recruitment strategy, professional SIG web pages (such as musculoskeletal and research forums on the Interactive Chartered Society of Physiotherapy – iCSP, Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP), Musculoskeletal Association of Chartered Physiotherapists (MACP), Physiotherapy Research Society (PRS)) formed part of the recruitment strategy. These professional networks were selected based on their interest in supporting UK physiotherapy research and/or having a specialist interest in CSR assessment and/or management research and education in practice. The lead researcher (MM) produced a study advert and sought permission via email from the gatekeepers of professional networks to disseminate the advert. All professional networks disseminated the advert through their Twitter platforms. In addition, the MACP professional network placed a study advert on its public-facing webpage, which was also shared through its membership e-newsletter. The PRS and ATOCP professional networks shared the study invitation through their

membership email mailing lists. The lead researcher (MM) publicised an advert through the iCSP discussion forums. A follow-up message was sent one week later to the gatekeepers of the professional networks. **Appendix 5.15** presents the study advert through the iCSP platform. **Appendix 5.16** presents evidence of dissemination support from gatekeepers. **Appendix 5.17** presents a summary of the multi-modal survey recruitment strategy.

5.6. Data management

The online survey responses were downloaded from Microsoft Forms and imported into Microsoft Excel. This was securely stored using the UEA OneDrive software, managed by the research team only. The UEA OneDrive was protected through the UEA password protection system. This met UEA's research governance expectations and ethics approval. Once all data had been processed and the findings disseminated, the study data will be stored for five years on the UEA's secure cloud-based system and then deleted.

5.7. Data analysis

Data were imported into Microsoft Excel (Microsoft Corp., Redmond, WA, USA) and data analysis were performed with SPSS statistical software (IBM Corp, Chicago, Illinois, USA). Data were analysed descriptively using mean and mode. Results were displayed visually through bar graphs. This form of analysis is consistent with other survey studies, including greater trochanteric pain syndrome (Stephens et al., 2018), lateral elbow pain (Cioce et al., 2020) and frozen shoulder (Hanchard et al., 2011). Any free-text comments or answers were presented as unexpected responses, and their frequency was recorded. These comments or answers were further explored in Phase 2 through qualitative interviews. The data analysis formed part of the integrated results, presented in Chapter 7.

5.8. Survey reporting

The Consensus-Based Checklist for Reporting of Survey Studies (CROSS) (Sharma et al., 2021) was selected for this survey to provide transparent and

accurate survey reporting (Altman et al., 2008, Johnson and Christensen, 2020). CROSS follows the typical sections needed for peer-reviewed publications and helps researchers create a thorough research plan before conducting a survey (Sharma et al., 2021). For example, the results section of CROSS provides information about the respondents' characteristics, as well as the descriptive and main results, which are not covered in other reporting tools such as the Survey Reporting Guideline (SURGE) (Grimshaw, 2014) and Checklist for Reporting Results for Internet Based E-Surveys (CHERRIES) (Eysenbach, 2004).

5.9. Next steps

The results of this survey are presented in **Chapter 7**. The survey results provided insight into the possible barriers and facilitators of using pain-screening questionnaires and somatosensory testing modalities when establishing CSR. This has informed the next phase of this mixed methods research study, namely the qualitative interview development (**Chapter 6**). The next chapter (**Chapter 6**) will discuss the methods completed to explore UK physiotherapists' experiences establishing CSR and the reasons underpinning decision-making around assessment strategies utilised. Integrating quantitative (survey) and qualitative (interview) findings through narrative joint display will be presented and discussed in **Chapters 7 and 8**, respectively.

Chapter 6: Understanding cervical spine radiculopathy assessment practices among United Kingdom physiotherapists. Phase 2: a qualitative study

6.1. Introduction

This chapter will discuss and justify the qualitative interview for this phase of the mixed methods research study. The qualitative interview question development, lead researcher's positioning and reflexivity, recruitment and data analysis are then presented and justified. The explanatory sequential mixed methods research design adopted means that integrated results and analysis of the quantitative survey (**Chapter 5**) and qualitative interviews (**Chapter 6**) are presented and discussed in **Chapters 7** and **8**, respectively.

6.2. Aims and objectives

This Phase 2 qualitative study aimed to investigate UK physiotherapists' experiences establishing CSR in clinical practice. The qualitative interviews objectives were to answer three overarching research questions:

1. What physical assessment practices do physiotherapists utilise when establishing a CSR diagnosis and the reasons underpinning this decision-making?

2. Which somatosensory testing practices do physiotherapists utilise when establishing a CSR diagnosis and the reasons underpinning this decision-making?

3. What pain-screening questionnaire practices do physiotherapists utilise when establishing a CSR diagnosis and the reasons underpinning this decision-making?

6.3. Qualitative interviewing

Interviews are a research method used by researchers to gain insight into how individuals subjectively interpret social phenomena (Kvale, 1996). Participants can express their emotions, biases, opinions, and attitudes towards the different experiences they encounter (Kvale, 1996). Unlike quantitative research that tests causal relationships, qualitative interviews reveal how individuals give meaning to their social experiences (Denzin, 2001). This approach comprehensively explains unexplored phenomena that predetermined hypotheses cannot explain. In addition, interviews are particularly useful when little information is available about study or when detailed insights are required from participants (Alsaawi, 2014). Conducting interviews is crucial in recognising the importance of human relationships (Dowling, 2006). It allows researchers to establish a meaningful connection with participants throughout the research process (Dowling, 2006). This helps to ensure that the participants' subjective views and the researcher's interpretations of these views are the foundation of the interview approach (Warren, 2002).

Focus groups were considered an alternative method of data collection for this research phase. Focus groups are used to explore the expertise and experiences of participants, including why and how they behave in certain ways (Braun and Clarke, 2022, Gill et al., 2008, Gundumogula and Gundumogula, 2020). Focus groups are beneficial for gathering individuals with similar expertise and experiences to share detailed information on a specific topic (Acocella, 2012, Tritter and Landstad, 2020). The advantage of this interaction is that it encourages participants to question and explain their perspectives to each other, providing valuable insights into their level of agreement and diversity of responses (Tritter and Landstad, 2020). Another advantage of focus groups is that researchers can directly ask participants to compare their experiences and views, rather than relying solely on aggregated data to understand differences among interviewees (Goodwin et al., 2020).

Despite the possible advantages of focus groups, the lead researcher (MM) considered the importance of the emergence of group-think or power dynamics within the group (Kornbluh, 2023). It was anticipated that the physiotherapists would

have different experiences gained through years of work and NHS banding, which may result in some individuals not feeling able to contribute as much as they would like or others 'over' contributing to the conversation (Kornbluh, 2023). This was considered a major disadvantage of a focus group approach to answer this research question.

Observations were another alternative data collection method considered. It is acknowledged that conducting observations of practice may gain deeper insights into real-world dimensions of the research problem at hand (Jamshed, 2014) and understanding of a specific setting and actual behaviour (Lofland et al., 2022). However, given the aim of the research to understand the rationale and reasons why UK physiotherapists assess CSR, observing behaviour in healthcare settings would not be appropriate to address this.

A search investigating the use of qualitative interview research in spinal pain with or without radiculopathy was conducted on 20th October 2023. The search terms and results are presented in **Appendix 6.1**. Qualitative interviews exploring clinical practice in spinal pain have mostly focused on understanding the experiences of physiotherapy treatment for LBP without radiculopathy (Ampiah et al., 2022, Boutevillain et al., 2017, Braeuninger-Weimer et al., 2019, Calner et al., 2017, Costa et al., 2022, Holt et al., 2015, Hsu et al., 2014, Kahere et al., 2022, Lin et al., 2014, Maiers et al., 2016, Plank et al., 2021, Setchell et al., 2019, Sharpe et al., 2021, Stisen et al., 2016, Stomski et al., 2014, Tankha et al., 2023). Qualitative interviews have also facilitated the exploration of treatment choices and stratified care for people with persistent spinal pain (Bishop et al., 2015, Bunzli et al., 2015, Cowell et al., 2018, Haskins et al., 2014, Karstens et al., 2018, Monk et al., 2023, Noblet et al., 2020, Schlett et al., 2022, Waterfield et al., 2015). Further, qualitative interviews have been used to explore self-management choices in LBP (Achten et al., 2022), stratified care in Nigeria for acute pain (Adje et al., 2022), psychosocial consequences of LBP mapped against radiology findings (Alhowimel et al., 2022), and the biopsychosocial model in treatment decision-making (Horment-Lara et al., 2022, Hsu et al., 2014, Lin et al., 2014).

Despite some evidence in this area, understanding the rationale and reasoning of assessment strategies for CSR has not been investigated using qualitative interview methods. Previous qualitative research employing interviewing to understand how and why clinicians assess spinal pain has focused on how physiotherapists and orthopaedic surgeons triage LBP in orthopaedic surgical centres (Braeuninger-Weimer et al., 2019, Murray et al., 2023) and the use of biopsychosocial screening questionnaires when assessing LBP (Cowell et al., 2018, Cowell et al., 2019, França et al., 2019, Lindbäck et al., 2019). Four studies had used qualitative interview research to explore clinical reasoning among physiotherapists when designing healthcare services (Gorgon et al., 2022), understanding the words used to describe pain and function (Jensen et al., 2013, Ryan and Roberts, 2019) and the use of independent prescribing among physiotherapists (Noblet et al., 2020).

The lead researcher (MM) considered three different types of interview for implementation in Phase 2 of this research programme: structured, semi-structured, and unstructured (Alsaawi, 2014). **Table 6.1** presents three different interview types. Despite their differences, they all share some key features. Firstly, there is an exchange of dialogue between two or more people, whether face-to-face or online (Alsaawi, 2014). Secondly, the researcher has specific topics, themes, or issues they want to explore, but with varying degrees of structure (Stuckey, 2013). Thirdly, knowledge is seen as situated and contextual, so the researcher needs to bring relevant contexts into focus to create situated knowledge (Stuckey, 2013). This means that meanings and understandings are co-produced through interaction and the construction or reconstruction of knowledge (Stuckey, 2013)

Table 6.1 Types of qualitative interviews. Adapted from Alsaawi (2014), Sorsa et al., (2015), Stuckey (2013)

Qualitative interview	Description	Relevant examples in the context of the current study
Structured	Fixed list of pre-planned questions Suitable for rapid interview completion It may be beneficial for interview participants with reading or arithmetic challenges. Restricts the range of responses from interview participants	Subialka et al., (2022) A structured qualitative interview to determine patient expectations prior to beginning physical therapy for individuals with musculoskeletal conditions The interviews followed a prior agreed question list with their participants, each participant was read the same question, in the same format during the interview.
Unstructured	No predetermined theories or ideas Typically lasts several hours No set questions to guide the conversation Often used when there is limited information about the topic	Sofaer et al., (2005) Unstructured interviews to gather information from older individuals about their physical, psychosocial, and practical limitations caused by chronic pain.
Semi-Structured	Ask specific questions to delve into a particular subject Interview questions can be adaptive and allows for 'probing' questions Flexible in nature and facilitate researchers to explore concepts that may have been overlooked	Semi structured qualitative interviews to explore the preparedness of new graduate physiotherapists in the field of chronic pain management and their experiences in clinical practice, semi-structured interviews were conducted (Ingram et al., 2019).

Researchers can analyse conversations and initial responses during a semi-structured interview to gain valuable insights. Researchers can uncover hidden information that may be useful in data analysis by paying attention to verbal and non-verbal cues, such as pauses or silence (Opdenakker, 2006). Multiple themes with interviewees can be discussed and synthesised to add flexibility (Oltmann, 2016, Opdenakker, 2006). Additionally, interviewers can use their interpersonal skills to explore significant issues raised by the participant, which are central to comprehensive data collection.

For this study, an online qualitative interview method was selected. In-person interviews were considered, as it is suggested that face-to-face interviews enhance the establishment of rapport between interviewer and participant and communicate complex topics clearly (Lo Iacono et al., 2016, Opdenakker, 2006). However, online interviews reduce travel costs (for the lead researcher and participant) and save time for the interview participants, which may, therefore, enhance the recruitment to this Phase 2 qualitative interview study (Lo Iacono et al., 2016). In addition, similarly to Chapter 5, regarding online surveys, at the time of developing the protocol and ethics submission, the global health pandemic (COVID-19) restricted the movement of individuals, further supporting the decision to complete an online qualitative interview.

Several obstacles can reduce the credibility of online interviews, which can include deciding who researchers want to talk to, which is distinct from the problem of participant selection (Adhabi and Anozie, 2017). The 'who' question identifies the nature of the population that the research aims to communicate with, taking into account the aspect of communication (Adhabi and Anozie, 2017, Roulston and Choi, 2018). For instance, when working with people exhibiting multiple co-morbidities and persistent pain, good communication skills are essential to elicit responses from these individuals (Beuscher and Grando, 2009). Therefore, communication poses an immediate challenge based on the type of people interviewed. Consequently, researchers often face the challenge of selecting the 'right' participants for their studies (Robinson, 2014). During online semi-structured interviews, participants may share personal and sensitive information with the interviewer (Robinson, 2014). It is important to recognise the power dynamic between the researcher and participant. Since the conversation may discuss personal topics, the interviewer should listen attentively, show respect, and be mindful of the sensitive nature of the discussion (Anyan, 2013, Durkin et al., 2020). To establish a good rapport, the interviewer should be genuine and receptive to the interviewee's perspective (Anyan, 2013). The interviewee is considered the expert and should be treated as such. Power dynamics are discussed in more detail later in this chapter.

An online semi-structured interview type allows a flexible nature to questions, helping to uncover significant information that the research team may have overlooked in the quantitative survey stage (Adams, 2015). This is not always possible with set questions and format in a structured interview. The target sample was physiotherapists working in clinical practice, and it was assumed that they have time pressures to volunteer for research participation (Sorsa et al., 2015). Therefore, having unstructured interviews, which can last several hours (Adams, 2015), was not practical to recruit participants. Furthermore, the targeted participants to interview were all qualified physiotherapists unlikely to have significant challenges in conversing on a physiotherapy topic, and therefore being more suited to semi-structured versus structured interview methods (Adhabi and Anozie, 2017).

6.4. Role of the interviewer: positioning, reflexivity and power dynamics

When conducting qualitative research, the researcher is critical as the research instrument. The researcher is responsible for gathering data from respondents by creating a comfortable environment where they can share their experiences (DiCicco-Bloom and Crabtree, 2006). This is achieved through the researcher's facilitative interaction, which helps to identify cues, establish a flow of communication and put respondents at ease (DiCicco-Bloom and Crabtree, 2006). During interviews, the interviewer must establish a positive relationship with the interviewee (Jack, 2008). Building rapport involves developing trust, respecting the interviewee and the information they disclose (Jack, 2008). This creates a safe and comfortable environment for the interviewee to share their experiences and attitudes as they truly occurred (Bengtsson and Fynbo, 2018). Spradley (2003) outlined various stages of rapport development, such as apprehension, exploration, cooperation, and participation.

The concept of reflexivity recognises that researchers are not simply observers of a phenomenon, but active participants in the process of creating knowledge (Watt, 2007). In recognition of this, the lead researcher (MM) examined his identity as a physiotherapist, a clinician and academic and how this can be identified as both subject and object (Patnaik, 2013). Introspective reflexivity refers to the researcher's

awareness of their own experiences and how they might impact their choice of subject matter, methodology, and themes (Takhar-Lail and Chitakunye, 2015). For the qualitative interviews in this study, the lead researcher (MM) noted immediate observations, thoughts and interpretations after every interview in a diary. This captured any thoughts or reflections in its raw state. These actions aimed to maintain research focus by setting aside any biases or attitudes that may influence the research process to practise introspective reflexivity (Patnaik, 2013). This reflective diary approach, namely post-interviews, is recognised as good practice in qualitative research reporting guidelines (Tong et al., 2007). Previous research has utilised this approach when investigating spinal stenosis treatment decisions (Peterson et al., 2021), patient experiences of radicular pain (Ryan and Roberts, 2019) and understanding adherence to musculoskeletal exercise programmes for musculoskeletal neck pain (Himler et al., 2023).

Methodological reflexivity is a way of recognising the relationship between the researcher and the research while still following standardised procedures (Patnaik, 2013). Power dynamics are also recognised by the lead researcher (MM) with this relationship, which is discussed later in this sub-section. Based on prior clinical experience, the lead researcher (MM) anticipated that physiotherapists being interviewed may have had a full day of clinical patient contact. Additional adjustments were made in terms of their time preference (after the working day) and using a video platform to complete the interview supported interview participation.

In the initial phase of an interview, there may be uncertainty due to the newness of the situation for both the interviewer and interviewee (Kallio et al., 2016). The main goal during this phase is to encourage the interviewee to ‘open up’ and start talking (Kallio et al., 2016). To support this aim, the lead researcher (MM) used ‘warm-up’ questions. The first question asked by the lead researcher (MM) was broad and open-ended (“Tell me about your area of clinical practice?”), reflecting the nature of the research and not be threatening in any way (Roberts, 2020). During the exploration phase, the qualitative interview participants became more involved and provided a detailed explanations CSR assessment. This phase involved the lead researcher (MM) utilising active listening and a sense of bonding and sharing (DeMarrais, 2004). The lead researcher (MM) reflected answers back to the interview participant and sought to confirm understanding (DeMarrais, 2004). It was

acknowledged that the greatest degree of rapport was achieved at this stage, and the interview participant may guide and teach the lead researcher (MM).

The lead researcher (MM) acknowledged his role in the interview relationship (Brinkmann, 2014). To maintain the interview's integrity, the lead researcher (MM) acknowledged his reactions to participants' disagreements with the quantitative survey results and recognised the importance of ensuring that any responses are supportive and encouraged further elaboration instead of debating the quantitative survey findings (Adams, 2010). Another issue that was prospectively identified was how the lead researcher's (MM) responses might influence how participants interpret events, thus affecting the data collected during the interview (Dickson-Swift et al., 2006). To minimise this, the lead researcher (MM) planned to encourage participants to elaborate on their answers but refrain from giving therapeutic responses to avoid imposing their biases on the topic (Dickson-Swift et al., 2006). Furthermore, a self-reflective journal was developed at the end of each interview and debriefing sessions with the PhD supervision team (TS, SJ) were planned.

Qualitative interviewing poses challenges for researchers regarding instrument rigour and bias management (Chenail, 2011, Roulston and Shelton, 2015). The researcher's personal affinity with the population under study, including being a group member themselves, may also introduce bias into the study (Bergen and Labonté, 2020, Mehra, 2002). This insider perspective may limit the researcher's curiosity to only focus on what they think they do not know, rather than exploring what they may not realise they do not know (Bergen and Labonté, 2020). To minimise this possible bias, the lead researcher (MM) acted to carefully prepare the topic guide, complete reflective journal entries and transcribe data from previous interviews (Roulston and Shelton, 2015).

The role of the interviewer is also in managing power dynamics within the interviews. Power can manifest in various ways in interviews, including dictating opinions and imposing one's agenda on others (Durkin et al., 2020). Power dynamics in interviews are often influenced by examples such as socioeconomic status, education, professional experience, gender and ethnicity of those involved (Durkin et al., 2020). Before starting and following the completion of each interview, the lead researcher (MM) reflected on three dimensions of power: direct confrontation,

indirect contest of power and understanding of the least powerful person (Lukes, 2007).

When there is a direct confrontation between two parties, control is explicitly displayed with open power. For example, if an interviewee stops the interview or refuses to answer a question, this demonstrates the first dimension of power. To minimise this, the lead researcher (MM) detailed at the start that there are no “right or wrong” answers, followed by the ‘warm-up’ questions to establish rapport, and the lead researcher (MM) followed up with a clarification that he understood the answer the interview participant provided (Kvale, 2006). By regularly checking and testing assumptions, the lead researcher (MM) aimed to establish the truth of the research (Finlay, 2002). The second dimension involves an indirect contest of power, which involves commanding and controlling the situation, influencing the rules, discouraging actions, and setting agendas (Lukes, 2021, Lukes, 2007). This dimension was minimised by asking open questions at the end of each theme in the topic guide and at the end of the interview. These included asking the interview participant whether there were “any aspects not covered that you would like to discuss” and “were there any items missed so far that are important to share about the assessment of CSR?”. The third dimension involves influencing what the less powerful party thinks and understands about the world and their interests (Lukes, 2021). Similarly to first two power dimensions, the lead researcher (MM) used an introductory message at the start of the interview and ‘warm-up’ questions to minimise the possibility of dimension having influence. Notwithstanding this, the lead researcher (MM) acknowledged that interviews often have a hidden power imbalance between participants due to their designated roles in the conversation (Anyan, 2013).

6.5. Interview topic guide development

When conducting health-related research, pilot studies are frequently employed to gather qualitative data (Gudmundsdottir and Brock-Utne, 2010). A pilot study’s main goal should be to identify any necessary modifications to questions or procedures that are not producing suitable responses or valuable data for researchers (Gudmundsdottir and Brock-Utne, 2010). Two pilot interviews were completed by the lead researcher (MM) to test the accessibility and relevance of the questions

(Roller and Lavrakas, 2015). Throughout this process, the lead researcher (MM) practiced and assessed interview skills and became familiar with the practical aspects of conducting a qualitative interview such as recording and transcribing. The lead researcher (MM) sent emails to colleagues at the University of Birmingham (employer) who had qualitative research and/or CSR clinical practice experience, seeking volunteers to partake in two pilot interviews. The first pilot interview, which lasted 40 minutes, was conducted with a senior physiotherapist with expertise in qualitative research and experience of assessing CSR. At the end of the interview, the interview topic guide was reviewed with the participant, and feedback was provided (**Appendix 6.2**). A second pilot interview was arranged with a musculoskeletal physiotherapist with experience in working in spinal rehabilitation outpatient clinics. The same review process was completed. The feedback is presented in **Appendix 6.2.** The finalised topic guide is presented in **Appendix 6.3.**

During the two pilot interviews, some practical issues required addressing. Scheduling interviews was a challenge due to participants' varying commitments and schedules. However, the researcher learnt to be flexible with timing, accommodating participants' personal and work responsibilities. Additionally, it became clear that asking more specific questions was necessary. For example, instead of asking about a participant's experience with CSR assessments, the researcher enquired about the specific physical assessment strategies used to diagnose CSR. This modification was made in response to pilot participant feedback that suggested physiotherapists were not accustomed to being asked questions in such an unstructured manner. Consequently, the lead researcher (MM) tailored the questions to be slightly more specific, while remaining open-ended.

In one pilot interview with a physiotherapist working in a spinal rehabilitation clinic, the participant asked the question, "Is it acceptable to declare a problem in our healthcare delivery system?". As the interviewer, it felt like the roles had switched (interviewer to interviewee). To answer this, the participant was reassured by the lead researcher (MM) that perceived weaknesses are likely to be present across most healthcare systems and stakeholders and that recognising, reflecting on, and making an action plan from them is important. During the piloting, it was recognised that modifying interview questions based on the interviewee's responses was possible. For example, questions about challenges and barriers in assessing CSR were moved to the end of the interview, as discussing these topics at the beginning

made participants feel like the situation was outside their control and they could not change it. The pilot qualitative interviews also enhanced the lead researcher's (MM) confidence to build and establish a rapport with participants, earning their trust and ensuring they were comfortable. Moreover, the pilot study allowed the researcher to practise taking reflective notes post-interview, guiding thoughts and reflections for the main study (Williams-McBean, 2019).

6.6. The ethics of qualitative interviews

The extent to which participants are willing to engage with qualitative interviews depends on their willingness to share their personal experiences (Brinkmann and Kvale, 2005, Orb et al., 2001). The intention of the lead researcher (MM) was to listen to the voice of participants and interpret these experiences; this is usually described as an emic perspective (Brinkmann and Kvale, 2005). In this way, the lead researcher (MM) recognised the participants as autonomous people who will share information willingly (Arifin, 2018). This was achieved by implementing ethical principles in the research design, data collection and analysis, including principles of autonomy, beneficence and justice.

The prospective participants for Phase 2 were assured of their right to be informed about the study, the right to freely decide whether to participate in a study, and the right to withdraw at any time without penalty. In the qualitative interviews, the prospective participant provided informed consent, meaning that prospective participants exercised their rights as autonomous persons to voluntarily accept or refuse to participate in the study (Qu and Dumay, 2011). The participant information sheet (PIS) **(Appendix 6.4**), signed consent form and introductory discussions at the start of the scheduled interview time support this aspect of autonomy.

A second ethical principle is beneficence – doing good for others and preventing harm (Richards and Schwartz, 2002). Strategies to adhere to beneficence in the qualitative interviews included the use of pseudonyms and security of data storage. In the qualitative online interviews, participants' identity is protected in the data analysis and subsequent research publications. Furthermore, participants were informed through the PIS and introductory discussions how the results will be published through this thesis and peer-reviewed publication in a scientific journal.

Quotations or other data from the participants, even though anonymous, could reveal identities (Husband, 2020). Therefore, pseudonyms were used to maintain anonymity (Husband, 2020). Furthermore, all interviewees were offered the opportunity to receive the interview transcript and review the use of quotations, which supported the maintenance of beneficence and adhered to qualitative research reporting guidelines. In addition, the recorded interviews were downloaded and imported into Microsoft Office, OneDrive. This ensured data were securely stored and password protected using the UEA OneDrive software. Furthermore, this were managed by the research team only and protected through the UEA password protection system. The data were only shared with the participant, investigator and research team. This followed the expected UEA research governance processes.

The lead researcher (MM) demonstrated understanding and application of the principle of justice by recognising participants' vulnerability and contributions to the study, exemplifying the principle of justice (Pietilä et al., 2020). For instance, the qualitative interviews targeted a sample of UK physiotherapists. All participants had the opportunity to review their own transcripts before analysis. All participants were invited to provide their general thoughts on the transcribed interview and its accuracy, including adding or removing any transcribed items with reasons why. Furthermore, permission was sought from interview participants in the introductory discussions and PIS that specific, anonymised quotes may be used in research outputs related to this study. All interview participants consented to this, which supported the principle of justice by acknowledging and respecting participants' contribution to these qualitative interviews (Pietilä et al., 2020).

6.6.1. Member checking

The act of returning interview or analysed data to a participant is referred to as member checking, respondent validation, or participant validation (Philipps and Mrowczynski, 2021). Various benefits have been proposed for adopting member checking of transcripts. Presenting transcripts to participants can ensure the researcher has an accurate representation of transcribed interviews ready to analyse and support the mitigation of misrepresentation during the transcript analysis process (Durkin et al., 2020, Hagens et al., 2009). Involving the interview participant in checking and confirming the transcript may help reduce the potential

for researcher bias and enhance transcript accuracy (Rowlands, 2021). Furthermore, member checking can align with constructivist epistemology in that knowledge is co-constructed with the researcher (Motulsky, 2021).

While member checking *per se* is widely accepted and utilised, member-checking transcripts can have some weaknesses (Durkin et al., 2020, Philipps and Mrowczynski, 2021). The opportunity for participants to delete or amend transcribed interviews can call into question the ownership of the data - whether it belongs to the interviewer, the interviewee or both (Durkin et al., 2020). Moreover, requesting participants to review the transcripts for potential transcription amendment can be misleading (Thomas, 2017). A participant can only see how their experience appears in the transcript, not how it will be presented to readers (Durkin et al., 2020; Hagens et al., 2009). Without appropriate preparation, such as guidance on managing disagreements in transcribed interviews, there is a risk of wasting participants' time with a technique that does not yield meaningful results (Durkin et al., 2020; Motulsky, 2021). Furthermore, when researchers request participant feedback on transcripts, they often receive very little information, which may be attributed to poor memory recount of what was said in the interview (Motulsky, 2021). In some cases, participants may not even respond to the request to review their transcript (Motulsky, 2021). This lack of response could be because they have nothing new to add or they do not have the time to read the transcript to ensure that the interview has been transcribed accurately (Durkin et al., 2020, Philipps and Mrowczynski, 2021, Rowlands, 2021). On balance, the lead researcher (MM) invited all participants to review transcripts for accuracy at the end of each interview. All participants declined the opportunity, stating that they did not have time to dedicate to member checking. As such, no changes were made to the transcripts.

6.7. Recruitment and sampling

Participants eligible for inclusion in Phase 2 of the research were qualified registered Health and Care Professions Council (HCPC) UK physiotherapists who 1) completed the online survey (**Chapter 5**, UEA ethics number: ETH2122-0455) and 2) responded ‘yes’ to the survey question regarding being contacted to take part in an interview (**Appendix 6.5**). The research question was specific to UK physiotherapists, and the survey’s findings were followed sequentially by the

qualitative interviews to understand and explain findings, justifying a purposive sampling and recruitment approach. Furthermore, purposive sampling facilitates researchers to make generalisations from the sample they are studying whether theoretical, analytical, or logical in nature (Etikan et al., 2016). The lead researcher (MM) sampled UK physiotherapists who had experience in assessing and managing CSR and, therefore, were suitable to meet the study objectives (Gentles et al., 2015). Additionally, the recruitment method was cost- and time-efficient because the survey respondents who expressed an interest in participating in interviews were selected (Gentles et al., 2015).

It is noteworthy that purposive sampling has some disadvantages due to its non-probability nature. Purposive sampling can lead to sampling bias (Campbell et al., 2020). The purposive sampling design employed in this study may have excluded population members who have experience in assessing and managing CSR in their physiotherapy practice but did not complete the online survey. Nevertheless, the interviews were utilised to explain the survey findings and recruiting participants who did not complete the survey may have questioned the transferability of the findings. Moreover, it is acknowledged that recruiting purposively from the UK physiotherapist sample population reduces the transferability of the findings to other geographical regions worldwide. Notwithstanding this, a purposive sampling method has been used in other musculoskeletal mixed methods, such as exploring hip osteoarthritis interventions among physiotherapists (Holden et al., 2019), managing musculoskeletal pain in UK occupational health (Skamagki et al., 2022), and persistent low back pain treatment decision-making (Pincus et al., 2006).

When conducting qualitative research, it is important to ensure that the sample's composition and size is appropriate and adequate (Sandelowski, 1995). This is known as sample adequacy. It plays a crucial role in assessing the reliability and credibility of the research (Boddy, 2016, Marshall et al., 2013). However, determining the ideal sample size for qualitative research is a topic of debate (Sim et al., 2018). Unlike quantitative research, which relies on statistics-based rules, the complexity of qualitative research stems from the various methodological, theoretical, epistemological, and ideological perspectives involved (Dworkin, 2012, Sim et al., 2018).

The concept of ‘saturation’ is debated when determining sample size for qualitative interviews (Braun and Clarke, 2021, Mason, 2010, Vasileiou et al., 2018). Theoretical saturation refers to the point where gathering more data about a theoretical construct reveals no new properties or insights about the emerging theory. This means that data collection has reached a stage where all significant issues or insights have been exhausted, and the conceptual categories that form the theory are fully ‘saturated’ (Vasileiou et al., 2018). However, guidance on assessing saturation has been vague. Vasileiou et al., (2018) conducted a systematic review of qualitative studies using in-depth interviews in health-related journals over a 15-year period and found the vast majority of articles did not justify their sample size. Where justifications were given, saturation was cited in 55% of articles; however, claims of saturation were not substantiated in relation to study procedures (Vasileiou et al., 2018).

Braun and Clarke (2019) have reported that data collected in qualitative research, such as interviews, are ‘raw views’. They argue that information collected from study participants can never be saturated because perspectives and words vary across participants shaped by various factors such as experience, beliefs, occupation, education and understanding of the subject under study (Braun and Clarke, 2021). Furthermore, according to Low (2019), relying solely on the number of themes or categories is not sufficient to determine saturation because they tend to merge with the narratives that provide answers to the research questions. Therefore, the focus should be on whether the data allow the researcher to effectively develop and test arguments that address the research objectives (Braun and Clarke, 2021, Low, 2019).

Based on the literature examined to adequately generate a rich, complex narrative to analyse (Braun and Clarke, 2021), the lead researcher (MM) employed a lower limit of eight participants and an upper limit of 16 participants. After each completed interview, the lead researcher (MM) reflected on and reviewed the data quality. The lead researcher (MM) invited each prospective participant one-by-one to an interview. MM emailed the PIS (**Appendix 6.4**) for consideration. The lead researcher (MM) followed-up after a minimum of 72 hours post-email to discuss the PIS, answer any questions, determine eligibility, signpost to online consent form (**Appendix 6.5**) and, if appropriate, organised an interview time. MM followed the

initial email invitation and followed-up with one further email invitation if no response was made within seven days. If no response was made following seven days, MM did not pursue any further. Following the completion of an interview, the lead researcher (MM) reflected and reviewed the data quality. The next prospective applicant was then contacted by email and invited to participate in an interview, following the same process as above.

6.8. Interview procedure

Individual online interviews were arranged to be conducted using the Microsoft Teams platform. This platform was selected following feedback from piloting that MS Teams is compatible with NHS technology systems. Furthermore, this platform integrates with the UEA-licensed software. The interviews were scheduled on a day and time convenient for each participant. At the beginning of each interview, the lead researcher (MM) introduced themselves as a postgraduate researcher at the UEA. The lead researcher (MM) summarised the aim and objectives of the study and explained that the interview would last 45 to 60 minutes, but the participant was able to stop the interview at any point.

Prior to the interview, all participants were required to sign a consent form informing participants that the interview would be audio and video recorded. To begin the interview, the lead researcher (MM) asked an open-ended question regarding the participant's employment, which allowed them to answer comfortably. Throughout the interview, the lead researcher (MM) asked probing questions and paraphrasing techniques to clarify responses and gather additional information (discussed in the qualitative interview development subsection). After each interview, the lead researcher (MM) made fieldnotes to document non-verbal behaviours and any comments made after the recording was stopped (an example can be found in **Appendix 6.6**). Additionally, the lead researcher (MM) kept a reflective diary to record initial thoughts and reflect on the interview process in greater detail (an example can be found in **Appendix 6.7**). All interviews were conducted between October 2022 and January 2023. The lead researcher (MM) transcribed all interviews.

6.9. Interview analysis

Qualitative data analysis approaches can be diverse, with different purposes and ontological and epistemological underpinnings (Braun and Clarke, 2012). An inductive, reflexive thematic analysis approach was used for the qualitative interviews in this research. Content analysis, grounded theory and Interpretative Phenomenological Analysis (IPA) were considered as alternative approaches to data analysis for this study and are presented in **Table 6.2**.

Table 6.2 Alternative approaches to data analysis

Analysis approach	Description	Rationale why this approach is not used in this current study
Content analysis	Aims to describe the characteristics of the document's content, including who says what, to whom, and with what effect (Kleinheksel et al., 2020).	Content analysis is better suited for handling large sets of data. The lead researcher's (MM) objectives did not involve coding and categorising large amounts of textual information to identify trends and patterns in the use of language, frequency, relationships, communication structures or discourses (Grbich, 2007).
Grounded theory	Seeks to explore how people make sense of social phenomena and uses data to generate hypotheses and theories (Charmaz, 2014, Walker and Myrick, 2006).	The lead researcher (MM) is a physiotherapist with academic and clinical experience in assessing and managing cervical spine radiculopathy. 'Removing' the lead researcher's previous experiences, knowledge, and subsequent perspectives was not possible. The lead researcher (MM) acknowledged that he was an active participant in the research process, which is better positioned for thematic analysis.
Interpretative Phenomenological Analysis	Focuses on individual participants' unique characteristics and the patterns of meaning that emerge across participants (Pringle et al., 2011) The emphasis is on developing each stage of analysis sequentially for each data item (Finlay, 2021).	This current study was not seeking to understand the participants trying to make sense of what is happening to them.

Table abbreviations. MM: Michael Mansfield.

Thematic analysis is useful for understanding participants' experiences, perspectives, behaviours, and practices (Terry and Hayfield, 2021). For example, it has previously been used to investigate the meaning and rationale of manual therapy for musculoskeletal healthcare (Case and Redhead, 2019) and the support resources needed for people with musculoskeletal spinal pain to return and stay in employment (Oakman et al., 2022). Additionally, thematic analysis can be applied within a critical framework to examine personal or social patterns of meaning and their implications (Terry and Hayfield, 2021).

Thematic analysis is an analysis method used to uncover patterns of meaning, or 'themes', within qualitative data (Braun and Clarke, 2019, Braun and Clarke, 2012). Thematic analysis is a method of organising and interpreting a researcher's observations (Braun and Clarke, 2021a). The goal is not simply to summarise data, but to identify and interpret key data features relevant to the research question (Braun and Clarke, 2021a). Unlike other qualitative approaches, it is not aligned to a specific theoretical framework, but instead offers a flexible tool for identifying and interpreting these patterns (Braun and Clarke, 2019). It is a flexible approach that can be used with various research questions, sample sizes, data collection methods, and approaches to meaning generation (Braun and Clarke, 2022).

Thematic analysis is a rigorous process that includes a two-stage review procedure to ensure high-quality results (Braun and Clarke, 2021). It involves breaking down data into smaller units, or 'codes', which capture interesting features related to the research question (Braun and Clarke, 2022). These codes are used to identify larger patterns of meaning, or themes, which are built around a central organising concept (Braun and Clarke, 2021).

Thematic analysis can face challenges related to subjectivity and potential biases (Harwood and Garry, 2003, Joffe and Yardley, 2003). When interpreting collected data, thematic analysis is at risk of biased readings due to the subjective nature of the analysis, as the researcher is part of the analysis (Jaspal, 2020). Furthermore, thematic analysis is susceptible to interpretation bias (Harwood and Garry, 2003, Joffe and Yardley, 2003). To minimise these potential biases, the lead researcher (MM) utilised a reflective journal log documenting observations and reflections after each interview. In addition, thematic analysis is considered to support deeper

analysis, or immersion, compared to content analysis, which allows it to bring a more in-depth understanding of the studied phenomenon. This facilitates a better alignment to the research aims of this study, which aims to understand the reasons and rationale of CSR diagnostic procedures used in physiotherapy.

6.10. Trustworthiness

One central tenet of qualitative analysis is demonstrating the credibility of the chosen qualitative analysis methods. To enhance the credibility of the methods undertaken, a 15-point checklist of criteria for good thematic analysis was used to guide the analysis in this study (Braun and Clarke, 2014). Descriptions of the criteria, along with the actions taken by the lead researcher (MM) are detailed in **Table 6.3**.

Table 6.3 The fifteen stages of Thematic Analysis (based on Braun and Clarke, 2014) and lead researcher's actions

Stage	Activity	Criteria	Lead researcher (MM) actions taken
1.	Transcription	The data have been transcribed to an appropriate level of detail, and the transcripts have been checked against the tapes for 'accuracy'	All interviews were transcribed and reviewed one-by-one.
2-6.	Coding	Each data item has been given equal attention in the coding process. Themes have not been generated from a few vivid examples (an anecdotal approach), but instead the coding process has been thorough, inclusive and comprehensive. All relevant extracts for all each theme have been collated. Themes have been checked against each other and back to the original data set Themes are internally coherent, consistent, and distinctive	Each transcribed interview was read several times before coding commenced. Code book set up. Initial coding was actioned for each individual transcript. Focussed coding was completed once initial coding was completed for each individual transcript. The lead researcher and one member of the research supervision team (SJ) independently coded three transcripts. A reflective journal was maintained throughout.
7-10.	Analysis	Data have been analysed – interpreted, made sense of - rather than just paraphrased or described. Analysis and data match each other – the extracts illustrate the analytic claims. Analysis tells a convincing and well-organised story about the data and topic. A good balance between analytic narrative and illustrative extracts is provided	The lead researcher (MM) and SJ discussed each theme generation for the three transcripts. A reflective journal was maintained throughout. Each theme was carefully considered, and illustrative quotes were used to illustrate the analysis. Narrative joint display utilised (discussed in Chapters 7 and 8)

11.	Overall	Enough time has been allocated to complete all phases of the analysis adequately, without rushing a phase or giving it a once-over-lightly	Each transcript was reviewed at least 24 hours apart from the next to facilitate reflection on each. Theme generation was reviewed on several occasions using the notes made on the transcripts and reflective diary to ensure accuracy. Dedicated, protected meeting times were scheduled between MM and SJ to facilitate discussion and consensus generation on three transcripts.
12-15.	Written report	The assumptions about, and specific approach to, thematic analysis are clearly explicated There is a good fit between what you claim you do, and what you show you have done – i.e., described method and reported analysis are consistent. The language and concepts used in the report are consistent with the epistemological position of the analysis The researcher is positioned as active in the research process	Qualitative interview methods development, lead researcher positioning and reflexivity, data analysis and interpretation discussed throughout the PhD thesis. The implications of the decision made during these processes are reflected upon and discussed.

Table abbreviations. MM: Michael Mansfield; SJ: Dr. Stephanie Jong.

For the current study, the lead researcher (MM) recorded and transcribed the interviews verbatim. It is recognised that verbatim transcription is a lengthy, time-consuming process (Eaton et al., 2019). The financial cost associated with a professional transcription service prohibited this option. Furthermore, using a professional transcription service may hinder the lead researcher (MM) from immersing himself in the recorded interviews, which can limit the credibility of analysis (Eaton et al., 2019). To understand the transcribed interviews comprehensively, the lead researcher (MM) read each transcript multiple times and listened to the audio files while reading. This allowed the lead researcher (MM) to make notes on any important information (such as any overlaps in speech, interfering noise and differing styles of speech, for example, distinguishing between “I don't, no” and “I don't know”). Additionally, an online reflective journal was used to record and reflect on any insights or new ideas that arose while becoming familiar with the material.

Coding is suggested to be an essential link between collecting data and developing reasoning or rationale to explain these data (Gibbs, 2007). Coding occurred in two stages – initial and focused. In the initial coding of transcripts, the lead researcher (MM) generated as many ideas as possible inductively. The lead researcher (MM) reviewed each transcribed line carefully and identified significant topics such as rationale, reasoning, motivations or areas that addressed the study’s aim and objectives. The lead researcher (MM) initially coded the data by highlighting, colour-coding and labelling certain sentences to help interpretation of the data. The lead researcher (MM) created a list of these codes and wrote a brief description of each code to ensure to remember its meaning.

In focused coding, the lead researcher (MM) pursued a selected set of central codes throughout the entire dataset and the study (Belotto, 2018). This required making decisions about which initial codes were most prevalent or important, and which contributed most to the analysis (Belotto, 2018). Coding was an iterative and an inductive process that organised data, from which the lead researcher (MM) constructed themes. A project coding list and codebook (group of coding themes) was developed to interpret any given text accurately. This formed an important component of enhancing the validity, reliability, trustworthiness, and perceived

quality of research conclusions. An example of this code book is presented in **Appendix 6.8**.

Within the next step, researcher triangulation was employed. Researcher triangulation occurs when two or more researchers are used to collect, process, or analyse data separately (Stahl and King, 2020). This type of triangulation can bring both confirmation of findings and different perspectives, adding breadth to the phenomenon of interest (Curtin and Fossey, 2007). Two researchers independently establishing and confirming coding can overcome the bias of using a single-researcher approach (Stahl and King, 2020). This increases the trustworthiness of the findings owing to the convergence and corroboration of data (Patton, 1999). This approach of independently coding a proportion of transcripts is consistent with similar musculoskeletal qualitative research studies (Kelly et al., 2022). Furthermore, including two or more coders in the coding process is a recommended step in enhancing coding reliability, whereby multiple coders achieve coding consistency (Kurasaki, 2000). It also created an additional level of scrutiny into the coding process through added perspectives of different researchers.

The lead researcher (MM) and SJ (second PhD supervisor) independently coded three of the same interviews (approximately 30% of the recruited sample) to align with the components of trustworthiness outlined earlier in this chapter. The second supervisor (SJ) is a trained and experienced qualitative researcher. MM and SJ discussed the codes in a meeting until a consensus was reached. A reflective journal entry of this discussion is presented in **Appendix 6.7**. MM and SJ reviewed, refined, and agreed on the inductive themes. The codes and overall themes were then discussed and negotiated among MM and SJ in a final discussion to reach a consensus. An excerpt of the audit document and a reflection of this discussion are presented in **Appendix 6.7 and 6.9.**

6.11. Reporting guidelines for qualitative interview research

The Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al., 2007) was used to support rigour, and aid in comprehensive reporting for this qualitative research. The Consolidated Criteria for Reporting Qualitative Research

(Tong et al., 2007) is specific to certain methods of data collection and analysis, such as interview studies and supporting the adoption for Phase 2.

While using checklists for qualitative research may not necessarily improve the quality of the research (Buus and Agdal, 2013, Buus and Perron, 2020, Tong et al., 2007), it is widely accepted that checklists and criteria are important in developing reporting standards (Tong et al., 2007). The COREQ criteria are included in the EQUATOR network (Altman, 2008), which is required by many clinical journals for submission and is designed specifically for qualitative interviews.

6.12. Next steps

Chapters 5 and 6 have discussed the rationale and methods of the quantitative survey and qualitative interviews. The next chapter (**Chapter 7**) will integrate the quantitative (survey) and qualitative (interview) results through narrative joint display. **Chapter 8** will discuss and contextualise these integrated findings.

Chapter 7: Integrated quantitative and qualitative results

7.1. Introduction

This chapter reports the results of the quantitative survey and qualitative interviews. Following this, the integrated findings are presented as visual joint displays. The integrated findings are compared and contrasted with existing research to address the aim of this part of the research programme in **Chapter 8**.

Implementing a joint display format for this mixed methods research phase can effectively convey the timing and implementation of the quantitative and qualitative phases of the study (Fetters et al., 2013). When analysing mixed data, the lead researcher (MM) assessed how well the qualitative and quantitative findings fit together (Fetters et al., 2013, Guetterman et al., 2015). This is known as the fit of the mixed data, and it determines how well the data reflects the constructs common to both types (Guetterman et al., 2015). To achieve this, the qualitative themes were displayed in the first column and used as the overarching concepts for both phases. The categories from the qualitative phase were then displayed in the second column and linked to the overarching themes. The survey research findings were mapped against the overarching themes and categories in the third column. The fourth column included participants' quotes linked to the overarching qualitative themes and categories. A mapping exercise was used to select appropriate illustrative quotes to establish linkages between the quantitative and qualitative findings. Comparing and contrasting the different component findings is an important part of the integration process.

7.2. Integrated findings

7.2.1. Online survey respondent demographic variables

A total of 64 individuals accessed the questionnaire. The demographic variables, healthcare employment sector, clinical speciality, highest education award and length of time working as a physiotherapist are presented in **Table 7.1**. Sixty-three eligible and completed surveys were included in the final analysis; one respondent

did not complete the questionnaire and exited before consenting. From the 63 survey respondents, 75% (47/63) self-reported working in the NHS. Forty-four percent (28/63) worked in primary care and 30% (19/63) worked predominantly in secondary care. Eleven of the 63 respondents (18%) worked in private practice and one respondent worked in a military healthcare setting. Eighty-nine percent (56/63) reported that their clinical speciality was musculoskeletal, whereas 5% (3/63) and 3% (2/63) of respondents specialised in musculoskeletal orthopaedic and pain management, respectively. Sixteen respondents (16/63, 25%) reported that their highest education award was a postgraduate MSc. Nineteen (30%) of the 63 respondents worked as a physiotherapist between 11 to 15 years, and 18 (29%) worked longer than 21 years. Eleven respondents had worked for 16 to 20 years (18%), seven respondents six to 10 years (11%), six respondents one to five years (10%) and two respondents less than one year (3%).

Table 7.1 Demographic data of the 63 survey respondents

Healthcare sector	Number (n=63)	Percentage (%)
National Health Service (NHS-England) – Primary care	28	44.4
National Health Service (NHS-England) - Secondary care	19	30.2
Private practice	11	17.5
Military	1	1.6
Other	4	6.3
Clinical speciality		
Clinical – Musculoskeletal	56	88.9
Clinical – Orthopaedics	3	4.8
Clinical - Pain management	2	3.2
None of the above	2	3.2
Highest education qualification		
BSc	16	25.4
MSc (Pre-registration)	10	15.9
MSc (Post-registration)	16	25.4
Post graduate certificate	8	12.7
Post graduate diploma	6	9.5
Graduate diploma in physiotherapy	4	6.3
MRes	1	1.6
PhD	1	1.6
Professional doctorate	1	1.6
Length of time working as a physiotherapist		
Less than one year	2	3.2
1 to 5 years	6	9.5
6 to 10 years	7	11.1
11 to 15 years	19	30.2
16 to 20 years	11	17.5
More than 21 years	18	28.6

Table abbreviations. BSc: Bachelor of Science; MRes: Masters of Research; MSc: Masters of Science; NHS: National Health Service; PhD: Doctor of Philosophy.

7.2.2 Qualitative participant demographic variables

The interview participant characteristics are reported in **Table 7.2**. Sixteen of the 63 online survey respondents agreed to be contacted about the qualitative interviews. A total of 11 physiotherapists were recruited over two months for the qualitative interview phase. The remaining five participants did not respond to two separate email invitations. No further communications were had with the participants who did not respond. No reasons for non-participation were noted. Nine participants worked

in the NHS and two in private practice. All interview participants specialised in musculoskeletal healthcare settings and self-rated as 'extremely confident' at assessing a person with CSR.

Table 7.2 Demographic data of the 11 qualitative interview participants

Participant number	Healthcare sector	Highest education award	Length of time working as a physiotherapist
001	National Health Service (NHS-England) - Primary care	MSc (Post-registration)	6 to 10 years
002	Private practice	MSc (Post-registration)	More than 21 years
003	National Health Service (NHS-England) - Primary care	BSc	1 to 5 years
004	National Health Service (NHS-England) – Secondary care	MSc (Post-registration)	6 to 10 years
005	National Health Service (NHS-England) – Secondary care	PhD	16 to 20 years
006	National Health Service (NHS-England) - Primary care	MSc (Post-registration)	6 to 10 years
007	National Health Service (NHS-England) - Primary care	MSc (Post-registration)	More than 21 years
008	Private practice	BSc	More than 21 years
009	National Health Service (NHS-England) - Primary care	MSc (Post-registration)	16 to 20 years
010	National Health Service (NHS-England) - Primary care	MSc (Post-registration)	16 to 20 years
011	National Health Service (NHS-England) – Secondary care	MSc (Post-registration)	16 to 20 years

Table abbreviations. BSc: Bachelor of Science; MSc: Masters of Science; NHS: National Health Service; PhD: Doctor of Philosophy.

7.3. Theme One: Perception of physiotherapist role in assessing cervical spine radiculopathy

This theme explores the participants' perceived role as a physiotherapist assessing CSR in clinical practice. Consistent from survey and interview data, participants made decisions based on three categories: CSR assessment informed by research, continuing professional development training needs, and their clinical experiences. The narrative joint display is presented in **Table 7.3**.

Table 7.3 Narrative joint display with the theme 'Perception of physiotherapist role in assessing cervical spine radiculopathy'

Overarching theme	Category	Survey results	Qualitative interview results	Meta-Inferences and interpretation	
Perception of role	Convince me	42.9% of respondents (27/63) and 25.5% (16/63), reported that somatosensory testing parameters and pain questionnaires or tools respectively, are more useful for researchers than clinicians 57% (36/63) of respondents reported that they prioritise other physical assessment methods in their practice 79.4% (50/63) of respondents suggested that more training on when to use QST would facilitate the use of somatosensory testing. 66.7% (42 respondents) and 47.6% (30 respondents) stated that training on the appropriate use and timing of pain questionnaires or tools could further enhance their utilisation	The accuracy of questionnaires is debatable… we do not use them. (Participant 002) The translation of research into practice is needed, they may be helpful in research, but I have not seen data in practice. (Participant 009) I need to "sell" to my staff that these assessment measures are better than what we are currently using (Participant 006)	Convergence Expansion	The qualitative interviews agreed with the survey findings. The translation of research into practice was the reason somatosensory testing and questionnaires are not used in physiotherapy practice. Some interviewees explained that as part of their physiotherapy role they mentor, and line-manage teams of physiotherapists. A clear rationale to justify a change in assessment practice is suggested as a requirement.

	Knowledge and education	66.7% (42 respondents) and 47.6% (30 respondents) stated that training on the appropriate use and timing of pain questionnaires or tools could further enhance their utilisation 42.9% of respondents (27/63) and 25.5% (16/63), reported that somatosensory testing parameters and pain questionnaires or tools respectively, are more useful for researchers than clinicians 17/63 of respondents (30%) lacked confidence in using and interpreting the collected somatosensory data 27/63 respondents (42.9%) cited confidence in using or interpreting somatosensory testing parameters	I have not been trained to know how and when to use these tests, so I wouldn't know where to begin (Participant 009) Training needs to take place with junior (newly qualified) physiotherapists to use contemporary assessment tests (Participant 002) Providing formal CPD training on the benefits might help change practice (Participant 005) I think pain and particularly pain of spinal origin is really poorly understood by physiotherapists (Participant 003) As much as people say that I want to understand pain, we can't. We don't. We don't know what causes pain (Participant 005)	Expansion Convergence	Interviewees explained that somatosensory testing and pain questionnaires were not part of their undergraduate physiotherapy curriculums. Therefore, they are not embedded into their current practice. Some interviewees explained that further formalised training will be necessary to adopt any new assessment practices. All interviewees agreed that further training is required to change physiotherapy practice. Interview participants said underlying pain symptoms are poorly understood across the profession. Therefore, using pain to establish diagnosis is not consistently used.

	Clinical Experience	27/63 respondents (42.9%) reported small fibre somatosensory testing parameters are more useful for researchers than clinicians (27/63; 42.9%) 5/63 (8%) and 21/63 (33%) of survey respondents reported that MRI is 'always used' or 'often' used when establishing CSR diagnosis, respectively. 17/63 (30%) of respondents reported that they lacked confidence in using and interpreting pain questionnaire data 36/63 (57%) of respondents reported that they prioritise other physical assessment methods in their practice	In my experience just cover your own back by completing myotomes, dermatomes and reflexes (Participant 001) I guess it kind of comes down to that awful term 'clinical experience'. You know you can always fall back on the clinical experiences to make decisions (Participant 001) Well, I can diagnose radiculopathy without having to do all these other tests. (Participant 009) I think it's fairly straightforward for me. Uhm, I mean, you know people have got referred pain from the neck then you know you've got radiculopathy. You know then to differential diagnose from the neck or shoulder (Participant 002)	Expansion Convergence Convergence	Some interview participants reported that physiotherapists can reach CSR diagnosis based on existing assessment strategies and their clinical experiences of recognising symptoms patterns. Nearly all interviewees reported that clinical experience and identifying patterns supported radiculopathy diagnosis more than clinical tests. Nearly all interviewees confirmed that manual muscle testing, reflex testing and light touch sensation testing was completed as part of their assessment of radiculopathy.

The online survey respondents reported the physical assessment tests they used for diagnosing CSR. The bar chart (**Figure 7.1**) illustrates the reasons why questionnaire respondents rarely use or do not use small-fibre somatosensory tests when establishing CSR diagnosis. The stacked bar chart (**Figure 7.2**) presents the frequency across the physical assessment methods when establishing a CSR diagnosis. All tests were 'always' or 'often used' when establishing CSR. Reflex testing (Always: 89%, 56/63; Often: 11%, 7/63), manual muscle testing (Always: 94%, 59/63; Often: 6%, 4/63), Spurling's manoeuvre (Always: 36%, 24/63; Often: 26%, 17/63), neurodynamic test (NDT) (Always: 40%, 25/63; Often: 35%, 22/63) and light touch (78%, 49/63; Often: 17%, 11/63). Twenty-seven survey respondents (43%) reported that small-fibre somatosensory testing is more useful for researchers than clinicians. Eleven respondents (18%) provided further free-text reasons why somatosensory testing is rarely or not used in their clinical practice (**Appendix 7.1)**. The reasons included reduced time availability in the clinic, limited understanding of how and when to perform small fibre testing and small-fibre testing having little bearing with onward referral decisions.

Figure 7.1 The reasons why respondents rarely use or do not use small-fibre somatosensory testing methods in practice as part of CSR diagnosis (n=63).

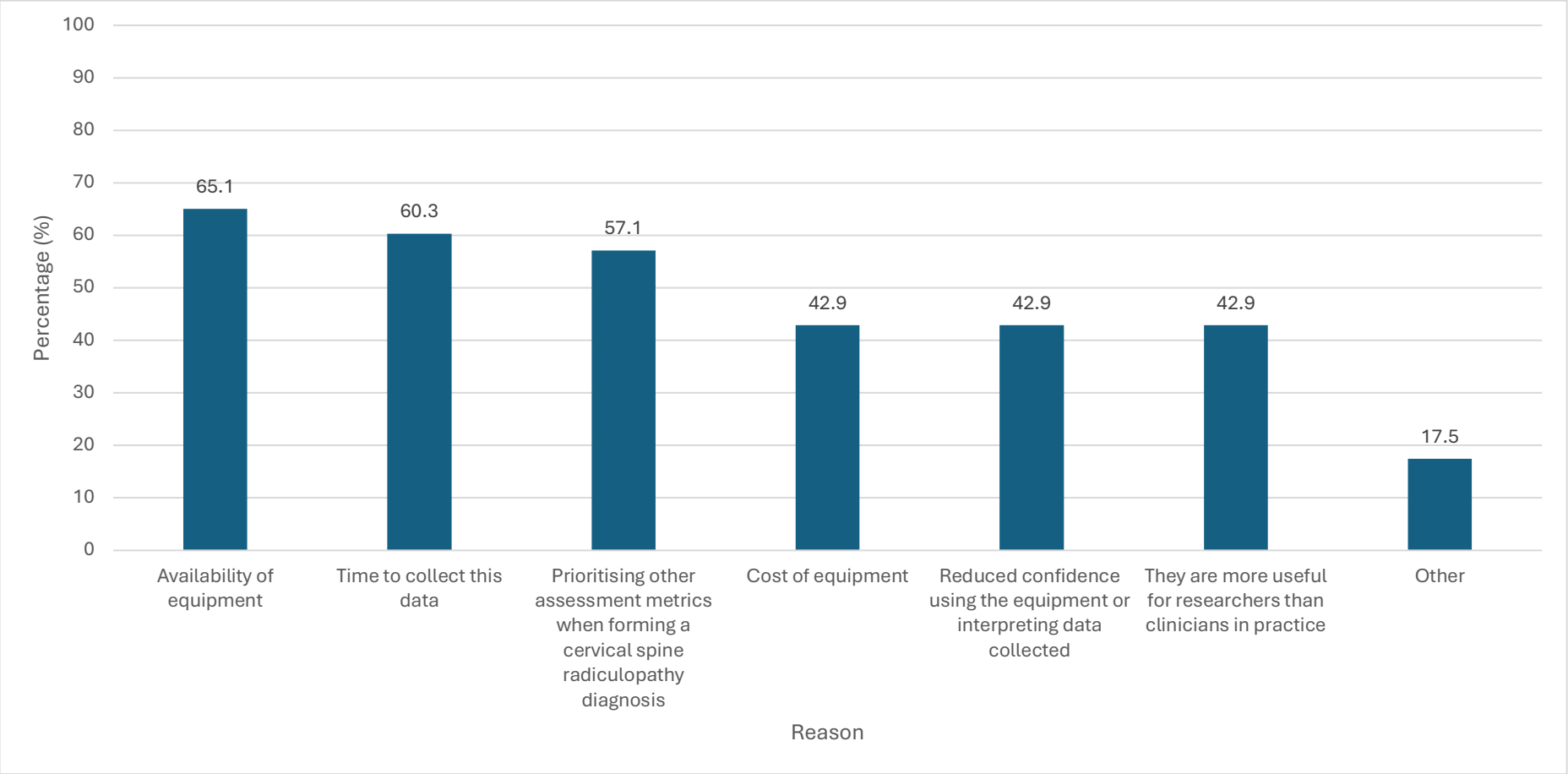
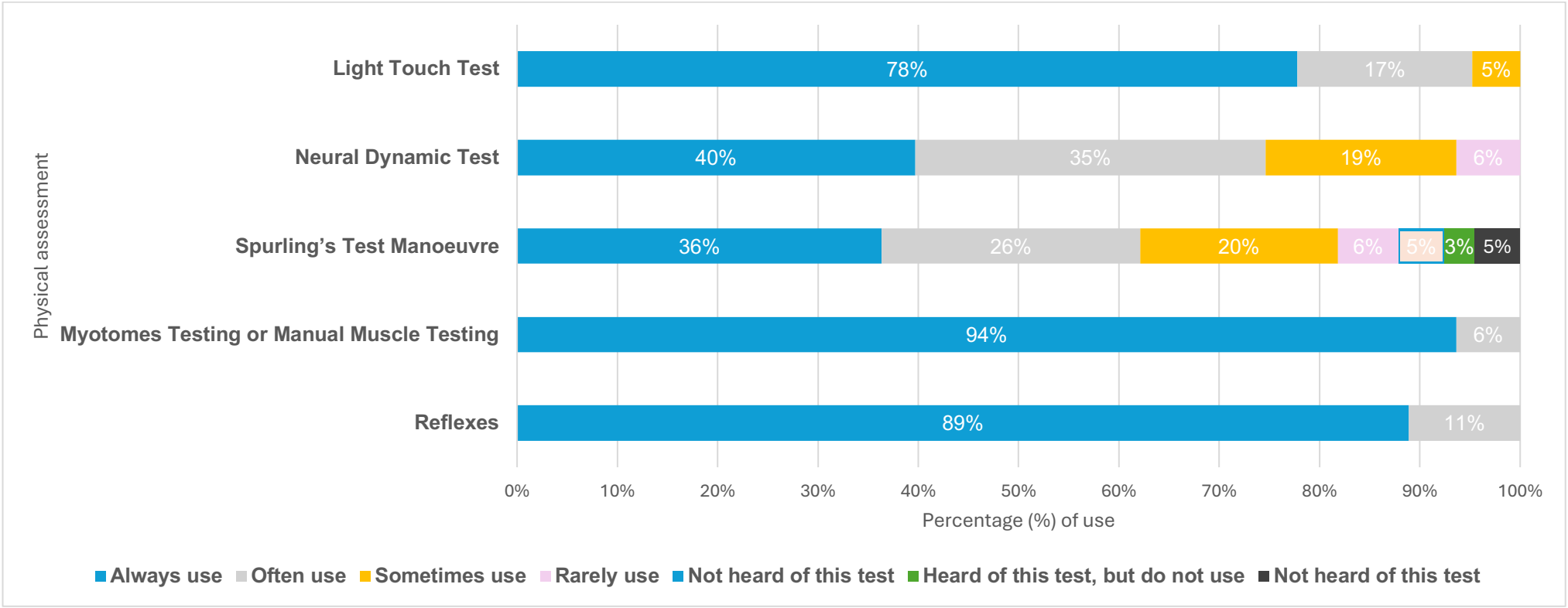


Figure 7.2 The frequency of use across all physical assessment parameters when establishing a cervical spine radiculopathy diagnosis (n=63).



Manual muscle testing was identified as an important assessment method, reported as always or often used by all survey respondents. When explored further in the qualitative phase, all interview participants justified their use of muscle strength testing, light touch sensation and reflexes in clinical practice, as these were easy to use and not time consuming considering their short appointments. One participant commented:

> *"…we operate on 30-minute appointments, every minute counts when assessing a patient with CSR. I am not surprised that some of these somatosensory tests are not used, they are too long to complete in practice."*
> *(Participant 003. Qualified for 1-5 years and working in primary care)*

Most interview participants explained that their service required robust data to change individual or departmental assessment practices before adopting more logistically challenging tests such as small-fibre testing. This is exemplified by an interview participant, who identified as a physiotherapy service lead:

> *"I would be surprised if physiotherapists used any of these (somatosensory) tests in practice… I am not aware of any data that would mean we should change our assessment tests from what we are doing already…"*
> *(Participant 007. Qualified for more than 21 years and working in primary care)*

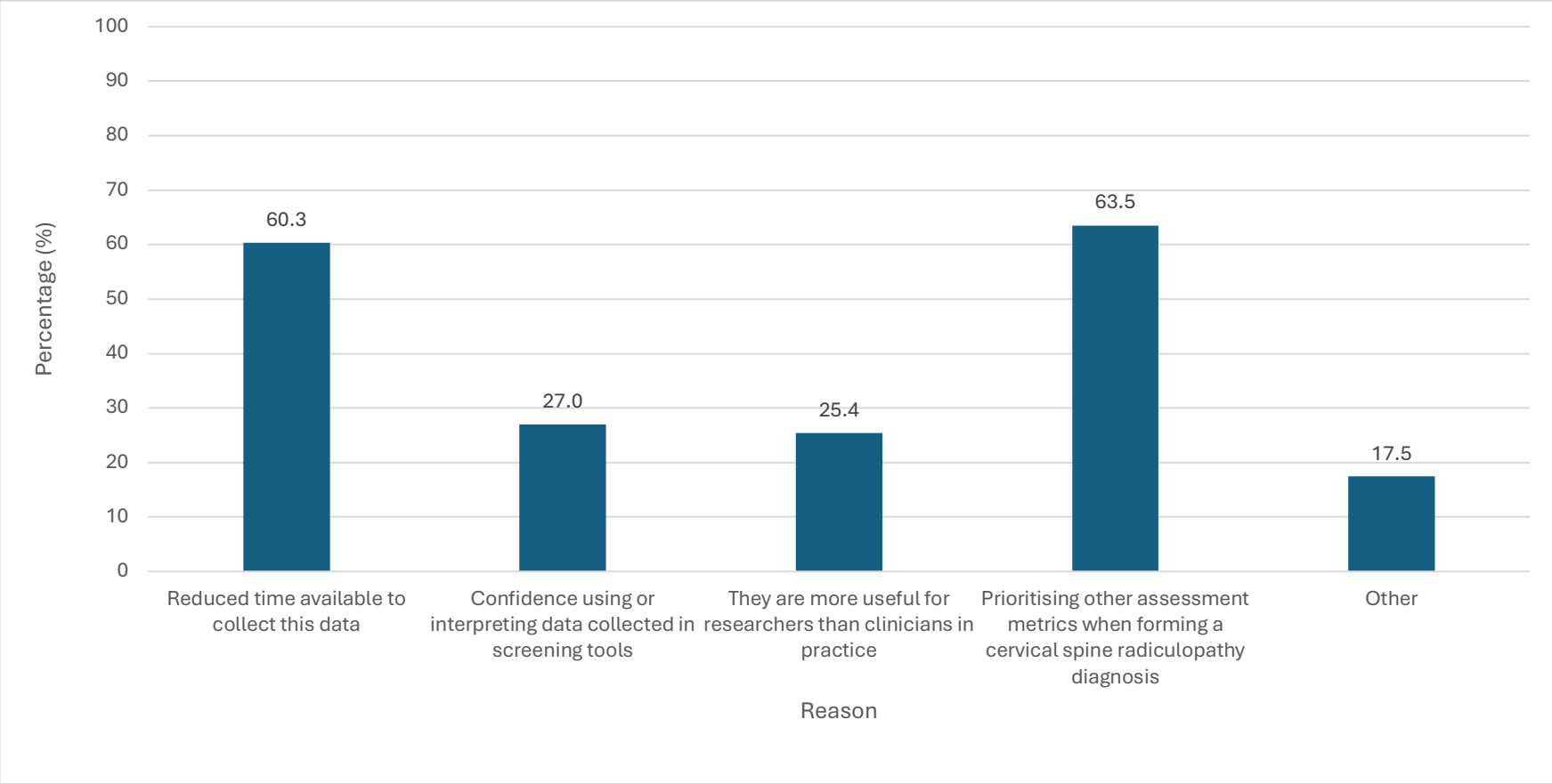
In contrast, one participant described completing somatosensory tests in their department as part of a previous research study:

> *"We have collected this before but as part of a research study where our department recruited these types of patients and these tests were completed…"*
> *(Participant 002. Qualified for more than 21 years and working in private practice)*

Figure 7.3 displays the reasons why the online survey respondents either rarely use or completely refrain from using pain questionnaires or tools for diagnosing CSR. Out of 63 respondents, 40 (64%) reported that they prioritise other assessment

metrics when making a CSR diagnosis. Additionally, 38 respondents (60%) reported not having sufficient time in their clinical practice to collect the necessary data. Some respondents believed that the questionnaires or tools were more useful for researchers than for clinicians (16/63, 26%), while other respondents lacked confidence in using and interpreting the collected data (17/63, 30%). Fifty-one survey respondents (81%) reported that providing online access to free pain-screening tools or questionnaires could increase their usage in clinical practice. Moreover, 67% (42/63) and 48% (30/63) of survey respondents stated that additional training on the appropriate use and timing of these tools or questionnaires might further enhance their utilisation.

Figure 7.3 The reasons why respondents rarely use or do not use pain-screening tools or questionnaires in practice as part of cervical spine radiculopathy diagnosis (n=63)



All interview participants supported the sentiment of the survey responses in that, if expectations of pain questionnaires or other somatosensory testing are to be introduced into practice, formal and informal continuing professional development education will be necessary. One participant reflected:

> *"Pain education is poor in physio education; I don't remember any education being provided around different sensory tests or screening tools at university… I was aware of these when I qualified and had a mentor to show me."*
> *(Participant 002. Qualified for more than 21 years and working in private practice)*

All interview participants explained that clinical experience of assessing patients is more valuable to physiotherapists than the outcomes of questionnaires or small-fibre somatosensory testing data. This influenced how other multi-disciplinary team clinicians assess CSR and pattern recognition reasoning:

> *"I learnt about neuro assessment by observing an ortho surgeon, they don't use any questionnaires or heat tests… I've adopted this in my triage assessments because I make referrals to ortho (orthopaedics)."*
> *(Participant 004. Qualified for 6-10 years and working in secondary care)*

Another physiotherapist shared this sentiment:

> *"I think that as you get more mileage as a spinal physiotherapist, you see patterns of presentations… the subjective assessment tells you what you want to know, and the physical assessment is for the patient's reassurance really."*
> *(Participant 006. Qualified for 6-10 and working in primary care)*

Most interview participants explained that physiotherapists may prioritise other assessment strategies because of the expectations of their line managers or the department they work in. This is exemplified with this participant:

"There is a difference across different departments, it depends on what the priorities of the manager are. Working in one department with a research focus meant we collected a lot of questionnaire data which helped researchers."
(Participant 008. Qualified for more than 21 years and working in private practice)

However, some interview participants explained how working as part of a multi-disciplinary team and the clinical lead's expectations influenced decision-making when assessing CSR. Noteworthy, these interview participants reported that orthopaedic surgeons were clinical service leads:

"The orthopaedic surgeon I work with would expect me to complete a basic neuro of myotomes, dermatomes and reflexes for every patient… this is foundation level triage assessment."
(Participant 003. Qualified for 1-5 years and working in primary care)

7.4. Theme Two: Service constraints

Participants explained how the health service that physiotherapists worked in may influence the decision-making and rationale of assessment strategies for CSR. This is presented in the narrative joint display in **Table 7.4**. Online survey respondents reported how time availability with patient appointments, the integration of testing and questionnaires into IT systems and software, the differences between public and private sector healthcare, and the cost and availability of equipment, influence their decision-making and justification of assessment strategies for CSR.

Table 7.4 Narrative joint display with the theme 'Service constraints'

Overarching theme	Category	Survey results	Qualitative interview results	Meta-Inferences and interpretation	
Service constraints	Time	38/63 (60%) of respondents reported that time availability in clinical practice to collect small fibre somatosensory testing data was barrier 35/63 (55.6%) respondents reported that more assessment time during clinical settings could improve the uptake of small fibre somatosensory testing. 38/63 respondents (60.3%) reported not having sufficient time in their clinical practice to collect pain questionnaire data. 39/63 (61.9%) of respondents reported that having more time in clinical practice would enhance the use of screening tools or questionnaires	It is quick to do isn't it, you know you've gotta brush the skin. Is it the same both sides, a Yes-No answer and you have your results – done. (Participant 008) You also have to spend the time to spend making sure that they're telling you the truth when patients interpret hot and cold, it's too long (Participant 010) So, to put another test on top of what they (physiotherapists) do already, I don't know whether it would be fair expectation when physios are already sort of busy (Participant 007) I think we spend too much time looking at questionnaires rather than looking at patients. (Participant 010)	Expansion Expansion	Interview participants explained that light touch sensation is time effective in the clinic. Some interview participants explained that any additional testing or data collection might not be fair practice as there is a perception that physiotherapists working in these healthcare settings are busy. Some interview participants further explain how the patient with suspected CSR is at the centre of decision making too. There was a perception that questionnaires detract from a patient's presentation. Furthermore, one interviewee questioned the reliability of symptom reporting from a patient. This may provide a rationale on which specific testing or questionnaires to complete.

	Software accessibility	81% (51/63) of respondents expressed that providing online access to free screening tools or questionnaires could increase their usage in clinical practice	The NHS spends a lot of money on adjuncts, it needs integration with patient notes software systems (Participant 008) The tools aren't free to access that's why people don't use them, make them cheaper and we would probably use them (Participant 003) Maybe if there was an app that they could use in the waiting area or at home to track symptoms that would help (Participant 005)	Expansion	Some participants reported that a reason for not selecting some of the pain questionnaires or tools is that they are not embedded into IT healthcare systems. Interview participants explained that some of the pain questionnaires are not free to use (licensing), therefore this negatively impacts the decision making when selecting strategies to assess CSR.
	Public to private sectors	38/63 respondents (60.3%) reported not having sufficient time in their clinical practice to collect pain questionnaire data	In private sector you see this person today. They've got, as far as I can see, an inflammatory disc bulge causing radiculopathy. What are we going to do with them? Stick them in the MRI scanner. Prove your point next day they go into a theatre. They have an injection and they come back round the course. It's much quicker like that in that sector (Participant 006) You have physios testing at different regions within a pathway, be it primary care with First Contact Practitioners or intermediate services like ours or you know your typical, you know private physios who Joe Bloggs has just walked in from the door. They have access to different things which could potentially impact on their assessments (Participant 009)	Expansion	Some interview participants reported that the access to early imaging and invasive intervention can help shape assessment decision making with CSR. The various healthcare systems across public and private sectors will mean that clinicians (and patients) will make decisions based on what is available in their practices

	Equipment	Twenty-seven respondents (42.9%) cited that cost of equipment prevented the use of somatosensory small fibre testing 324/63 (8.1%) of respondents reported that reducing equipment costs would help with their use in clinical practice	Well, if we were going to use some of these somatosensory tests like pinprick or thermal, I want to see, I'd want access to the equipment (Participant 003) I have to carry my own reflex hammer with my name on it, that's how bad things are! (Participant 001) Accessing tissue paper can be a challenge let alone hot-cold equipment (Participant 006) Traditional neuro testing like strength, reflexes just doesn't require expensive equipment does it – that's why us physios use it (Participant 007)	Expansion	Nearly all interviewees explained that because of equipment shortages in departments, clinicians make decisions on testing that does not require specialist equipment. Interview participants reported that the main reasons why muscle strength, light touch and reflexes are nearly always used in practice is because clinicians can complete these without specialist equipment.

The bar chart (**Figure 7.1)** illustrates the reasons why online survey respondents rarely use or do not use small-fibre somatosensory tests or pain questionnaires (**Figure 7.3**) when establishing CSR diagnosis. Time availability in clinical practice to collect data from small-fibre somatosensory testing (38/63; 60%) or pain questionnaires or tools (38/63; 60%) was reported as a reason these are not considered when forming CSR diagnoses. Seventy percent (70%; 39/63) of online survey respondents reported that having more time in clinical practice would enhance the use of screening tools or questionnaires. Whereas 56% (35/63) of respondents suggested that more assessment time during clinical settings could improve the usage of small-fibre somatosensory testing in practice. Qualitative results indicated that time availability with patient appointments was a key reason why these assessment forms were not used in practice. All interview participants explained that they selected assessment strategies because they were time efficient, as exemplified by Participant 10:

> *"I am not surprised the survey reported this, muscle strength, dermatomes and reflexes are so quick to complete… we are under pressure with patient activity… The questionnaires would eat into assessment time…"*
> *(Participant 010. Qualified for 16-20 years and working in primary care)*

Most interview participants who worked in primary or secondary care, reported challenging CSR patient presentations. The interview participants attributed the complexity to co-morbidities (for example, anxiety symptoms), which made it challenging to prioritise assessment strategies and interpret findings, subsequently taking longer to reach a diagnosis. This is reflected by Participant 5:

> *"The longer a person has symptoms, the more complex, this takes time as all aspects of their well-being should be considered…"*
> *(Participant 005. Qualified for 16-20 years and working in secondary care)*

Some physiotherapists explained that even if more time were allocated, they were unsure whether they would integrate further physical testing, as they were focused on ensuring that patients received timely and accurate management pathways. Participant 9 explains this:

"Even with more time, would the questionnaires change onward referral?… probably not… Reaching the right management pathway is most important when I see this patient…"
(Participant 009. Qualified for 16-20 years and working in primary care)

In contrast, one participant describes how they use additional physical testing to there is not an obvious CSR presentation:

"I would use more tests to confirm a CSR diagnosis, only when the clinical presentation is not obvious to me..."
(Participant 003. Qualified for 1-5 years and working in primary care)

Fifty-one online survey respondents (81%; 51/63) reported that providing online access to screening tools or questionnaires could increase their usage in clinical practice. When explored further in the qualitative interview, nearly all interview participants explained that the integration of questionnaires in clinical practice is mixed and not all departments or healthcare information technology systems can embed into practice. This is explained by Participant 1:

"The thing is, our IT systems are poor, the software to build questionnaires needs to be in place. We don't need more pieces of paper, if it was IT-based I bet physiotherapists would use them more often."
(Participant 001. Qualified for 6-10 years and working in primary care)

Some interview participants expanded upon this, reporting that the timing of when to introduce questionnaires to patients is unclear. They perceived that this lack of clarity negatively impacts some clinicians and patients, as exemplified by one participant:

"When would we ask the patient to complete these questionnaires… Some patients don't have IT access… and if (completed) in the waiting area, it would mean more time wasted."
(Participant 011. Qualified for 16-20 years and working in secondary care)

Whereas two different participants had a divergent view and explained that their service issues questionnaires online (through email) before the patient arrives in the clinical department. Participant 9 explained:

> *"Our admin team has an automated send (by email) to patients before they attend an initial appointment…"*
> *(Participant 009. Qualified for 16-20 years and working in primary care)*

Some interview participants discussed the different healthcare systems in the UK in relation to assessment practice for CSR. They had worked in public and independent sectors, where there were perceived differences in expectations of assessment and management strategies for CSR. The differences centred around access to specialised testing and the time to order and complete assessments such as imaging or nerve conduction studies. This is explained by one participant:

> *"There is more immediate access to assessment, like MRI the next day, that is why they may be used in practice more often."*
> *(Participant 008. Qualified for more than 21 years and working in private practice)*

Some interview participants described employment in clinical departments with a research culture. They reported that screening tools and outcome measures were selected because of existing service improvement projects or funded research studies that the department prioritises. One participant provides a description of research culture:

> *"Yeah, I can imagine in some big departments there are multiple research studies that would collect the data, this can provide some ideas on the types of pain patients coming through the door…"*
> *(Participant 001. Qualified for 6-10 years and working in primary care)*

This was further explained by another interview participant, who detailed how data collection using pain-screening tools or questionnaires can support service managers in building a business case to justify physiotherapy services to commissioning groups:

"Depending on the culture, I've worked with ESPs that encourage this data collection as it helps justify physio to commissioners, it depends on where the department wants to develop as a team…"
(Participant 005. Qualified for 16-20 years and working in secondary care)

All interviewees agreed with the online survey findings reporting that the cost of equipment is a barrier to use some somatosensory testing. Interview participants explained that equipment shortages often exist in the department and with small budgets to replace any equipment. These interview participants perceived that decisions were then based on availability rather than clinical reasoning:

"I currently carry my own reflex hammer, paid for by me with my name on it, that tells you why physios don't decide to use anything else when assessing…"
(Participant 006. Qualified for 6-10 years and working in primary care)

7.5. Theme three: Minimise risk

This theme explores the perception of minimising risk when assessing a person with CSR. The narrative joint display is presented in **Table 7.5**. Interview participants described that decisions made in practice are often made due to two external factors: medico-legal expectations and influences of a line manager.

The stacked bar chart (**Figure 7.2**) reports the frequency across the physical assessment methods when establishing a CSR diagnosis from the online survey. The physical assessment strategies were always or often used when establishing CSR diagnosis: reflex testing (Always: 89%, 56/63; Often: 11%, 7/63), manual muscle testing (Always: 94%, 59/63; Often: 6%, 4/63), Spurling's manoeuvre (Always: 36%, 24/63; Often: 26%, 17/63), neurodynamic testing (Always: 40%, 25/63; Often: 35%, 22/63) and light touch sensation (78%, 49/63; Often: 17%, 11/63).

Table 7.5 Narrative joint display with the theme ‘Minimise risk’

Overarching theme	Category	Survey results	Qualitative interview results	Meta-Inferences and interpretation	
Minimise risk	External influences: Medico legal and managers	36/63 of respondents (57%) prioritised other physical assessment methods when diagnosing CSR 55.6% (35/63) of respondents suggested that more assessment time during clinical settings could also improve the use of small-fibre somatosensory testing methods Questionnaires or tools were more useful for researchers than for clinicians (16/63, 25.5%) Survey respondents reported that MRI is ‘always used’ (8%, 5/63) or ‘often’ used (33%, 21/63) when establishing CSR diagnosis	The fact that we have to, you know, use kind of qualitative and quantitative measures for insurance based patients. So, we use them because we need to justify more treatment sessions. It makes the process smoother (Participant 008) It makes sense to use questionnaires because it just makes life easier. You know if they ever want to audit you, or if you want to request additional treatment, you refer to the problems on the questionnaire (Participant 011) You've got to cover all the bases really so you know it always gives me a lot of comfort, doing a full neuro upper limb assessment and everything is normal, so surely it can't be anything to worry about that you’ve missed something that you get called out on (Participant 011) For first contact practitioners, you know our job is really to make sure this person is not gonna die in the next six months of something horrific, and anything that's not that we're not overly worried about anymore	Expansion Expansion	Some interview participants reported that their first contact practitioner role means that they select testing to rule out sinister pathology, not necessarily to build a CSR diagnosis. Some interview participants explained that small fibre somatosensory testing does not change decision making when referring to other clinicians. Some interview participants explained that using questionnaires might provide further justification to insurance companies to fund additional sessions. Providing this data supports the justification for more treatment.

			(Participant 002) And unless we are transferring that information for an onward referral, it's probably not going to bring anything to my assessment doing these things (Participant 004) I would expect my staff to complete myotomes, dermatomes and reflexes as part of an assessment – this is standard practice (Participant 007)		

All interview participants supported the sentiment of the survey responses in that, if expectations of pain questionnaires or other somatosensory testing are to be introduced into practice, formal and informal continuing professional development education will be necessary. One participant reflected:

> *"Pain education is poor in physio education; I don't remember any education being provided around different sensory tests or screening tools at university… I was aware of these when I qualified and had a mentor to show me."*
> *(Participant 002. Qualified for more than 21 years and working in private practice)*

All interview participants explained that clinical experience of assessing patients is more valuable to physiotherapists than the outcomes of questionnaires or small-fibre somatosensory testing data. This influenced how other multi-disciplinary team clinicians assess CSR and pattern recognition reasoning:

> *"I learnt about neuro assessment by observing an ortho surgeon, they don't use any questionnaires or heat tests… I've adopted this in my triage assessments because I make referrals to ortho (orthopaedics)."*
> *(Participant 004. Qualified for 6-10 years and working in secondary care)*

Another physiotherapist shared this sentiment:

> *"I think that as you get more mileage as a spinal physiotherapist, you see patterns of presentations… the subjective assessment tells you what you want to know, and the physical assessment is for the patient's reassurance really."*
> *(Participant 006. Qualified for 6-10 and working in primary care)*

Most interview participants explained that physiotherapists may prioritise other assessment strategies because of the expectations of their line managers or the department they work in. This is exemplified with this participant:

"There is a difference across different departments, it depends on what the priorities of the manager are. Working in one department with a research focus meant we collected a lot of questionnaire data which helped researchers."
(Participant 008. Qualified for more than 21 years and working in private practice)

On the other hand, some interview participants explained how working as part of a multi-disciplinary team and the clinical lead's expectations influenced decision-making when assessing CSR. Noteworthy, all these participants reported that orthopaedic surgeons were their clinical service leads:

"My orthopaedic surgeon I work with would expect me to complete a basic neuro of myotomes, dermatomes and reflexes for every patient… this is foundation level triage assessment."
(Participant 003. Qualified for 1-5 years and working in primary care)

7.6. Theme Four: Understanding Symptoms

This theme explores participants' understanding of symptoms related to CSR when establishing a diagnosis. The narrative joint display is presented in **Table 7.6**. Survey respondents reported how frequently pain detection or pain threshold testing are used when formulating a CSR diagnosis. These decisions were explained by interview participants detailing that CSR assessment focuses on two categories, namely pain symptoms and nerve descriptors.

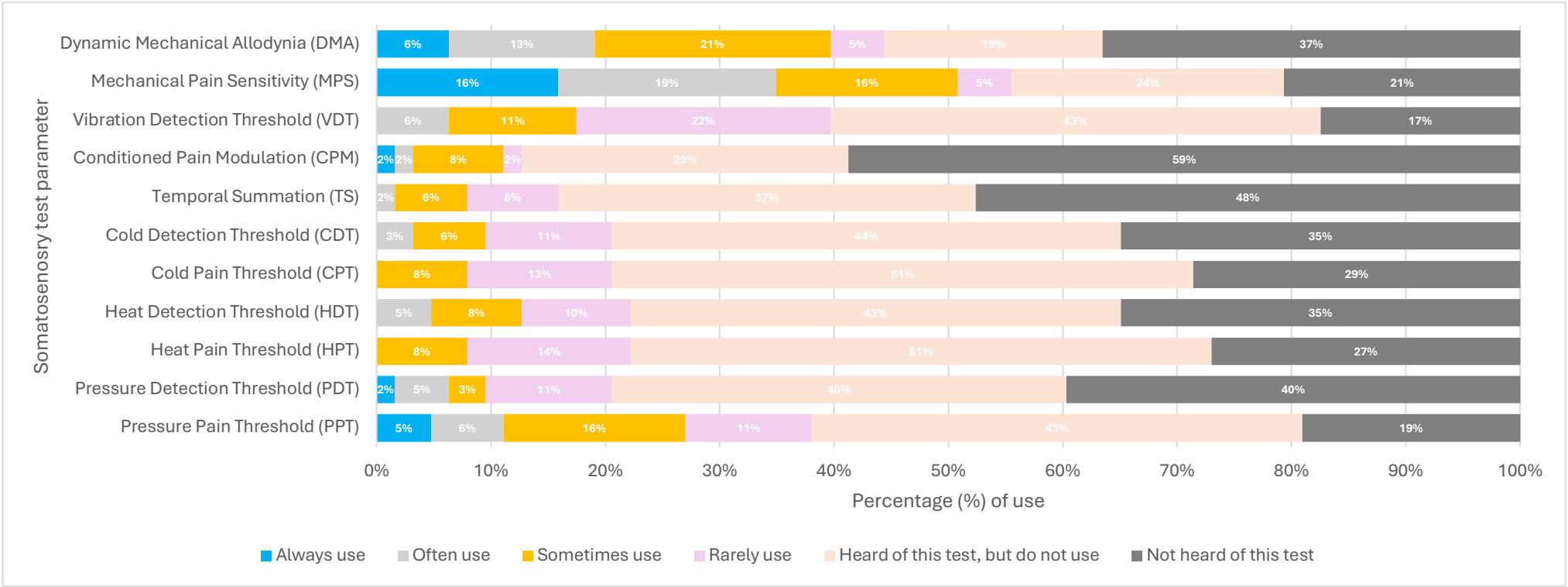
Table 7.6 Narrative joint display with the theme ‘Understanding symptoms’

Overarching theme	Category	Survey results	Qualitative interview results	Meta-Inferences and interpretation	
Understand symptoms	Pain	When diagnosing CSR, 36% (24/63) of respondents reported always using Spurling's manoeuvre, while 26% (17/63) reported often using it. Mechanical pain sensitivity was used 'always' by 16% (10/63) and 'often' by 19% (12/63) of respondents. Pressure pain threshold was used ‘always’ by 5% (3/63) and ‘often’ used by 6% (4/63) of respondents. None (0%) of the 63 survey respondents selected ‘always use’ for heat pain threshold or cold pain threshold when diagnosing CSR. 13% (8/63) of respondents ‘rarely use’ cold pain threshold and 14% (9/63) ‘rarely use’ heat pain threshold when diagnosing CSR.	The primary symptom is always pain. But pain, from a clinical point of view, is the thing that we're bothered about the least when diagnosing CSR (Participant 009) I suppose it can also be a painless experience too (Participant 009) Our job is to basically is to establish whether what we're treating is something which is mechanical pain or non-mechanical pain. Is it something we're gonna be able to affect or not? (Participant 010)	Expansion Expansion	Not all interview respondents reported that pain was the main symptom for CSR. There were differences of opinion on whether pain provocation testing (such as Spurling’s manoeuvre) is used. Some interview participants reported that the spinal triage clinical setting they work in focuses on whether presentations are mechanical (symptoms can be reproduced with objective tests) or not. This positioning influences treatment pathways, not necessarily diagnosis formulation.

	Nerve descriptors	When diagnosing CSR, 36% (24/63) of respondents reported always using Spurling's manoeuvre, while 26% (17/63) reported often using it. Nerve conduction studies were 'often used' with 13% (8/63) and no survey respondents (0/63) 'always' and 32% (20/63) of respondents 'rarely' used when establishing CSR diagnosis.	Well, the symptoms are going to predominantly be pain, pain, numbness, tingling, pins and needles (Participant 003) I think that we maybe don't do enough of is thinking about the range of sensory tests for nerve symptoms, like you know you maybe do light touch, but I think it's not particularly objective (Participant 004) I suppose a lot of it's how you're taught and the traditional way of listening for nerve signs or symptoms (Participant 006) I might not necessarily be talking the same language as spinal surgeons with some of these, so it is not useful (Participant 001)	Convergence Expansion Expansion	All interview participants reported that recognising nerve signs or symptoms supports CSR diagnosis which aligns with the survey results that nerve symptoms are reproduced with physical testing. Some interview participants explained that reaching a diagnosis of CSR can be achieved through the subjective assessment. The objective testing confirms diagnosis formulation. Some interview participants reported that medical colleagues (for example, orthopaedic surgeons) do not use small fibre somatosensory tests when forming a diagnosis, therefore they are not used. The use of subjective symptoms is a 'common language' used across professions.

Testing that involved pain or symptoms reproduction was identified as an important assessment method when establishing CSR diagnosis. The stacked bar chart (**Figure 7.2 and Figure 7.4**) illustrates the frequency across the physical assessment methods and somatosensory testing when establishing a CSR diagnosis, respectively. Thirty-six percent (36%; 24/63) of online survey respondents reported always using Spurling's manoeuvre, while 26% (17/63) reported often using it. Mechanical pain sensitivity was used 'always' by 16% (10/63) and 'often' by 19% (12/63) of respondents. Pressure pain threshold was used 'always' by 5% (3/63) and 'often' used by 6% (4/63) of online survey respondents. However, none (0%) of the 63 survey respondents selected 'always use' for heat pain threshold or cold pain threshold when diagnosing CSR. Thirteen percent (13%) (8/63) of respondents 'rarely use' cold pain threshold and 14% (9/63) 'rarely use' heat pain threshold when diagnosing CSR.

Figure 7.4 The frequency use across all somatosensory test parameters when establishing a cervical spine radiculopathy diagnosis (n=63)



Participants in the qualitative interviews reported a mixed explanation of these results. Some of the participants explained that, although pain is a common symptom with CSR, the completed physical testing does not always relate to these symptoms. Conversely, other interview participants explained that their role was to understand whether the symptoms related to CSR were a result of a serious spinal pathology. This is illustrated by Participant 10's clinical decision-making interpretation:

> *"Pain is usually the main complaint with radiculopathy, but tests to assess pain are unreliable… I think it is more useful to understand whether it's mechanical pain or non-mechanical pain… this helps to justify onward referral to surgeons or imaging for something nasty."*
> *(Participant 010. Qualified for 16-20 years and working in primary care)*

Most interview participants stated that pain provocation tests are challenging to interpret because the symptoms may be persistent (lasting longer than three months), meaning that pain provocation tests have limited use when establishing a diagnosis, which is a discourse from questionnaire results.

> *"…most patients coming through the service will have pain lasting more than three months… this means chronicity… that questions whether pain tests like Spurling's is actually useful as they are already in pain before we start."*
> *(Participant 004. Qualified for 6-10 years and working in secondary care)*

Some participants expanded on this explaining that a possible explanation for why assessment strategies did not focus on pain symptoms may be because of physiotherapists' perceived lack of knowledge related to underlying pain mechanisms.

> *"These nerve tests should probably be used but I reckon most physios' understanding of pain mechanisms is not good, that's why they are not used…"*
> *(Participant 006. Qualified for 6-10 and working in primary care)*

This sentiment was shared by another participant:

> *"I remember covering these with my pain masters course… it's about nerve function… we only assess light touch, though… that's only one aspect of how a nerve works which might mean we miss some (CSR diagnosis)."*
> *(Participant 007. Qualified for more than 21 years and working in primary care)*

Nerve-related symptom descriptors by patients were identified as an important component of establishing CSR diagnosis. All interview participants recognised that sensory changes such as paraesthesia or dysaesthesia were likely to be descriptors reported by patients who had CSR. This was often asked in the subjective questioning stage of an assessment by interview participants. This was explained by one participant:

> *"Pins and needles, numbness… that would raise my suspicion of CSR."*
> *(Participant 005. Qualified for 16-20 years and working in secondary care)*

There were, however, some differences in the explanation of how sensory symptoms related to nerve dysfunction should be assessed. Some interview participants explained that small-fibre somatosensory testing would not change the treatment pathway for the patient with suspected CSR, as exemplified by one participant:

> *"Pins and needles or change in sensation are unlikely to change management pathway… so things like thermal or pinprick detection would still mean conservative treatment, this can be justified by doing light touch anyway… but something like power loss would mean workup for imaging."*
> *(Participant 005. Qualified for 16-20 years and working in secondary care)*

Testing that is used by other healthcare professionals was explained as an important consideration for interviewed physiotherapists when establishing CSR diagnosis. There were some interview participants who expanded upon the reasons why some assessment practices, such as small-fibre somatosensory testing and nerve-related pain assessment questionnaires, may depend on whether other

clinicians in the management pathway utilise them too. One participant reflected on this working practice with colleagues:

> *"My consultant does not use these tests… so we wouldn't speak the same language if they were used."*
> *(Participant 011. Qualified for 16-20 years and working in secondary care)*

7.7. Next steps

This chapter presented the integrated quantitative (survey) and qualitative (interview) results through narrative joint display. **Chapter 8** will discuss and contextualise these integrated findings.

Chapter 8: Integrated quantitative and qualitative discussion

8.1. Introduction

In this chapter, the integrated results from Chapter 7 are discussed with existing research to address the aim of this mixed methods research study.

8.2. Theme: Perception of role

It is unclear how physiotherapists prioritise the access and utilisation of research among the competing clinical practice demands. Participants reported time pressures when making decisions on assessment approaches, suggesting that it would be unreasonable to assume that physiotherapists would prioritise accessing evidence above seeing patients and completing administration tasks such as medical record writing. To ensure clinicians purposefully access and appraise evidence, initiatives such as evidence-based case discussions may be helpful to support, guide and justify assessment decision-making (Castellini et al., 2020). However, adding such initiatives to an already busy clinical schedule may force the physiotherapist to juggle more competing demands, making them unsustainable or less valuable. Therefore, it is necessary to understand how clinicians prioritise research among competing demands of their clinical workload delivery and under what circumstances this can influence CSR assessment decision-making. There is a clear desire of a systemic enhancement in healthcare system infrastructure to facilitate physiotherapists the time and space to engage with research.

Participants in this study reported that some assessment strategies, such as small-fibre somatosensory assessment, were unsuitable for clinicians and more suited to research environments. This may provide insight into the transition and application of academic research into clinical settings. A study investigating physiotherapists' opinions towards how evidence is accessed, factors influencing evidence access, and factors influencing evidence application reported a lack of clinically relevant evidence as a significant barrier to applying evidence in practice (Gleadhill et al., 2022). This lack of relevance can occur when researchers focus on problems that are not significant for clinicians or include treatments that are not easily implemented

in practice (Gleadhill et al., 2022). However, the findings from Gleadhill et al., (2022) were based on physiotherapists in New South Wales, Australia, which may limit some of the transferability of their results to UK physiotherapists due to different healthcare systems. Nevertheless, continued collaboration and co-production between researchers and clinicians should be considered essential to bridge this gap between clinicians' needs and the information that evidence justifies. This collaboration can facilitate a contextual appreciation of the challenges of evidence-based care delivery included in research that are 'real-world' implementable.

Knowledge translation, integrating the best available research-based knowledge, clinical expertise, and patient preferences were identified as a crucial component of the assessment and management of CSR. Participants explained that different healthcare settings may require different assessment approaches when assessing CSR. This finding is similar to a study which reported that it was essential to adapt research-based knowledge to meet the unique demands of varying clinical contexts for physiotherapists and patients (Worum et al., 2019). Participants reported a tension between standardisation and individualisation of the knowledge derived from research into practice. Worum et al., (2019) reported that research-based knowledge should be adapted to meet the patient's specific needs and the physiotherapist's experiences. However, findings are limited to falls prevention research, which may restrict the generalisability to CSR populations. Nonetheless, it is essential to use research-based knowledge as a template that can be customised according to the needs of the patient and the experiences of the physiotherapist assessing CSR.

Interview participants in this study explained that the reasons for selecting assessment strategies were related to pattern recognition reasoning strategies developed over years of clinical experience. Large-fibre somatosensory testing was selected over small-fibre somatosensory testing based on previous CSR presentations assessed and managed throughout their clinical careers. Those with more clinical experience and expertise tended to use inductive reasoning, while student and novice professionals relied on deductive reasoning. Deductive reasoning, where one moves from information gathering through pattern recognition and through to differential diagnoses, is subject to a range of cognitive biases, including confirmation and availability bias (Carr et al., 2020, Hayes and Heit, 2018).

This approach is often used by experienced professionals where patient presentations are more straightforward. For students or novice physiotherapists, this reasoning approach increases the risks of inaccuracies and biases (Almond et al., 2021). However, with an atypical clinical presentation, the expert, like the novice, will rely more on deductive clinical reasoning patterns (Almond et al., 2021). Therefore, the results of this study can be interpreted that interview participants perceive CSR as a 'straightforward presentation', relying on pattern recognition for CSR diagnosis formulation. Notwithstanding this, it is acknowledged from this study that clinical reasoning in assessing CSR cannot be separated from diagnostic decision-making and is thus a critical consideration for both recognising and managing CSR. There is a clear indication for future research to investigate the understanding of novice and experienced physiotherapists' clinical reasoning frameworks when assessing and managing people with CSR.

Results from this mixed methods research study uncovered that understanding a person's pain and related symptoms was an integral component of a physiotherapist's assessment for people with CSR. Interview participants further detailed that physiotherapists' understanding of underlying pain symptoms is poorly understood across the profession, which may be a reason why small-fibre and pain questionnaires, or screening tools, are not consistently used. In the UK, the Chief Medical Officer's annual report emphasised the importance of pain education for healthcare professionals to enhance pain management provision among UK healthcare services (Whitty, 2023). However, there is variability in pain education across healthcare programmes in the UK. In a study examining the content of pain curricula, Briggs et al., (2011) conducted a cross-sectional survey investigating the nature and content of pain curricula in undergraduate/pre-qualification programmes for healthcare professionals in UK university programmes. Ten higher education institutions that deliver pre-registration physiotherapy programmes responded they had a median of 37.5 hours of pain education across the length of the degree programme and eight domains, including neurophysiology, pain assessment, analgesics, non-pharmacological treatment, multidimensional nature and multimodal management, policy, guidelines, and audit in pain (Briggs et al., 2011). This equates to less than 1% of the physiotherapy curriculum. The results of Briggs et al.'s (2011) survey suggest a discrepancy between theory and practice. Interview participants in this mixed methods research study explained that physiotherapists

have an under-developed understanding of pain and symptoms associated with CSR, which reflect the decisions made with assessment strategies in practice. Notwithstanding Briggs et al.'s (2011) results, it is acknowledged that this cross-sectional survey was completed in 2011. In light of updated standards of education and training of physiotherapy in the UK, these figures may have changed. Furthermore, the survey respondents in Briggs et al.'s study (2011) described pain content as challenging to identify as it is often implicit across a range of learning modules. The IASP has developed physiotherapy-specific and pain education curricula (Wong and Kirk-Sanchez, 2021). This curricula uptake and usage should now be mapped and evaluated among physiotherapy educators, clinicians and students in the UK (Watt-Watson et al., 2017).

8.3. Theme: Service constraints

Survey respondents reported that reasons for not using small-fibre somatosensory testing were due to limited time to assess in practice, equipment availability and integration of IT systems of assessment results. During the qualitative interviews, participants explained that they faced time pressures due to the appointment time slots being 20 to 30 minutes. Interview participants explained that physiotherapists were likely to select assessment testing that was time efficient. This reasoning was also reported in Langridge's (2019) qualitative study, where physiotherapists were interviewed to determine the necessary skills, knowledge, and attributes for first contact practitioners (FCPs). Langridge (2019) reported that physiotherapists who worked as FCPs had shorter appointment times than in their regular musculoskeletal physiotherapy roles. As a result, one of the key challenges these physiotherapists faced was making timely assessment decisions (Langridge, 2019). The time pressures for physiotherapists working in primary care can be attributed to the expectation that physiotherapists are required to evaluate multiple physiological systems, including musculoskeletal, neurological, cardiovascular and respiratory systems, to ensure safe care practices are followed (Goodwin and Hendrick, 2016). Notwithstanding this service constraint, somatosensory nervous system assessments should encompass small and large-fibre assessments to robustly assess nervous system integrity and function (Schmid, 2020) (as discussed in **Chapter 1**). Selecting assessment based on time efficiency may mean that some CSR presentations are not robustly assessed (Norman and Eva, 2010). The current

standard for evaluating somatosensory nervous system dysfunction is QST and, as discussed in **Chapter 1**, this can take up to 1.5 hours for untrained clinicians (Reimer et al., 2020). There is a clear indication to develop, validate and evaluate a comprehensive and time-efficient clinical sensory test battery that can detect somatosensory nervous system integrity and function to support the formulation of CSR diagnosis.

Survey respondents reported that assessment strategies selected to diagnose CSR were partly attributed to equipment availability and cost. Interview participants explained that minimal equipment was required to complete large nerve fibre testing such as manual muscle strength, light touch dermatomes sensation and reflex testing (such as a reflex hammer and tissue paper). On the other hand, small-fibre somatosensory testing, such as thermal detection and threshold, required specialised equipment that was unavailable in clinical departments. Quantitative sensory testing using the DFNS protocol requires specialised equipment, such as a Medoc machine (Gierthmuhlen et al., 2019). However, these machines are expensive and require specialised training to operate and interpret (Vollert and Schmelz, 2021), which aligns with the current study findings. Despite this, the findings from this mixed methods research study align with clinical bedside somatosensory testing using cotton wisp, tuning fork, metal, brush and von Frey filament, which are reported to be inexpensive (Reimer et al., 2020). Future research should now consider validating bedside somatosensory assessment before implementing such an approach in clinical trials (Reimer et al., 2020).

Participants in the Phase 2 qualitative interviews explained that physiotherapists' diagnostic decisions when formulating CSR may be influenced by whether assessment tests or questionnaires are integrated into electronic medical record systems. Digital integration of clinical assessment can enable benchmarking and ongoing monitoring during management phases of care (Zischke et al., 2021). Integrated digital health technologies offer an opportunity to provide uninterrupted care services across stakeholders involved in patient care (Zischke et al., 2021). A scoping review of digital integration in health assessment technologies indicated that using patient digital records can improve healthcare efficiency for both staff and patients (Jimenez et al., 2020). This is also supported by the King's Fund (Jefferies et al., 2023), which reported that electronic medical record digital integration can

enhance remote monitoring, access to treatment, and patient choice of assessment and care pathways. One reason why this has not been implemented to date may be the cost of digital integration for healthcare providers (Zischke et al., 2021). However, caution must be taken when implementing digital integration of assessment strategies for CSR, as its success will depend on patients' and clinicians' digital literacy and technological issues, such as information governance. Clinicians and patients may lack access or training to digital equipment or assessment services, leading to exclusion from digital integration and widening health inequalities.

8.4. Theme: Minimising risk

Interview participants in the current study explained that assessment decisions made when establishing CSR diagnosis are rationalised into two categories, namely external and internal factors. External factors include medico-legal expectations, line managers or clinician influences. To practice lawfully, safely, and effectively, a physiotherapist must possess knowledge, skills, and experience grounded in standards and competencies (Madsen et al., 2021). This means that physiotherapists are legally responsible for their actions, and their decision-making and conduct can have complex medico-legal implications. Subsequently, a physiotherapist's standard of care would be judged against that of other healthcare professionals in their field (Madsen et al., 2021). For example, if a physiotherapist works in primary care alongside medical doctors, their conduct and decision-making would be judged alongside a reasonably competent doctor in primary care (Tawiah et al., 2021). This mixed methods research study recruited survey respondents and interview participants who worked in various public and private healthcare settings. Establishing practice boundaries that cover all job roles and the remit against which they will be judged (Armitage and Shepherd, 2005) can be challenging due to the diversity of job roles (Armitage and Shepherd, 2005). However, physiotherapists must demonstrate their competence to practice, ensure that their knowledge and skills meet the required standards for their specific healthcare setting, and recognise when they require additional support with decision-making (Buttress and Marangon, 2008, Madsen et al., 2021).

Interview participants in this mixed methods research study explained that medico-legal expectations related to CSR assessment decisions were, in part, related to guidelines or protocols from their local working environment, regionally or nationally. Furthermore, some interview participants explained that not completing large-fibre somatosensory testing may mean their assessment practice is vulnerable to exposure to medico-legal complaints. Despite this, as discussed in **Chapter 1**, there are no nationally agreed assessment guidelines or protocols for diagnosing CSR. In addition, a physiotherapist's decision to complete assessment tests or procedures based only on potential negative medico-legal implications risk stifling clinical reasoning (Suckley, 2012). This risk of stifling clinical reasoning may, in fact, negatively impact the autonomy of physiotherapists. Furthermore, protocols can produce a false sense of security for a physiotherapist. For example, when a patient's presentation is atypical and a physiotherapist chooses not to adhere to an agreed protocol, they must be able to justify this decision due to the regulatory principles and associated medico-legal implications (Suckley, 2012). If a defendant claims to have a certain skill or knowledge, according to case law, it must be a proven skill or knowledge acquisition. Failing to provide evidence would breach the clinician's duty of care (Bruce and Standley, 2011, Buttress and Marangon, 2008). Therefore, the justification to complete assessment testing for CSR diagnosis based on actual or potential medio-legal expectations requires careful reflection and well-reasoned justification.

This mixed methods research study findings indicated that MRI was 'always' or 'often used' by 41% of survey respondents (25/63) when establishing CSR. Interview participants detailed that imaging was available to specialised clinical settings (such as musculoskeletal assessment and triage interface services) and was expected to be used to establish diagnosis and inform management plans. Imaging for radiculopathy is supported in some patient presentations (NICE, 2020). The NICE guidelines for LBP with or without sciatica report that imaging may be considered in specialist care settings such as a musculoskeletal interface clinic only if the result is likely to change management (Jenkins et al., 2018, NICE, 2020). However, imaging is not routinely offered to establish diagnosis in non-specialist settings for these populations (Jenkins et al., 2018, NICE, 2020). Furthermore, the guidelines are not mandatory; it is expected that clinicians use their clinical judgement, considering the unique needs, preferences, and values of their patients

who use healthcare services. Additionally, these LBP guidelines have limited external validity for people with CSR. Therefore, in order to diagnose CSR, it is important to have a well-reasoned justification for completing imaging investigations.

Interview participants explained that the reason why physiotherapists use large-fibre somatosensory testing or imaging when establishing CSR diagnosis is, in fact, to 'rule out' serious spinal pathology. This suggests that CSR may be a diagnosis of exclusion, which can create uncertainty in how CSR diagnosis can or should be formulated among physiotherapists. Helou et al., (2020) described uncertainty as tolerating ambiguity within the clinical decision-making process. Diagnostic uncertainty is considered prevalent within primary care due to heterogeneous clinical presentations and time pressures (Danczak and Lea, 2014). Furthermore, missing serious pathology has been reported by first contact practitioners in primary care (Goodwin and Hendrick, 2016). Some physiotherapists working in primary care have expressed concern regarding the unpredictable nature of the work and diagnostic uncertainty associated with the first contact practitioner role (Goodwin et al., 2020). This is reflected in the results from this mixed methods research study, with some interview participants explaining how physiotherapists working in primary care are accountable for ensuring that sinister or serous pathology is not missed. This is despite the fact the prevalence of serious pathology is rare (Budtz et al., 2021), but the possible worry associated with uncertainty appeared to reinforce the burden of responsibility and increased potential for litigation claims amongst physiotherapists working in primary care FCP roles. The FCP is considered unique from other physiotherapy roles and generates an additional layer of accountability, emphasising managing uncertainty and clinical risk (Langridge, 2019).

Findings also revealed that assessment decision-making for CSR is also related to the negative influence of physiotherapists' line managers or clinical service lead. Cervical spine radiculopathy assessment decisions were attributed to, in part, performance-related monitoring such as clinical record auditing or justifying additional treatment sessions, rather than the clinical reasoning justification based on signs, symptoms and potential management plans for a person presenting with CSR. This rationale may threaten professional autonomy in decision-making among physiotherapists. The inability to execute clinically reasoned assessment

approaches can lead to frustration and elevated work stress among physiotherapists (Lim et al., 2021). In a scoping review investigating the influences of physiotherapists' autonomy, 13 low to moderate-quality studies reported that reductions in autonomous decision-making with assessment and treatment plans could negatively influence clinical reasoning and clinical decision-making (Lim et al., 2021). However, the included studies were from low to middle-income countries, which may limit the transferability of findings to UK physiotherapy practice. Notwithstanding this, participants felt empowered when service leaders respected their autonomy and clinical decision-making skills and provided support by being available for consultation on practice issues, resulting in increased perceived autonomy, higher job satisfaction and enhanced patient care (Lim et al., 2021).

8.5. Theme: Understanding symptoms

The provocation of symptoms through pain provocation testing and NDT was not always or often used when establishing CSR diagnosis among survey respondents. Interview participants explained that assessment decisions are associated with whether pain and symptom descriptors are present, and which are related to nerve dysfunction or injury. Study findings revealed that using physical assessment testing (such as NDT) guided whether the CSR diagnosis was 'mechanical' or 'non-mechanical' and, importantly, supported the formulation of management plans.

Neurodynamic tests are used to identify changes in mechanosensitivity in neural tissue (as discussed in **Chapter 1**). It is postulated that neurodynamic tests elongate the nerve bed, placing more mechanical strain on neural structures, which can exacerbate a person's CSR-related pain or nerve symptoms. There is conflicting evidence on their value (Wainner et al., 2003). This may be attributed to the differences in what constitutes a positive test. An NDT can be considered positive if any of the following criteria are present: reproduction of the patient's symptoms or side-to-side range of motion deficit (Wainner et al., 2003). However, Ghasemi et al., (2013) reported a positive finding if the patient experienced any pain during testing. The conflict may explain the variance in diagnostic accuracy and lead to false positive or negative conclusions. Moreover, as discussed in **Chapter 1**, the expression of pain or nerve-related symptoms is complex and is not uniformly present among those people with CSR. Therefore, 'mechanical' responses to

physical assessment testing such as NDT in people with CSR may have varied responses, and the interpretation of this and what constitutes a positive or negative test may lead to further diagnostic inaccuracies.

Pain perception is unique, yet neuropathic, nociceptive or mixed-pain mechanisms can be features of CSR (Tampin et al., 2018), depending on the pathophysiological mechanisms at play. As discussed in **Chapter 1**, CSR can present as a painful or painless radiculopathy (Siller et al., 2018). The phenotypic somatosensory sub-groups of people with CSR may account for some of the heterogeneity of presentation. People with CSR can have mixed, bidirectional sensory abnormalities, i.e., signs of a loss of function and a gain of function. People with CSR may experience sensory changes in the area where they feel the most pain (maximal pain area). This includes a decrease in the ability to detect temperature, pressure, and vibrations. It can also affect the dermatome of the nerve root, which is the skin area innervated by a single spinal nerve (Tampin et al., 2012). The mixed somatosensory presentations with CSR reinforce the indication to assess large and small somatosensory fibres in clinical practice.

8.6. Strengths and limitations

This is the first mixed method research study to identify and explain the assessment strategies of UK physiotherapists when diagnosing CSR. The survey and interview sample was a mix of UK physiotherapists working in NHS primary and secondary care and private practice, thus increasing the likelihood that the findings of this study can be transferable to other UK physiotherapists. However, there were 63 respondents in the cross-sectional survey of physiotherapists practising in the UK. This very low response rate is likely to under-represent the number of UK physiotherapists who assess CSR in clinical practice. Very low response rates increase the risk of selection bias (Bethlehem, 2010, Greenacre, 2016). While reasons for non-response were not collected in the current study, different reasons for low or non-response rates have previously been identified, such as refusal or ineligibility to respond, survey length, lack of incentives, or return of empty or spoiled surveys (Saunders et al., 2009).

The planned recruitment strategy was considered robust. This included professional network engagement across multiple special interest groups across physiotherapy, which included 'gate keeper' endorsements and social media sharing across physiotherapy and pain science groups in the UK with approximately 8,000 impressions (times viewed on Twitter). It was not possible to ascertain the number of online questionnaires accessed. This is considered a common problem with online surveys (Bethlehem, 2010, Johnson, 2014, Palys and Atchison, 2021). As a result, it was not possible to determine an accurate response rate. Using an online survey with an e-link was time and cost-efficient. However, the strategy relied upon the connections of social media and physiotherapists registered to receive e-bulletins through the relevant professional physiotherapy networks, which may have created selection bias (McRobert et al., 2018, Ruel et al., 2015). Due to resource constraints, a paper version and distribution was not available. As a result, the sample size was small, which may limit the generalisation of the findings.

Despite efforts to minimise bias in the mixed methods sequential study design, some bias was still present. The survey was not restricted to a specific group, with survey links and adverts sent to gatekeepers across UK professional networks/special interest groups. The gatekeepers then passed the survey on to their members with a clinical interest in CSR. This approach aimed to obtain the views of those who assessed and/or treated people with CSR, but it also allowed for heterogeneity in the participating physiotherapists, potentially leading to variation in their experiences. A more purposive sampling strategy could have recruited physiotherapists from various NHS bandings and clinical working environments, to deepen the breadth of the survey results.

During the development of the survey, the lead researcher (MM) considered the survey length, and the time needed to complete it to enhance response rates. While the survey length did not seem to impact the completion, there is evidence suggesting that respondents may fatigue from a long or overly complicated survey (Braun, 2021). Schofield and Forrester-Knauss (2010) recommended that a questionnaire should take less than 20 minutes to complete. Lengthier response times are associated with incomplete questionnaires and a decrease in response rates (Schofield and Forrester-Knauss 2010). Malhotra (2008) conducted an observational cross-sectional study to explore the connection between the duration

of questionnaire completion and the resulting data quality. The findings identified that respondents typically abandoned the survey after 31.4 minutes. This finding suggests that, in the case of online surveys, participants may opt to close their internet browser rather than persist with the survey (Rea and Parker, 2014). To investigate this possible issue for the current PhD survey study, respondents who formed the pilot study cohort were asked if they felt the survey's length was reasonable and if it affected their ability to complete it. No issues were reported by this group, so this was not considered significant. Nevertheless, it is possible that some potential respondents may have been deterred by the length of the survey.

The offer of financial incentives, such as a prize draw or certificate upon survey completion, was considered to increase the response rate. Financial incentives have been employed to boost response rates for postal questionnaires. A Cochrane systematic review, which included 481 RCTs assessing 110 different methods for increasing response rates to postal questionnaires across various populations, reported a two-times greater response rate through monetary incentives (Edwards et al., 2009). However, it is important to note that these findings may not be applicable to online survey methods. Wilson et al., (2010) completed an RCT where participants were contacted by email and invited to complete an online survey. Participants were randomly assigned to groups with either 'knowledge of' or 'no knowledge of' a financial incentive (£10 Amazon gift voucher) to be provided upon completion of the survey. However, the knowledge of a financial incentive did not significantly increase the response rate to an online questionnaire ($p=0.08$). Nevertheless, it is possible that some potential respondents may have been deterred by the lack of incentive to complete the survey.

The multi-modal methods detailed in **Chapter 5** were completed. This included professional network engagement across multiple special interest groups across physiotherapy, which included UK 'gatekeeper' endorsements across physiotherapy and pain science groups. However, on reflection, to boost response rates, further requests could have been made to clinical departments to print and post the survey link (in paper form) on physiotherapy notice boards. Furthermore, a notification could have been made on social media, in print journals and/or an e-bulletin alerting potential respondents to the survey and 'preparing' potential

participants to respond before the questionnaire went live online. These alternative recruitment strategies might have further improved the response rates.

An explanatory sequential design was conducted, which utilised a parallel sequential sample design. Participants in the qualitative interviews were recruited from the quantitative online survey (as discussed in **Chapter 6**). This sampling strategy possibly excludes population members who have experience of assessing and managing CSR in their physiotherapy practice but did not complete the online survey. Nevertheless, the interviews were utilised to explain the survey findings and recruiting participants who did not complete the survey may have questioned the transferability of the findings. As discussed in **Chapters 5 and 6**, it is possible that the interview participants who were recruited for the study may have unintentionally or intentionally introduced bias into the sample. Self-selection can lead to biased results (Greenacre, 2016), as participants with certain attitudes or characteristics may be more likely to volunteer to participate. This bias can have a bidirectional impact, meaning that participants volunteered to participate based on their strong opinions (positive or negative) about the reasons behind CSR assessment decisions.

The lead researcher's position (MM) was that of a musculoskeletal higher education academic, not working alongside any of the interview participants in clinical practice, discussed in **Chapter 6**. The lead researcher's (MM) position may therefore have supported rapport-building participants. The impartiality of the lead researcher (MM) not working in the same clinical setting as the interview participants seemed to support interview participants' discussion of both the positive and negative reasons associated with CSR assessment. Conversely, an independent interviewer may have produced further insights from the participants, as the lead researcher (MM) was already known to some participants in his musculoskeletal academic roles. Participants may have been reluctant to disclose any negative reasoning with the lead researcher (MM) for fear of their practice being 'judged'. To address potential concerns before the interviews, participants were informed that all information discussed would be kept confidential and anonymised.

8.7. Conclusion

This mixed methods research study reported the assessment strategies UK physiotherapists use to establish CSR diagnosis in a quantitative survey and the rationale for selection. The most frequent assessment strategies used to diagnose CSR included manual muscle strength, light touch dermatomes sensation and reflex testing. The least frequent assessment strategies included the use of pain-screening tools or questionnaires and small-fibre somatosensory testing, including thermal detection and pain thresholds, pressure detection and temporal summation. Four qualitative themes contextualised the reasons underpinning the choices made when assessing CSR. These themes were perception of role, service constraints, minimising risk and understanding symptoms.

8.8. Next steps

This mixed methods research study provided valuable insights to support the development and implementation of a case-control study investigating the somatosensory profile of adults with CSR.

Chapter 9: Somatosensory profiling of people with cervical spine radiculopathy and healthy controls

9.1. Introduction

This chapter reports a study assessing quantitative sensory testing (QST) and conditioned pain modulation of healthy control participants and people with CSR. The background and justification of this chapter build on the findings of **Chapters 1 to 3**. In this chapter, the methodological approaches for this study are discussed. The chapter concludes with clinical implications as well as a discussion of the limitations of this study.

9.2. Background

As discussed in Chapter 1, CSR is associated with altered processing at various sites along the neuroaxis. This relates to sensory and motor functioning alterations. Chapters 1 and 8 reported that people with CSR are likely to have different underlying pain mechanisms, co-morbidities, psychosocial factors and other contextual factors contributing to their CSR symptoms. Therefore, understanding a person's symptoms associated with CSR and associated functional impairments should continue to be considered part of a holistic and robust clinically reasoned assessment approach.

The traditional approach to musculoskeletal and NeP assessment involves classifying and managing people based on the cause or location of their complaint. However, this approach has limitations, especially for people with central sensitisation (or nociplastic) dominant pain mechanisms, where the cause and nature of the disorder may be uncertain, and the role of pain mechanisms is not well understood. As discussed in Chapter 1, failing to identify people with dominant NeP symptoms has important implications (Bouhassira and Attal, 2023). Individuals with CSR and NeP report higher levels of pain and disability, reduced quality of life, and increased psychological issues compared to those with CSR but without NeP symptoms (Attal and Bouhassira, 2019, Bannister et al., 2020, Bouhassira and Attal, 2023). This latter finding is further supported by the results in Chapter 3, which

demonstrate how psychosocial factors have a negative impact on health outcomes of individuals with CSR.

The German Research Network on Neuropathic Pain (DFNS) aimed to standardise the evaluation of somatosensory function through QST by using consistent tools and parameters to measure sensory loss and gain (Baron et al., 2017; Rolke et al., 2006). Two studies have examined adults with CSR using QST (Chien et al., 2008; Tampin et al., 2012). However, Chien et al.'s (2008) QST protocol did not target the patient's maximal pain area, which is necessary to assess NeP components (Treede et al., 2008). Tampin et al., (2012) did not differentiate between sensory and/or motor sub-groups of radiculopathy, a clinically important distinction as each condition indicates a nerve root dysfunction. Furthermore, to this author’s knowledge, no study has investigated somatosensory profiling in adults with painful CSR using pragmatic CSR diagnostic criteria (Chapters 2 and 3). This study in Chapter 9 aimed to overcome these specific limitations.

Chapters 1 and 2 discussed how nerve root compression might impact both large and small sensory fibres, and the degree of sensory fibre dysfunction. Chapter 3 reported how mental health conditions and symptoms negatively impact the prognosis of people with CSR. Chapters 7 and 8 indicated that a paucity of evidence regarding sensory testing (using QST) for assessing CSR was a significant reason for its limited adoption in clinical practice. The clinical utility of QST in this context is therefore unclear. To begin to address this, Chapter 9 sought to understand how sensory profiles, assessed through QST, and mental health conditions or symptoms, are associated with CSR when compared to healthy adults.

9.3. Objective and hypothesis

The objective of this study was to establish the somatosensory profile of adults with painful CSR and healthy age-matched controls.

It was hypothesised that:

I. The somatosensory phenotypes between the CSR group and healthy control groups would be different.

II. Adults with CSR will have localised sensory abnormalities which would be restricted to the maximal pain area.
III. There will be an association between depressive symptoms and anxiety and QST findings in adults with CSR.

9.4. Methods

9.4.1. Ethical approval

Ethics approval (Ref: ERN_21-1404) was gained from the University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee approval number on 30th March 2022 and from the Health Faculties (Purple) Research Ethics Subcommittee, King's College London (KCL) on 27th March 2023 (Ref: RESCM-22/23-34421) (see **Appendix 9.1** for approval screenshots). The Health Research Authority (HRA) online decision-making tool was used to support this decision (**Appendix 9.2**). The research project does not use past or present NHS patients, service users, prisoners, embryology or human tissue. No medical device or ionising radiation are being investigated. As a result, the study did not require HRA approval.

9.4.2. Lead researcher training

The lead researcher (MM) underwent formal training in the DFNS QST protocol at Mannheim University, Germany on 9-10th November 2021 (**Appendix 9.3**).

9.4.3. Sample size

To detect a clinically significant difference in pressure pain thresholds of 36% between the symptomatic and asymptomatic arm, a sample size of 25 in each patient group was estimated. The study had a power of 80% and a 5% level of significance. The sample size calculation was based on QST data from a sample of healthy control subjects (Rolke et al., 2006). The mean PPT of this sample was 512 (191.6) kPa. A difference of 36% in mean PPTs between sides has been reported as clinically significant (Rolke et al., 2006).

9.4.4. Testing sites

Testing was completed at the Centre of Precision Rehabilitation of Spinal Pain (CPR Spine), School of Sport, Exercise and Rehabilitation Sciences, Birmingham, University of Birmingham and Central Modulation of Pain Group, Wolfson Centre for Age-Related Diseases, King's College London. Both sites had dedicated somatosensory testing space to conduct the relevant testing.

9.4.5. Equipment calibration and safety considerations

All QST and CPM cuff algometry equipment at both study sites were calibrated or newly purchased before the study began. All sensory testing equipment was CE-marked and the machines had safety limitations. It was clearly stated to potential participants during recruitment that this is a pain study, and participants would experience painful sensations ranging from mild to transient, at which point the test will stop. Participants were informed that they could stop testing if they felt uncomfortable. All participants had the contact details of the lead researcher (MM), which they could use to contact if there were any queries or questions following their testing.

9.4.6. PPIE engagement

As discussed in **Chapter 4**, the importance of co-producing research with stakeholders, including patients and the public, is acknowledged.

During the design of this study, the research ideas were presented and discussed with individuals who have spinal pain from the clinical academic research group. These took place in research centre meetings in the Centre of Precision Rehabilitation for Spinal Pain at the University of Birmingham in November 2021. In the research centre meeting, there was a diverse mix of members, including senior academics, students and three adults with lived experience of spinal pain. The lead researcher (MM) delivered research presentation of this study detailing the rationale, aims, objectives and proposed methods of data collection. The feedback from those with lived experience of spinal pain was positive. All three adults with

lived experience of spinal pain reported that understanding why nerve symptoms are present and if there are differences between symptoms can better support understanding. They also expressed a need for more accurate information on symptoms and why they may relate to nerve function, which the study design supported. Noteworthy, one senior researcher and two people with lived experience of spinal pain did feedback that the number of questionnaires during the somatosensory testing appointment appeared lengthy. This feedback was considered, and subsequently, the number of questionnaires was reduced.

In January 2022, the lead researcher (MM) delivered a further research presentation of the study progress to the same research centre at the University of Birmingham. In particular, the progress of participant recruitment. The feedback provided by one senior researcher and one person with lived experience of spinal pain suggested whether financial incentives could be considered to complete the testing and whether the testing could be completed at an alternative testing site. The financial incentives option is further discussed in **sub-section 9.14.1.** The additional opening of a testing site was then subsequently explored and subsequently agreed upon with Ascenti, the lead researcher's (MM) supervision team and the Bannister Laboratory research team at King's College London.

9.4.7. Inclusion and exclusion criteria

The inclusion criteria used the adapted CSR classification criteria adopted in the systematic reviews published from **Chapters 2 and 3**. The exclusion criteria justification has been discussed and justified in **Chapters 2 and 3**.

Potential participants were able continue their usual medication, which may include paracetamol, non-steroidal anti-inflammatory medication, NeP medication (anti-convulsants and anti-depressives) and/or opiates. Participants were recruited if they satisfied the following inclusion/exclusion criteria (**Table 9.1**):

Table 9.11. Inclusion and exclusion criteria

Cervical spine radiculopathy group	
Inclusion criteria	People aged 18-70 years. Able to provide informed consent. Idiopathic neck pain and arm pain/paraesthesia distribution consistent with radicular distributions lasting one week or more. Pain intensity more than two on a numeric pain rating scale.
Exclusion criteria	History of neck trauma, known spinal bony lesion or cervical spine orthopaedic surgery. Upper motor neurone neurological condition or diseases (such as Multiple Sclerosis, Stroke, Parkinson's Disease). Clinically significant or unstable medical, metabolic or psychological conditions. History of lumbar surgery and/or 'sciatica' or other musculoskeletal disorders that potentially might affect the sensation in the foot. Insufficient level of English. Ongoing medico-legal claim(s) related to their symptoms. Currently receiving any NHS treatment for their neck and arm symptoms. Known dermatological condition impacting skin integrity at the neck, forearm, hand and/or calf sites.
Healthy asymptomatic volunteers	
Inclusion criteria	People aged 18-70 years. Able to provide informed consent. No neck pain and/or associated upper limb pain/paraesthesia in the previous seven days before testing day.
Exclusion criteria	History of neck trauma, known spinal bony lesion or cervical spine orthopaedic surgery.

	Upper motor neurone neurological condition or diseases (such as Multiple Sclerosis, Stroke, Parkinson's Disease). Clinically significant or unstable medical, metabolic or psychological conditions. History of lumbar surgery and/or 'sciatica' or other musculoskeletal disorders that potentially might affect the sensation in the foot. Insufficient level of English. Ongoing medico-legal claim(s) related to any symptoms. Known dermatological condition impacting skin integrity at the neck, forearm, hand and/or calf sites.

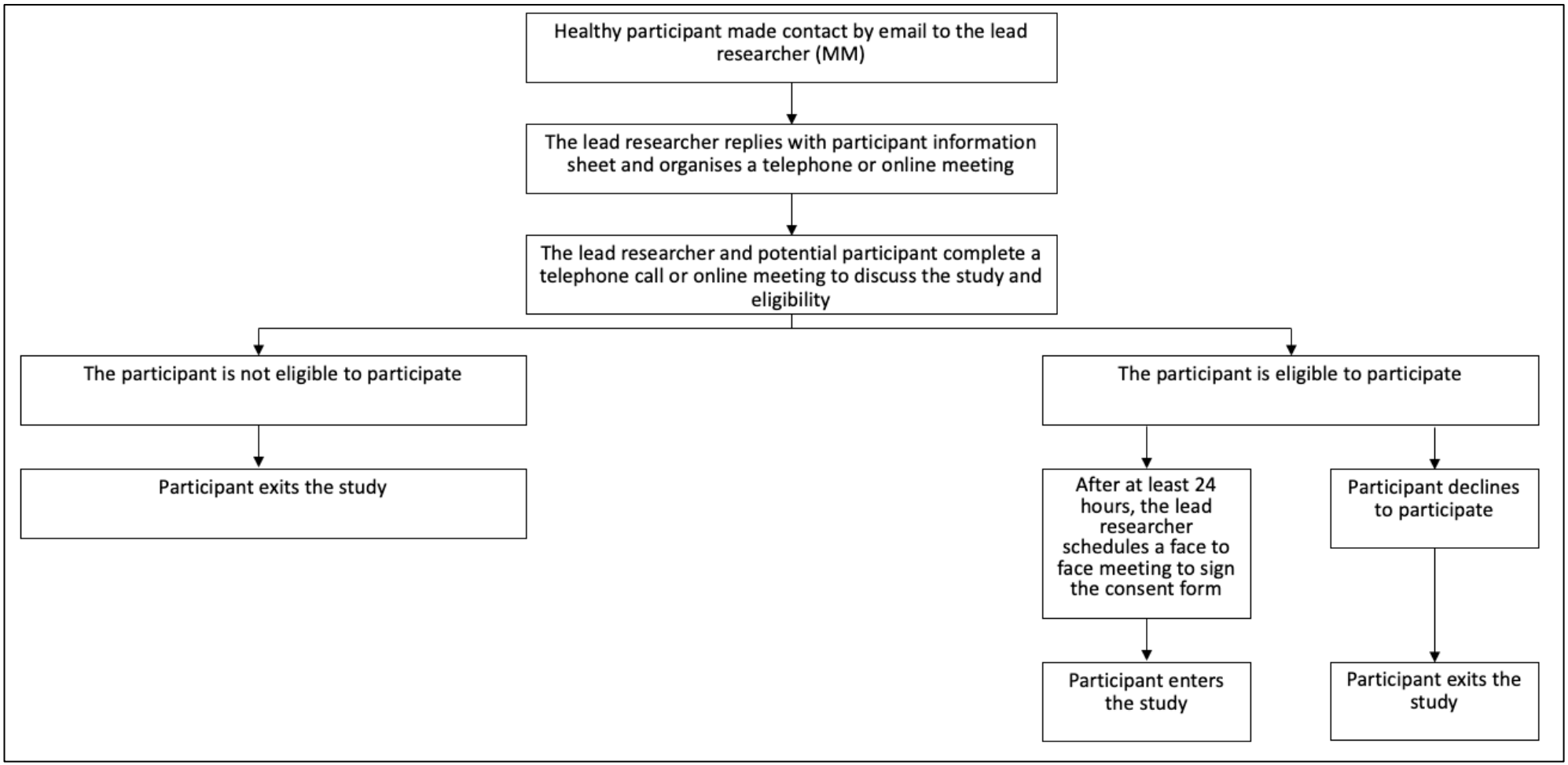
9.5. Recruitment and consent process

9.5.1. Healthy controls

The healthy control recruitment process is presented in **Figure 9.1**. Participants were recruited from the University of Birmingham student and staff network. Study adverts were placed in communal areas in the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, and an identical soft-copy advertisement was disseminated using the University's intranet research advertisement system (**Appendix 9.4**). Potential participants contacted the lead researcher (MM) for an initial telephone meeting. In this meeting, lasting approximately 15 minutes, the lead researcher (MM) screened for eligibility (using the aforementioned inclusion criteria), provided further detail on the research project and ensured participants understood and were willing to participate in the research project. All potential participants that were telephoned were alone and the lead researcher (MM) confirmed that they were in a place where they were able to talk and listen about the research study. The telephone call was completed between the hours of 8am-6pm, Monday to Friday using a University of Birmingham landline telephone. The detail of the telephone screening process is presented in **Appendix**

9.5. Each participant was given a minimum of 24 hours to consider all information, request clarification via email, phone, or in person and to consult others if necessary. After making the decision to participate in the study, participants were invited to meet the lead researcher (MM) in person. At the meeting, the lead researcher (MM) explained precisely what participating in the study entailed and the participant would then be asked to sign a consent form if they wished to enrol onto the study.

Figure 9.1 Healthy control recruitment process



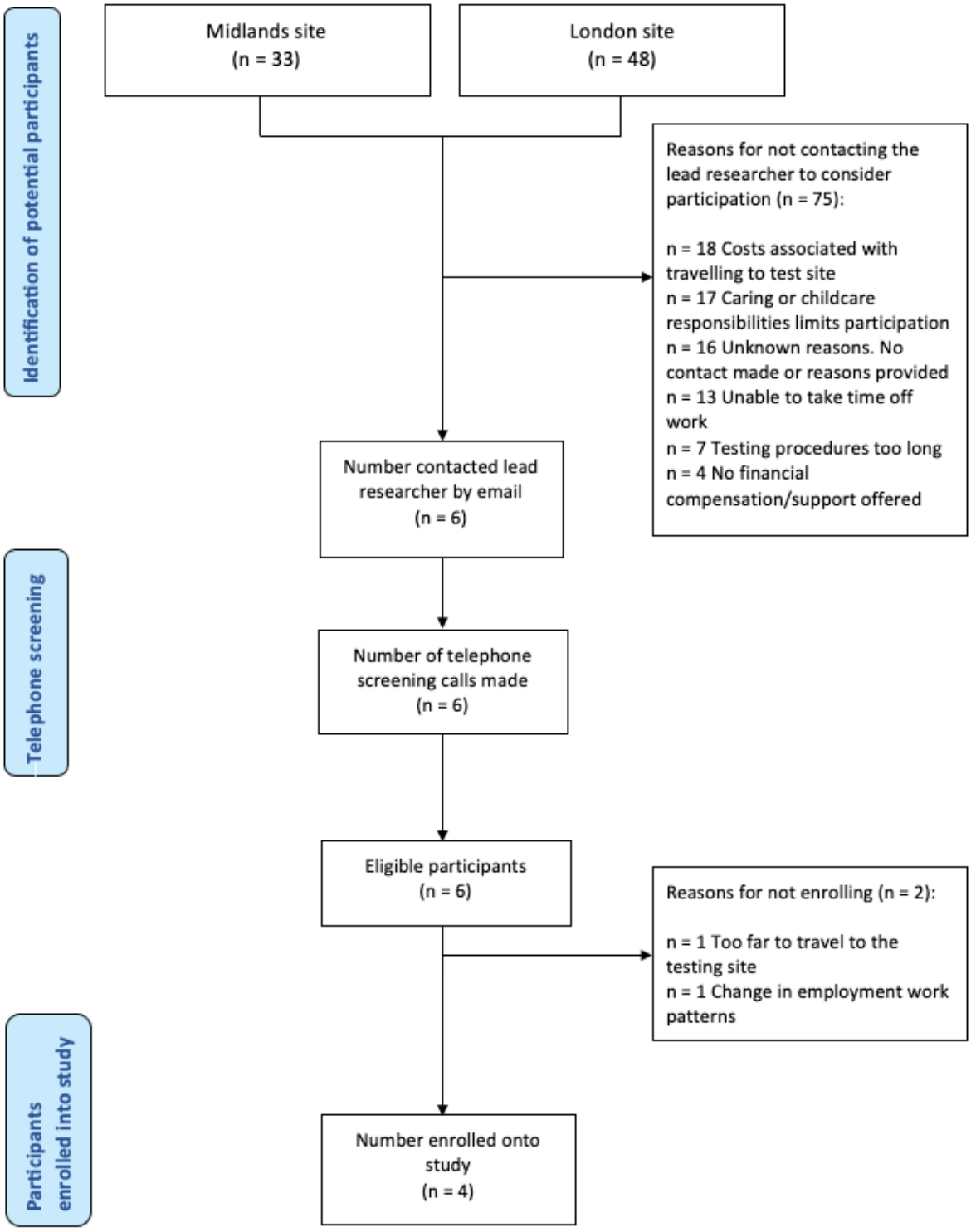
9.6. People with cervical spine radiculopathy

9.6.1. Screening

Potential participants were identified through Ascenti clinical practice. Ascenti is a registered United Kingdom healthcare provider (Ascenti Registered Number 04530716 and 03225768, England and Wales). People with CSR were first recruited from the West Midlands area by Ascenti. Recruitment was then expanded to Ascenti London after opening the West Midlands site. The Ascenti West Midlands area network had five musculoskeletal physiotherapy clinics, which operated from 07:30 to 18:00 Monday to Friday. The Ascenti London area network had eight musculoskeletal physiotherapy clinics, which operated from 07.30 to 18:00 Monday to Saturday.

Ascenti physiotherapy teams were provided with study adverts and participant information documents. If Ascenti physiotherapists perceived a participant may be suitable to take part, these two documents were provided to the prospective participant. The possible participant would read the participant information sheet (PIS) (**Appendix 9.6 and 9.7**) and make contact by email to the lead researcher (MM) to arrange an initial telephone meeting. At this telephone meeting, lasting approximately 15 minutes, the lead researcher (MM) provided further detail on the research project, determined eligibility (using the aforementioned inclusion criteria), and ensured that participants understood and if they were provisionally willing to participate in the research project. All potential participants that were telephoned were alone (although every participant had the opportunity to have a family member or friend present) and the lead researcher (MM) confirmed that they were in a place where they were able to talk and listen about the research study. The telephone call was completed between the hours of 8am-6pm, Monday to Friday using a University of Birmingham landline telephone. Each participant was given at least 24 hours to consider participation, ask any questions and/or consult with friends/family members as required. **Figure 9.2** details the overview of recruitment process.

Figure 9.2 Overview of recruitment process



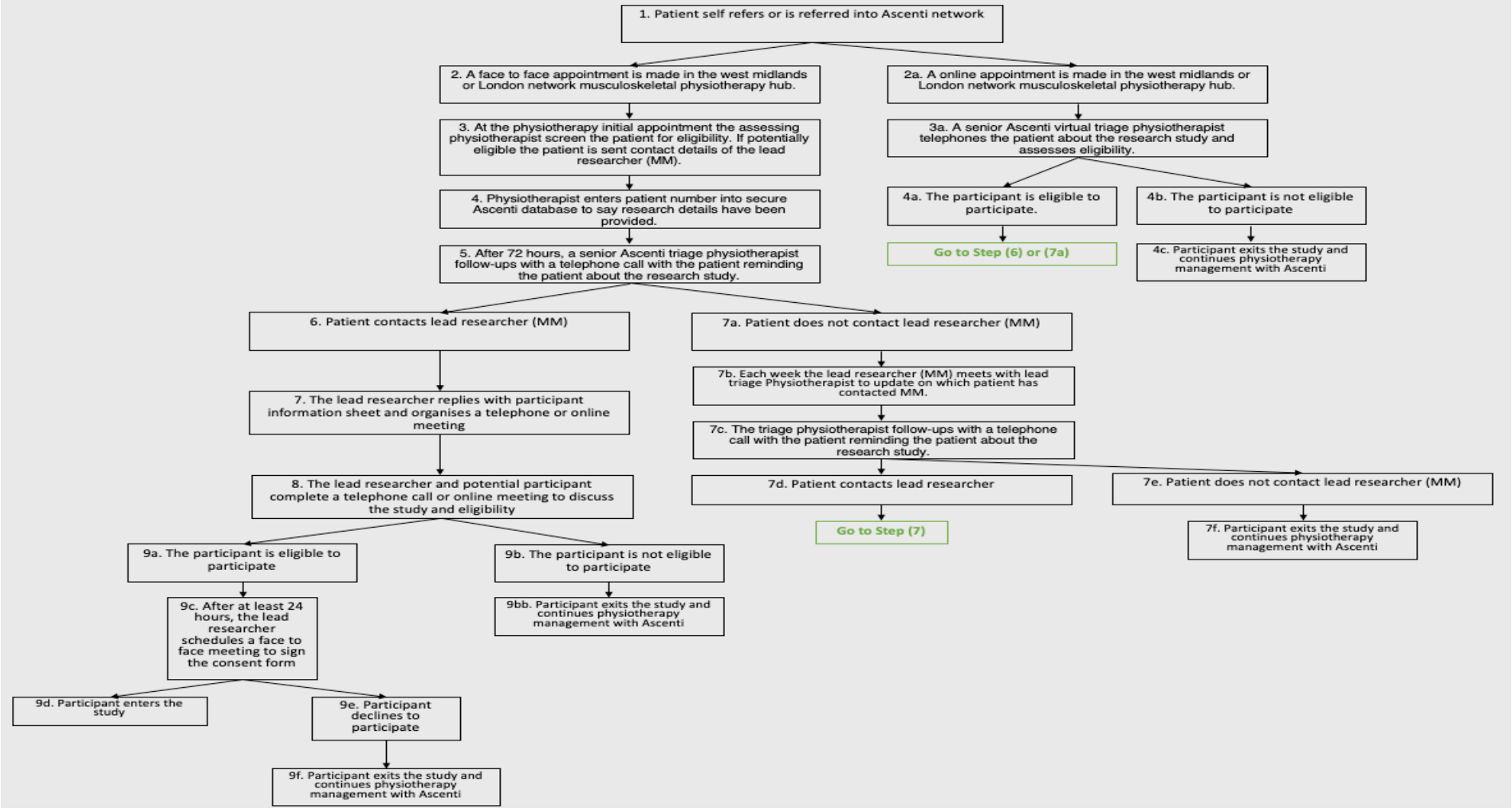
9.6.2. Consent

After making the decision to participate in the study, the participant was invited to meet the lead researcher (MM) in person. At the meeting, the lead researcher (MM) explained what participating in the study entailed, and the participant, if they wished to enrol, would then be asked to sign a consent form (**Appendix 9.8 and 9.9**).

9.6.3. Data collection

The participant recruitment process is presented in **Figure 9.3**. The study recruitment was open for 19 months (March 2022 to October 2023). There were two to five physiotherapists working at each site on each day. The physiotherapy clinics in the West Midlands and London comprised adult (18 years and over) self-referral and private medical insurance referrals with musculoskeletal spinal and peripheral joint pain and conditions. Prior to the commencement of recruitment, the lead researcher (MM) completed a site initiation visit for West Midlands and London area Ascenti staff, presenting the research project and recruitment methods.

Figure 9.3 People with cervical spine radiculopathy recruitment flowchart



9.7. Strategies to promote recruitment

Each week, the lead researcher (MM) provided an electronic bulletin notifying physiotherapists of the recruitment rates and study adverts. Furthermore, the lead researcher held bi-monthly 'drop-in' sessions for West Midlands and London Ascenti physiotherapists to discuss any queries or questions about the study. The study was also advertised as part of the weekly operational team meetings across the West Midlands and London clinical sites. Paper adverts were placed in each waiting area across the clinical sites.

For the remaining six months of participant recruitment, in consultation with the Ascenti national physiotherapy lead, a dedicated Ascenti physiotherapist was allocated 12 hours a week to act as Ascenti recruitment lead (AS) across the London area. AS held an existing role as a senior physiotherapist and clinical mentor supporting physiotherapists across London. In the role of Ascenti research recruitment lead, AS reviewed the diagnosis classification of each patient contact in the Ascenti clinical notes system. When a diagnosis classification was likely to meet the inclusion criteria for this research study, AS contacted the physiotherapists with the study advert and PIS and recommended forwarding them to the patient under care. If this had been completed already, AS would contact the patient by telephone on one occasion to determine whether the patient would consider contacting the lead researcher (MM) and participate in the study.

9.7.1. Questionnaires

9.7.1.1. painDETECT

Enrolled participants completed the painDETECT tool (Freynhagen et al., 2006), a questionnaire designed to predict whether patients' persistent pain states were likely to have a predominantly peripheral aetiology or may involve a 'neuropathic' component (Freynhagen et al., 2006b). It is important to note that this does not imply that they are patients with a clearly identifiable nerve root lesion, according to conventional diagnostic triaging paradigms. Rather, these are patients who demonstrate a significant neuropathic component to their pain, irrespective of their lesion or pathological status. The principal reason for this decision was that we

sought to classify people with a significant neuropathic component to their pain as CSR, rather than people with specific nerve root or stenotic presentations that correspond to conventional CSR triaging protocols. The painDETECT questionnaire is specifically designed to identify this cohort of people, who present with an occult neuropathic component that may not be identified by examining clinicians (Freynhagen et al., 2006). Furthermore, in a research context, use of the painDETECT questionnaire has the value of standardising the identification of patient groups (Freynhagen et al., 2006). While acknowledging the limitations of the painDETECT questionnaire, use of the questionnaire allows a consistent approach to all participants and allows comparison across studies using an objective measure. There are no reported minimal clinically important difference (MCID) figures for painDETECT (Cappelleri et al., 2017).

9.7.1.2. McGill pain questionnaire

Participants completed the McGill pain questionnaire (MPQ) (Melzack, 1987) to assess the quality of their pain. The questionnaire consists of 15 elements created to evaluate multiple aspects of pain, including sensory-discriminative, affective-motivational, and cognitive-evaluative dimensions. The MPQ uses 20 sets of verbal descriptors that are ordered by intensity to assess the sensory (10 sets), affective (five sets), evaluative (one set), and miscellaneous (four sets) dimensions of pain (Melzack, 1987). Patients select the words that describe their pain, and these words are converted into a pain rating index by assigning them a rank value and then totalling the number of words chosen. The MCID is 2.3 points in a population who had received spinal cord stimulation for chronic low back pain (Sabourin et al., 2021). The internal consistency of the MPQ has been examined, and significant correlations ($P \geq 0.89$) were found between the pain rating index, the number of words chosen, and the present pain index (Strand et al., 2008). However, only fair to moderate test-retest reliability (Kappa 0.70) was determined (Strand et al., 2008). The MPQ has been widely used in adult chronic pain populations, including CLBP (Ruoff et al., 2003). It also has modest predictability in the discrimination of NeP and musculoskeletal pain in spinal cord injury (Jumbo et al., 2021).

9.7.1.3. Neck Disability Index

The Neck Disability Index (NDI) (Vernon and Mior, 1991) was used to evaluate participants with CSR neck disability perception. The NDI was created to measure the activities of daily living (ADL) in patients with neck pain. It comprises 10 items with six response categories, with scores ranging from zero to five and a total score range of 0 to 50 (Vernon and Mior, 1991). According to a systematic review that evaluated the measurement properties of the original versions of neck-specific questionnaires, the NDI has a Cronbach α of 0.87 to 0.92 (Schellingerhout et al., 2012), suggesting very good reliability.

9.7.1.4. State-Trait Anxiety Inventory

The State-Trait Anxiety Inventory (STAI) is a questionnaire consisting of 40 Likert scale questions designed to measure anxiety symptoms and differentiate them from depressive syndromes (Spielberger et al., 1971). The questionnaire is divided into two sections: state anxiety and trait anxiety. The state anxiety section consists of 20 items that assess the intensity of feelings at the current moment. Respondents are required to choose one of the four possible responses, ranging from ‘not at all’ to ‘very much so’. The trait anxiety section also comprises 20 items that assess general feelings. Respondents choose among the following four options: ‘almost never’, ‘sometimes’, ‘often’, or ‘almost always’. The scores of the items are summed to obtain subtest total scores, ranging from 20 to 80 for each subtest. A higher score indicates higher levels of anxiety. The STAI has an MCID of 10 points in healthy adults increasing physical activity levels (Corsaletti et al., 2014). The questionnaire has high internal consistency (Cronbach’s α=0.95) and validity (r=0.85). Researchers have used the STAI to evaluate anxiety in patients with chronic pain (Newcomer et al., 2010). It has also been shown that the questionnaire can differentiate between individuals diagnosed with an anxiety disorder and nonclinical controls (Curtiss and Klemanski, 2015).

9.7.1.5. Short Form-36

The Short Form 36 (SF-36) is a health questionnaire comprising 36 questions (Ware and Sherbourne, 1992). It evaluates general health over the last four weeks across

eight domains, including physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Each domain has a score range of zero to 100, where higher scores indicate better self-reported health (Ware and Sherbourne, 1992). By combining the eight domains, two summary scores – the physical component summary and the mental component summary (MCS) – are calculated using weighted aggregates of all eight domains of the SF-36 (Ware et al., 1996). The MCID of the SF-36 is four points in adults with musculoskeletal neck pain (Jayadevappa et al., 2017). A higher score in PCS or MCS suggests better self-reported health (Ware et al., 1996). Brazier et al., (1992) reported that, from 80 healthy people aged 16 to 74 years, the reliability of the SF-36 was 0.75 (Cronbach's alpha), suggesting good reliability.

9.8. Quantitative sensory testing procedure

Participants were tested with a standardised battery of tests to determine their baseline sensory profile. The standardised QST protocol of tests measuring 13 sensory parameters was established by the DFNS (Rolke et al., 2006), which has been discussed in **Chapter 1**.

The protocol tests detection and pain thresholds for specific thermal and mechanical stimuli were carried out, providing a complete sensory profile for one skin region within 70 minutes, while each participant was seated in a comfortable chair. Participants first received instructions; the tests were then practised on the contralateral hand's dorsal aspect. All QST testing was conducted on the ipsilateral volar forearm, with the exception of vibration detection threshold (VDT), which was tested at the base of the ulna styloid and pressure pain threshold (PPT) was tested at the thenar eminence. A standardised script was followed throughout the testing (**Appendix 9.10**). Test results were manually recorded on the DFNS QST Documentation Form (**Appendix 9.11**).

Thermal (cool/warm) and mechanical (tactile/vibration) detection thresholds assess small and large nerve fibre function, as discussed in **Chapter 1**. Thermal detection thresholds were tested using a computerised machine (TSA-II NeuroSensory Analyser, Medoc) that circulates both warm and cool water through a 3.2 cm^2 thermode, which is secured against the forearm by a fabric-covered Velcro strap.

Thermal thresholds were tested using a baseline temperature of 32°C and ramping at 1°C/second. The participant pressed a STOP button when they felt a change in the temperature above or below the starting temperature of 32°C. This stops the heating/cooling of the thermode; therefore, the participant is in full control of the computer program and can terminate the heating/cooling of the thermode at any point. Measures were repeated three times and means calculated. The mean cold and warm detection threshold is expressed as the degrees plus or minus from 32°C; cold and heat pain detection mean is expressed as the mean raw score. Cut-offs of 5°C and 50°C were used for all thermal tests.

Cold and heat pain thresholds were assessed using the same methods as described for cool/warm thermal detection; however, the temperature increases from the baseline of 32°C to a maximum temperature of 50°C, and decreases from baseline temperature to a minimum of 0°C. The temperature increased and decreased in increments of 1°C/second and the participant pressed a STOP button to stop the programme at the point when the temperature first began to feel painful.

Mechanical Detection Threshold (MDT) (**Figure 9.4**) using glass von Frey filaments (Optihair2-Set, Marstock Nervtest, Germany) was assessed. These monofilaments apply forces when bent ranging from 0.25 to 512mN and were applied for 1 to 2 seconds. To determine the threshold, a method of limits where the alternation between increasing and decreasing stimuli was used, and which calculated the geometric mean from the five thresholds obtained.

Figure 9.4 Mechanical Detection Threshold (MDT) von Frey filaments



Mechanical pain threshold (MPT) (**Figure 9.5**) was assessed by pain response to punctate stimuli (i.e., pricking) using specialised, weighted pinprick stimulators ranging from eight to 512mN (pinprick stimulator, MRC, Heidelberg, Germany). Probes with forces ranging from eight to 512 mN were applied in an alternating ascending and descending order. The geometric mean of five detections of sharpness was calculated. The stimulators are blunt-ended and do not penetrate the skin; however, they cause a pricking sensation via activation of A-fibre nociceptors. This was followed by a test of MPS using the same pinprick stimulators and included the assessment of dynamic mechanical allodynia (DML) using a cotton wisp, a Q-Tip and a standardised brush (Somedic, Sweden). Participants were asked to rate the painfulness of each stimulus on a zero to100 numerical rating

scale, with zero indicating no pain and 100 the most intense pain imaginable. Fifty stimuli were applied (35 pinprick; 15 tactile) in a pre-randomised order. Mechanical pain sensitivity was calculated as the geometric mean of the pain ratings for pinprick stimuli.

Figure 9.5 Mechanical Pain Threshold (MPT) pinprick stimuli



To evaluate the wind-up ratio, a single stimulus application was used with a 256mN pinprick stimulator probe. The test involved applying a series of 10 identical pinprick stimuli in the same skin area at intervals of 10 seconds. Participants were asked to rate the intensity of the stimulation using a numeric rating scale zero to 100 immediately after the single stimulation, and again after the series of 10 stimuli. The test was repeated five times, and the wind-up ratio was calculated as the ratio of the mean rating of the five repeated stimuli divided by the mean rating of the five single stimuli. If the single stimulus with the 256mN was rated as zero or non-painful, the testing proceeded with the 512mN stimulator. However, if the 512mN stimulator was also rated as zero, the wind-up ratio could not be calculated.

During the assessment of VDT, a Rydel-Seiffer graded tuning fork (**Figure 9.6**) with a frequency of 64Hz was used. The tuning fork has calibrated weights on its distal arms imprinted with a nine-point scale ranging from zero to eight, and a triangle

shape beside the scale. After striking and vibrating, the tuning fork produces a triangle on each arm that appears as two virtual intersecting triangles. The intersection moves up the nine-point scale with decreasing vibration amplitude of the arms. The vibration detection threshold is recorded as the nearest value to the closest half-point of the intersection of the triangles when the participant can no longer sense vibration. Testing was repeated three times, and the mean disappearance threshold was calculated.

Figure 9.6 Vibration Detection Threshold (VDT) tuning fork



Pressure pain threshold (PPT) was the last test to be performed. It was completed at the thenar eminence with a pressure algometer (FDN100, Wagner Instruments, Greenwich CT, USA) (**Figure 9.7**). The algometer has a surface area of 1cm^2 and pressure was applied at a rate of 1kg/cm^2 per second. PPT was measured with three ascending intensities and the arithmetic mean calculated.

Figure 9.7 Pressure Pain Threshold (PPT) pressure algometer

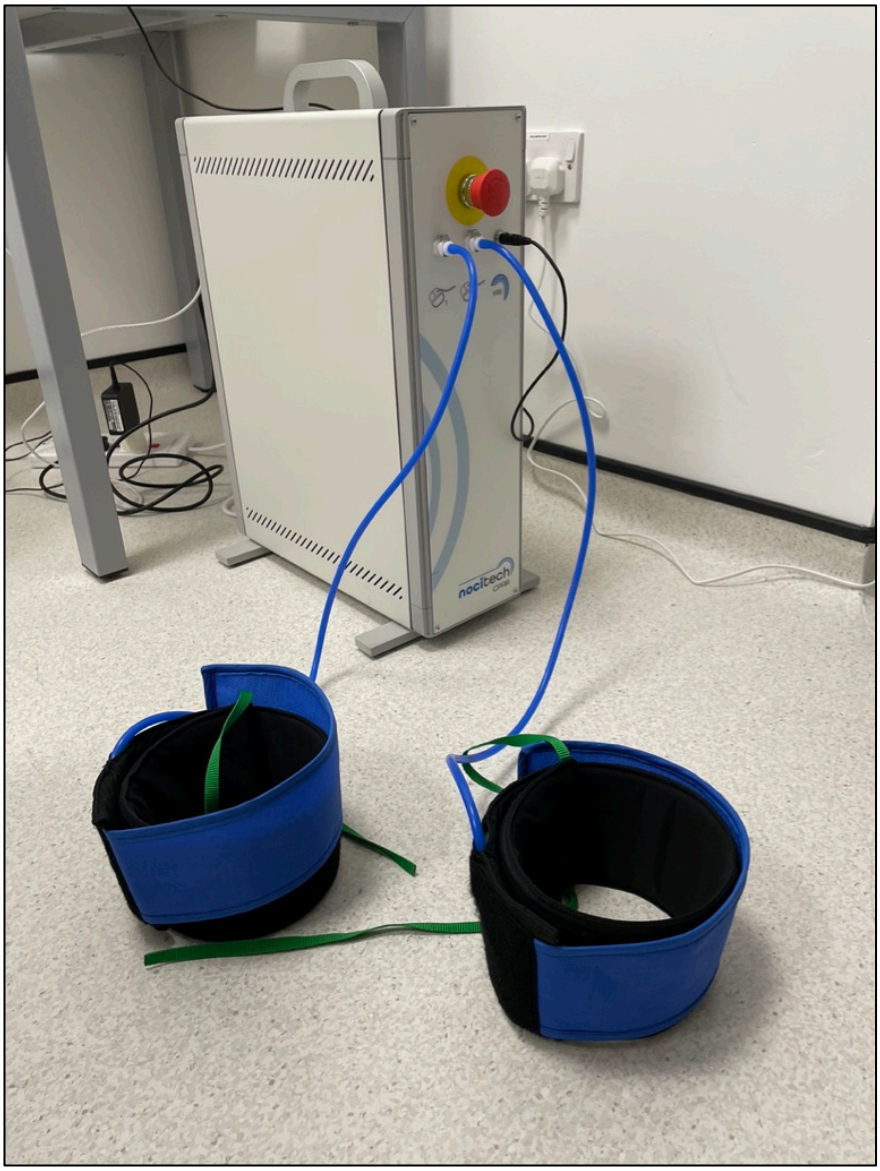


9.9. Conditioned pain modulation

9.9.1. Measure 1

Computer-controlled cuff algometry was used as a tool for measuring CPM (**Figure 9.8**). This set-up uses two inflatable pressure cuffs (similar to those used to measure blood pressure) that are secured around the biceps muscle of the upper arms and then inflated at a computer-controlled steady rate using compressed air.

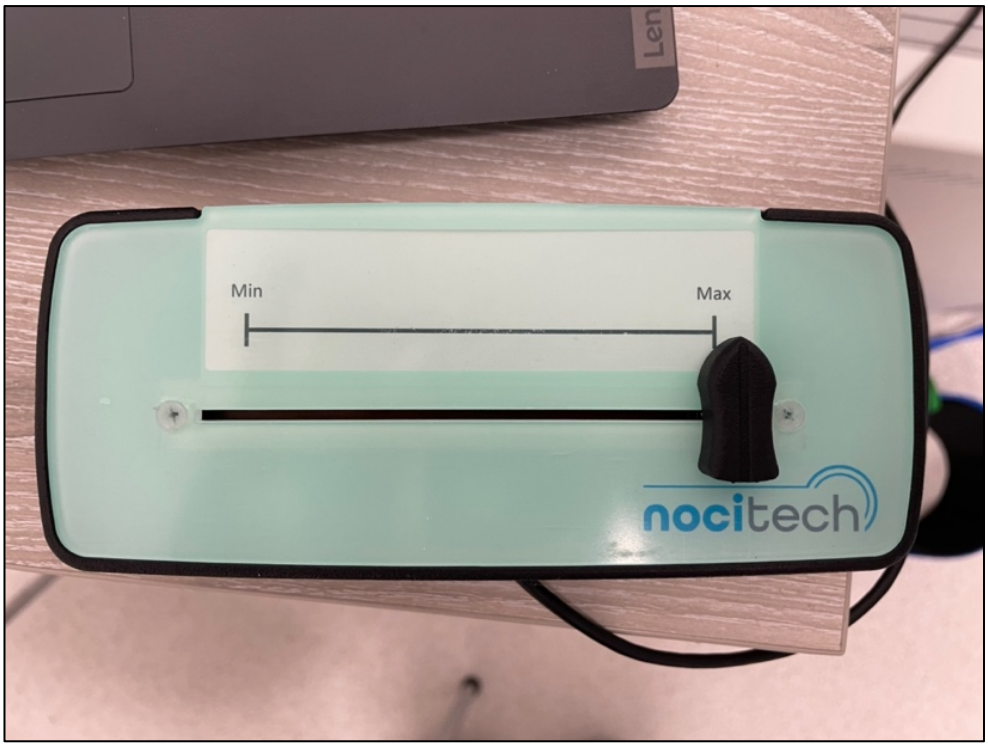
Figure 9.8 Conditioned pain modulation (CPM) cuff algometry



Participants were positioned in long sitting on a medical couch at a slight incline (pillows were provided: one for the head and the other to place under the knees); one cuff was secured around the biceps upper arm region, and the other cuff secured in either of the contralateral body sites. Cuffs were secured over clothing. Participants first had their baseline pressure pain detection threshold (PDT) and PPT assessment on their dominant upper arm. To do this, the participant rated PPT (defined as the first sensation of pain identified as the point at which the participant began to use/slide the bar along the visual analogue scale (VAS)) and pain tolerance (defined as the point the participant no longer wants inflation of the cuff to continue). The VAS device has a STOP button, which the participant presses to immediately deflate the cuff during the pressure pain tolerance assessment).

The VAS device (**Figure 9.9**) is a psychometric response scale measuring subjective characteristics or attitudes that cannot be directly measured. Participants reported pain levels by moving a sliding button along a continuous line between two endpoints (0 = no pain to 10 = worst pain imaginable). The position of the slider corresponds to their pain level. In the case of the PPT test, the cuff inflation is terminated when it is no longer tolerable; importantly, however, this does not correspond to a VAS=10, as tolerance is determined more by affective and/or motivational components than pure pain response. The PPT test is a tolerance test (when the sensation first becomes intolerable). It is not an endurance test (i.e., how long the participant can endure an intolerable sensation). It was clearly explained to the participants that they must stop the test at the first point they can no longer tolerate the sensation.

Figure 9.9 Conditioned pain modulation (CPM) cuff algometry visual analogue score slider



9.9.2. Measure 2

Following the temporal summation protocol, participants had a second baseline measure on the non-dominant arm. This procedure is identical to that described above (i.e., measure 1).

9.9.3. Measure 3

Having acquired data from measures 1 and 2 (PDT and PPT) on each arm, participants are then ready for the CPM assessment (measure 3). The CPM paradigm required two noxious stimuli, namely a test stimulus and a conditioning stimulus. For CPM assessment using cuff algometry, two cuffs were used: one cuff was used as the test stimulus, the other cuff was used as the conditioning stimulus. The conditioning cuff (non-dominant arm) was inflated to 70% of the participant's pressure pain tolerance level for 100 seconds; after 15 seconds, the test stimulus cuff (dominant arm) was steadily inflated at a rate of 1 kPa/sec. The participant's PPT and pressure pain tolerance was reassessed (the participant slid the VAS bar at the first sensation of pain and slid it until their tolerance level was met and they pressed the STOP button to deflate the test stimulus cuff). If pain modulation was achieved, the participant showed an increased threshold and tolerance levels during inflation of the test stimulus during conditioning. The CPM-effect is defined as the difference between baseline and conditioning measurements of both PPT and pressure pain tolerance.

9.10. Statistical analysis – healthy control participants

All continuous data were planned to be tested for normality of distribution. Quantitative sensory testing data were log transformed to achieve normal distribution and expressed as z-scores using the data of the healthy participants matched for each measurement site [z-score = Valuepatient – _Meancontrol/Standard deviationcontrol] (Rolke et al., 2006). Z-scores above 0 were interpreted as gain of function and thus increased sensitivity, whereas values below zero represent loss of function and decreased sensitivity. Data were analysed with the Statistical Package for Social Sciences (SPSS Version 25.0) for MacOS X 10.5.8. Quantitative sensory testing data were first entered onto an Excel

spreadsheet provided by DFNS, which automatically generated thresholds and average ratings, as well as numbers of observed paradoxical heat sensations. Mean and standard deviation (SD) was calculated for the physical and mental health questionnaire measures.

9.11. Statistical analysis – people with cervical spine radiculopathy

Participant characteristics and distribution of symptom severity measures were summarised using descriptive statistics. The raw data from the physical and mental health questionnaire measures, QST and CPM testing was presented. The median and interquartile ranges for the four people with CSR were presented for each questionnaire and somatosensory testing modality.

9.12. Results

9.12.1. Healthy control characteristics

Table 9.2 presents the healthy control volunteer demographics. There were 25 healthy control volunteers (female number: 13) with a mean age of 35 years (SD: 9.89).

Table 9.22 Healthy control demographics and quantitative sensory testing data

Demographics					
Number	25				
Females, n (%)	13 (52)				
Age, Years (SD)	35 (9.89)				
Quantitative sensory testing					
	Mean (SD) Raw data	**Mean (SD) Log data**	**Z-Score (95%CI)**	**Skewness/Kurtosis Raw data**	**Skewness/Kurtosis Log data**
Cold Detection Threshold, ^{O}C	-1.4 (1.12)	0.31 (0.44)	1.4211e-16 (-0.41, 0.41)	-0.69/-0.19	-0.99/0.44
Warm Detection Threshold, ^{O}C	1.92 (0.55)	0.27 (0.13)	2.3245e-16 (-2.21, 1.47)	0.16/-0.66	-0.45/-0.32
Thermal Sensory Limen, ^{O}C	-0.07 (2.08)	0.99 (0.1)	1.6584e-15 (-2.31, 2.22)	0.31/1.71	-0.57/1.0
Cold Pain Threshold, ^{O}C	1.01 (5.66)	N/A	2.4286e-17 (-1.77, 2.44)	0.21/0.5	N/A
Heat Pain Threshold, ^{O}C	43.76 (3.3)	N/A	1.05252e-15 (-2.08, 1.87)	-0.03/0.1	N/A
Paradoxical Heat Sensation, x3	3	N/A	N/A	N/A	N/A
Mechanical Detection Threshold, mN	6.49 (1.43)	0.8 (0.1)	1.1102e-16 (-1.85, 1.52)	0.03/-1.05	-0.34/-1.01
Mechanical Pain Threshold, mN	50.78 (24.26)	1.65 (0.25)	1.0686e-15 (-2.26, 1.24)	0.21/-0.84	-0.84/0.17
Mechanical Pain Sensitivity, 0 to 100 mm	5.73 (9.94)	0.33 (0.68)	-3.1225e-17 (-2.2, 2.01)	3.8/16.45	-0.38/0.18
Dynamic Mechanical Allodynia, 0 to 100 mm	0 (0)	N/A	N/A	N/A	N/A
Wind Up Ratio, Ratio	2.92 (1.31)	0.43 (0.19)	3.2353e-16 (-1.59, 1.83)	0.94/-0.08	0.33/-0.91
Vibration Detection Threshold, x8	7.96 (0.21)	0.9 (0.01)	-9.2079e-15 (-4.8, 0.2)	-5.0/25.0	-5.0/25.0
Pressure Pain Threshold, kPa	480.04 (84.85)	2.67 (0.08)	-8.2434e-15 (-2.43, 1.92)	0.05/0.21	-0.49/0.42

Table abbreviations: kPa: Kilopascal; mm: Millimetre; mN: Millinewton; N/A: not applicable; n: Number; ^{O}C: degrees centigrade; SD: Standard Deviation.

Table 9.3 presents the physical functioning, role limitations related to physical or emotional health. The SF-36 scores for each domain (or dimensions) range from zero (worst health) and 100 (best health). None of the healthy control group reported pain symptoms or role limitations to physical health domains. The remaining domains including physical health, energy, emotional well-being, social functioning and general health domains had mean scores above 81%. **Table 9.3** presents the state and trait anxiety mean scoring for healthy control group. The state and trait anxiety mean scores were above 45, suggesting ‘high anxiety’.

Table 9.33 Mean (SD) of physical and mental health measures from the healthy control group (n=25)

			Skewness/Kurtosis
Short-Form 36			
Physical functioning, % (SD)	91.20 (5.82)		-0.51/1.93
Role limitations due to physical health, % (SD)	100 (0)		N/A
Role limitations due to emotional problems, % (SD)	92.00 (14.53)		-1.30/-0.35
Energy/fatigue, % (SD)	83.80 (11.75)		0.59/-1.44
Emotional well-being, % (SD)	81.44 (7.11)		-0.50/-0.38
Social functioning, % (SD)	83.00 (12.44)		-0.84/-0.47
Pain, % (SD)	100 (0)		N/A
General health, % (SD)	95.75 (5.63)		-0.71/-1.42
State-Trait Anxiety Inventory (STAI)			
Anxiety – State, n (SD)	49.48 (4.15)		0.04/-1.06
Anxiety – Trait, n (SD)	45.24 (5.0)		1.12/0.37

Table abbreviations. n: Number; SD: Standard Deviation

Table 9.2 presents the QST raw data, log transformed and z-scores for the healthy control group. Mean cold detection threshold was -1.4°C (SD: 1.12), warm detection threshold 1.92°C (SD: 0.55), thermal sensory limen -0.07°C (SD: 2.08), mechanical detection threshold 6.49mN (SD: 1.43), and vibration detection threshold 7.96 out of 8.00 (SD: 0.21). Cold pain threshold was 1.01°C, heat pain threshold 43.76°C (SD: 3.3), mechanical pain threshold 50.78mN (SD: 24.76), mechanical pain sensitivity 5.73mm (SD: 9.94), wind-up ratio 2.92mm (SD: 1.31) and pressure pain threshold 480.04mN (SD: 84.85).

Table 9.4 presents the conditioned pain modulation mean values for the healthy control group. The mean percentage (%) of change for PDT, pain tolerance threshold and VAS was 27.69 (SD: 17.18), 19.02 (SD: 14.65) and 8.13 (SD: 20.03), respectively.

Table 9.44 Mean and standard deviation (SD) of conditioned pain modulation results from the healthy control group (n=25)

Conditioned Pain Modulation			
Baseline			**Skewness/Kurtosis**
Mean Pain Detection Threshold, kPa (SD)	25.22 (10.87)		0.80/0.23
Mean Pain Tolerance Threshold, kPa (SD)	55.52 (17.15)		0.24/-1.34
Mean Visual Analogue Scale, 0 to 100 mm (SD)	68.40 (15.99)		-2.04/6.5
Conditioned			
Mean Pain Detection Threshold, kPa (SD)	35.60 (13.75)		0.25/-0.27
Mean Pain Tolerance Threshold, kPa (SD)	69.03 (13.75)		-0.39/-0.56
Mean Visual Analogue Scale, 0 to 100 mm (SD)	74.40 (11.93)		-0.81/0.17
Difference between baseline and conditioned			
Mean Pain Detection Threshold, % of change (SD)	27.69 (17.18)		0.51/-0.14
Mean Pain Tolerance Threshold, % of change (SD)	19.02 (14.65)		0.59/0.36
Mean Visual Analogue Scale, % of change (SD)	8.13 (20.03)		1.73/6.17

Table abbreviations. kPa: Kilopascal; mm: Millimetre; SD: Standard Deviation

9.13. Cervical spine radiculopathy group characteristics

Table 9.5 presents those people with CSR demographics and QST data. There were four people with CSR healthy control volunteers (one male and three female) with a mean age of 41 years (SD: 3.87). All four people with CSR were right-hand dominant and their maximum pain area was in their right forearm region. All four people had a definite CSR diagnosis classification (Mansfield et al., 2021) with sensory changes in a dermatomal distribution, unilateral diminished biceps tendon reflex, and weakness in elbow flexion. **Table 9.6** presents the conditioned pain modulation values for the four people with CSR. All four people with CSR presented with a percentage increase in PDT and PTT with a conditioning stimulus. Three people reported an increase in VAS with a conditioning stimulus, and one person had no change in VAS with a conditioning stimulus.

Table 9.55 Demographics, raw values of quantitative sensory testing results, and median and interquartile ranges from four people with cervical spine radiculopathy

	Participant 1	**Participant 2**	**Participant 3**	**Participant 4**	**Median/Interquartile range**
	M	F	F	F	Male: 1 / Female: 3
	42	41	35	44	42/3.0
	Right forearm	**Right forearm**	**Right forearm**	**Right forearm**	**Right forearm: 4 (100%)**
Cold Detection Threshold, ^{O}C	-1.80	-1.23	-1.45	-2.29	-2.0/0.55
Warm Detection Threshold, ^{O}C	2.34	3.01	2.31	1.23	2.0/0.47
Thermal Sensory Limen, ^{O}C	0.77	1.53	-1.30	0.77	1.0/0.71
Cold Pain Threshold, ^{O}C	0.10	1.34	1.23	2.12	1.0/0.59
Heat Pain Threshold, ^{O}C	36.34	35.78	37.01	34.89	36.0/0.95
Paradoxical Heat Sensation, x3	3	3	3	3	N/A
Mechanical Detection Threshold, mN	21.45	22.43	22.89	19.34	22.0/0.54
Mechanical Pain Threshold, mN	24.34	23.23	25.89	26.91	25.0/1.85
Mechanical Pain Sensitivity, 0 to 100 mm	18.89	18.34	16.34	19.23	19.0/1.14
Dynamic Mechanical Allodynia, 0 to 100 mm	0.09	0.07	0.08	1.02	0.0/0.25
Wind Up Ratio, Ratio	1.39	1.27	1.01	1.78	1.0/0.28
Vibration Detection Threshold, x8	6.0	6.0	6.0	4.0	6.0/0.50
Pressure Pain Threshold, kPa	368	335	389	221	352.0/66.75

Table abbreviation. kPa: Kilopascal; mm: millimetre; mN: millinewton; N/A: not applicable; ^{O}C: degrees centigrade.

Table 9.6. Raw conditioned pain modulation data and median and interquartile ranges from four people with cervical spine radiculopathy

	Participant 1	Participant 2	Participant 3	Participant 4	Median/Interquartile range
Baseline					
Pain Detection Threshold, kPa	18.0	19.0	22.0	32.0	20.5/5.75
Pain Tolerance Threshold, kPa	24.0	26.0	28.0	36.0	27.0/4.5
Visual Analogue Scale, 0 to 100 mm	70.0	70.0	80.0	70.0	70.0/2.5
Conditioned					
Pain Detection Threshold, kPa	22.0	21.0	34.0	41.0	28.0/14.0
Pain Tolerance Threshold, kPa	43.0	34.0	32.0	47.0	38.5/10.5
Visual Analogue Scale, 0 to 100 mm	90.0	100	80.0	90.0	90.0/5.0
Difference between baseline and conditioned					
Pain Detection Threshold, % of change	18.2	9.5	35.3	22.0	20.1/9,27
Pain Tolerance Threshold, % of change	44.2	23.5	12.5	23.4	23.5/8.02
Visual Analogue Scale, % of change	22.2	30.0	0	22.2	22.2/7.5

Table abbreviations. kPa: Kilopascal; mm: Millimetre

Table 9.7 presents the SF-36, NDI, McGill Pain Questionnaire and painDETECT questionnaire scores. Across the eight SF-36 domains, percentage scores ranged from 50 to 93.75 for the four participants. Three out of four people with CSR had a McGill pain questionnaire score of above 40 and one person had a score of 37. Although there are no validated cut-off scores for the McGill Pain Questionnaire, all scores are out of a maximum score of 78; higher score indicating more severe impact of pain. Three of the four people with CSR had scores above 19 in the painDETECT questionnaire, suggesting that NeP is a likely component of their symptoms. One person with CSR had a score of 18 on the painDETECT questionnaire, which suggests that the NeP component is ambiguous, but a NeP component to their symptoms cannot be ruled out. The state and trait anxiety median scores were below 45, suggesting ‘low anxiety’ for all four people with CSR. Neck disability index scores across the four people ranged between 14 and 18, suggesting mild to moderate disability as a result of CSR.

Table 9.7 SF-36, STAI, NDI, McGill, and PainDETECT questionnaire raw data and median and interquartile ranges for the four people with cervical spine radiculopathy

	Participant 1	**Participant 2**	**Participant 3**	**Participant 4**	**Median/Interquartile range**
Short-Form 36					
Physical Functioning, %	80	60	80	60	70.0/20.0
Role limitations due to physical health, %	80	60	80	80	80.0/5.0
Role limitations due to emotional problems, %	80	100	80	100	90.0/20.0
Energy/fatigue, %	60	70	60	60	60.0/2.50
Emotional well-being, %	66	84	54	54	60.0/16.50
Social functioning, %	87.5	87.5	87.5	87.5	87.50/0.0
Pain, %	50	50	75	50	50.0/6.25
General Health, %	63.75	93.75	75.75	93.75	84.75/21.0
State-Trait Anxiety Inventory					
Anxiety – State, n	46	45	48	47	42.0/9.25
Anxiety – Trait, n	46	45	45	49	41.0/5.25
Neck Disability Index, n (%)	15 (30)	16 (32)	18 (36)	14 (28)	15.5/1.75
McGill Pain Questionnaire					
Total score, n/78	50	44	37	40	42/6.25
PainDETECT					
Final score, n	18 (Result is ambiguous, however a neuropathic pain component can be present)	19 (A neuropathic pain component is likely, >90%)	22 (A neuropathic pain component is likely, >90%)	22 (A neuropathic pain component is likely, >90%)	22.0/1.50

Table abbreviations. n: Number

9.14. Discussion

This case-control study sought to establish the somatosensory profiles of adults with painful CSR and health age-matched controls. Twenty-five healthy adults (13 female, mean age 35 years (SD: 9.89)) and four people (three female, median age 42 years (IQR: 3.0)) with CSR were recruited over a 19-month period. The QST and CPM results from the 25 healthy control groups were as expected. The mean z-score values suggested no gain or loss of function for thermal and mechanical detection and threshold parameters. The one exception to this was VDT, which had a negatively skewed distribution. This can be attributed to two reasons: firstly, one person not reaching the maximum score of eight on testing and, secondly, how this then impacts the mean score across a low number of group participants (n=25). The self-reported general health mean scores measured by SF-36 were 81 and above (out of a possible maximal score of 100), suggesting better general health across the eight domains.

Generalised anxiety disorder and depression are the two most common mental health conditions in the UK population (McCloud et al., 2023). The healthy control group presented with mean state (49.48 (SD: 4.15)) and trait (45.24 (SD: 5.0)) anxiety scores suggesting ‘high levels’ of anxiety. In 2022/23, the UK Office of National Statistics (ONS) completed a cross-sectional survey stating that a mean of 37.1% of women and 29.9% of men reported high levels of anxiety in the UK general population (ONS, 2023). This has increased from 21.8% of women and 18.3% of men reporting high levels of anxiety between 2012 to 2015 (ONS, 2023). Therefore, the self-reported anxiety from the healthy control group may be representative of the general population. Notwithstanding this, all people in the healthy control group were recruited from the University of Birmingham and were qualified physiotherapists undertaking further higher education qualifications. A longitudinal study of UK higher education students has reported that UK university students had more symptoms of common mental disorders than non-students (adjusted mean difference 0·36, 95% CI: 0·05-0·68; p=0.024) (McCloud et al., 2023). However, caution should be taken when interpreting these findings as they were taken from individuals who were less than 25 years of age. The cohort of people in this QST study had a mean age of 35 years (SD: 9.89), which limits the external validity. Nevertheless, the self-reported anxiety findings among the control group were not

unsurprising, given how common mental health conditions are among young adults in the UK.

The healthy control group had higher mean state anxiety scores compared to trait anxiety, which may be due to their anticipation of pain-related stimuli. None of the participants had any prior experience with QST or CPM and were informed in the PIS and standardised script that some of the QST parameters may induce “discomfort or pain, albeit transient”. This expectation can result in hypervigilance (Leeuw et al., 2007). A cross-sectional study has reported that people who engage with pain-related stimuli tend to report higher levels of anxiety before the commencement of pain-related tasks or stimuli (Fonteyne et al., 2009). This creates an attentional bias, as people selectively attend to pain-related stimuli (Fonteyne et al., 2009). However, in this QST study, all detection and threshold testing were within an expected level of ‘normal’ function for healthy people. Nonetheless, the STAI-State measure was completed before QST testing, which may not provide an accurate index of state anxiety during the experimental procedure (Thibodeau et al., 2013). To gain a better understanding of state anxiety during QST testing, future research may benefit from measuring it throughout the testing process and how state anxiety is linked to pain perception.

The CSR group aimed to recruit 25 people; however, only four people with CSR were recruited. As a result, the lead researcher (MM) used descriptive statistics to analyse the CSR group. This small sample size made it challenging to answer the research questions as it prevented the use of statistical modelling and estimation. Moreover, due to the inadequacy of the sample size, the study could not answer the question of how the distributions differed between the CSR experimental and the healthy control group. Additionally, this study was not powered to identify any significant differences between the groups, and any inferential statistical analysis performed would likely result in falsely negative findings, leading to a type II error. Nonetheless, there are QST case-control studies that complete inferential statistics using a student t-test or Wilcoxon’s test, based on group numbers of less than 25 participants in each group (Huet et al., 2018, Kaiserova et al., 2023, Vaughan et al., 2020). Whilst it is recognised that sample size calculations have been made to justify between-group comparisons, the effect size is often 0.8 or less, which may indicate false negative findings, and question the generalisability to the cohort studied.

9.14.1. Reflections on recruitment

9.14.1.1. Sampling approach. Eligibility criteria

Eligibility criteria are a crucial component of primary research studies. Optimal eligibility criteria are both well-selected, as they are collectively necessary and sufficient to help the study achieve its objectives and protect patients, and well-written, so that the intended meaning of each criterion is accurately and clearly communicated to everyone who needs to understand it (Treweek et al., 2013). Poorly selected or written criteria can negatively impact research quality and diminish the ability of eligibility criteria to fulfil the roles outlined above.

To address the potential negative impact, the lead researcher (MM) consulted with various stakeholders in this PhD research study, including primary supervisors, external advisors, practicing physiotherapists, and patient representatives before obtaining ethics approval. It was agreed that adults with CSR may exhibit a wide range of clinical symptoms, such as varying levels of pain, different symptom distributions, and impairments in the somatosensory nervous system. This was also in-line with the diagnostic criteria of the studies included in the systematic reviews published in **Chapters 2 and 3**. Therefore, a pragmatic decision was made to strike a balance between being restrictive and facilitating recruitment with the eligibility criteria. Furthermore, the lead researcher (MM) provided monthly seminars to the Ascenti clinical sites and used the opportunity to discuss whether any adjustments were needed to the eligibility criteria. During these discussions, clinical physiotherapists from Ascenti agreed that the criteria still accurately reflected the clinical presentation of CSR.

Nonetheless, differences in how eligibility criteria may have been interpreted at an Ascenti site level (Midlands and London) may have been present. Participant recruitment may be negatively affected if sites interpret the eligibility criteria too strictly or misinterpret them. Therefore, prior to the start of the study, the lead researcher (MM) held research study seminars with each region to clearly communicate the decisions made in defining eligibility, which could enhance transparency for recruitment sites. In hindsight, considering the low recruitment, the lead researcher (MM) and clinical leads in each Ascenti region could have tested the eligibility criteria against historical patient databases before starting the study to

understand the likely number of adults with CSR who meet the eligibility criteria. This may have enhanced the understanding of whether any further adjustments were needed to improve recruitment. Additionally, having a dedicated Ascenti research manager throughout the length of the research study may have improved recruitment by providing internal site training, coordinating advertisements, and ensuring clinicians are comfortable with applying the eligibility criteria when identifying potential individuals with CSR. However, this was not possible due to service restrictions on releasing staff from core activities.

9.14.1.2. Sampling approach. Opening an additional recruitment site

Recruiting participants for research studies is often a critical challenge for researchers. Almost 20% of studies either fail to recruit the required number of participants or have fewer participants than required (Briel et al., 2016). These issues can negatively impact on the generalisability of findings, increase the research costs and lead to delays in discovering solutions for important health problems (Briel et al., 2016). As a result of the actual recruitment rates across the West Midlands area, the lead researcher (MM), in consultation with the PhD supervisory team (TS, SJ) and Ascenti national physiotherapy lead, agreed that an additional site would be opened in central London. Personal communication from the Ascenti area managers stated that approximately 750 patient contacts were made on average each week across the Midlands sites and 1,100 patient contacts across the London sites during the recruitment window. The lead researcher (MM), in consultation with Ascenti and the supervision team, made the decision to open a second recruitment site. It was anticipated that utilising this known patient flow and maximising recruitment, opening multiple recruiter sites would have enhanced participant recruitment.

Having multiple sites for recruitment is suggested to be a positive strategy to enhance recruitment rates for research studies (Caldwell et al., 2010). Multiple sites allowed for exposure to more potential participants, improved study population diversity, and increased external validity (Caldwell et al., 2010). Conversely, a cross-sectional survey of 41 principal investigators' perceptions on factors associated with successful recruitment in clinical trials reported that having multiple recruitment sites does not always mean increased participants due to local competition, reduced resources across all active recruiting sites, and increased administrative complexity

in multi-site trials (Idnay et al., 2023). Nevertheless, a pragmatic decision was made to open a London recruitment site due to two people with CSR being recruited across the West Midlands between March 2022 and November 2022.

No further people with CSR were recruited between December 2022 and March 2023. To promote uptake, Ascenti allocated a dedicated clinician who was trained by the lead researcher (MM) to screen incoming referrals and telephone prospective patients, advertising the study and screening eligibility between April 2023 and September 2023. This method of personal telephone calls has shown success in recruiting patients into previous clinical trials (RR: 1.14, 95% CI: 1.01–1.28) (Mandelblatt et al., 2005). However, this was based on breast reconstruction surgical trials, which may limit the external validity of this QST study. Nevertheless, the provision of a personal telephone call with additional educational material about the QST study, which did not incur any financial costs to the lead researcher (MM), was a strategy that was implemented in an attempt to boost recruitment numbers. This strategy managed to recruit an additional two people with CSR. The informal feedback provided by physiotherapists screening patients' eligibility in the physiotherapy clinic and the dedicated Ascenti clinician telephoning the prospective patients for recruitment, was regarding the time taken to travel and complete the QST testing. **Appendix 9.12** presents the actual and anticipated recruitment targets across the 19 months that the study was open.

Despite opening a second recruitment site, the geographical location of London may actually exacerbate the low recruitment rates in this study. Some potential reasons for the lower recruitment rates in London are the more diverse ethnic population, which can find it more challenging to engage in medical research (Ekong et al., 2022, Wendler et al., 2006). Additionally, there is a higher population mobility (Jacques et al., 2022) which could result in people missing invitations or reminders to participate. Moreover, there are more research studies or clinical trials, leading to research fatigue as individuals are repeatedly approached to participate in research (Newington and Metcalfe, 2014). Research studies in London not only have to deal with the same recruitment issues as elsewhere but may also face additional issues related to their location (Chaudhuri et al., 2023).

One strategy that could be considered for Ascenti research and development teams going forward could be using an opt-out strategy to research recruitment across the Midland and London sites where potential participants are required to contact the research teams if they do not want to be contacted about a study (Newington and Metcalfe, 2014). This method has been identified as optimal across single or multiple recruitment sites and was investigated in a systematic review of 45 included studies (Treweek et al., 2013). However, this strategy is not currently employed by Ascenti, and further work is required to pilot the use of opt-out within Ascenti. Furthermore, it should be noted that Treweek et al., (2013) findings were based on recruitment strategies for RCTs, which may not be generalised to other observational studies.

9.14.1.3. Sampling approach. Randomisation

This QST study did not blind or randomise prospective participants into different experimental groups. The absence of blinding or randomisation has been shown to increase study enrolment (Caldwell et al., 2010). Recruitment rates are suggested as higher for non-blinded and non-randomisation trial designs, such as case-control or cohort designs compared to RCTs (RR: 1.14, 95% CI:1.02–1.28 and RR: 1.28, 95% CI: 1.19–1.37, respectively) (Caldwell et al., 2010). It is suggested that patients may be reluctant to enter a randomised trial where expected or standardised treatment may change with intervention group allocation (Caldwell et al., 2010). Therefore, this case-control research may aid in the recruitment of prospective individuals with CSR who can continue their ongoing Ascenti physiotherapy while taking part in the study.

9.14.1.4. Strategies to enhance recruitment. Training clinical staff

The lead researcher (MM) completed a site initiation visit to train clinicians and provide paper and electronic advert flyers to advertise the study. The use of paper-based and electronic adverts was a pragmatic decision based on the feedback from Ascenti site managers, physiotherapists, and patients in PPIE research meetings at the University of Birmingham and King's College London. Paper-based versus electronic advertisements have been reported as having no significant difference between the two methods (RR: 1.08, 95% CI: 0.74–1.57) (Caldwell et al., 2010).

Therefore, the lead researcher (MM) balanced this rationale, used both paper-based and electronic forms of advertisement, and trained clinicians to aid in the recruitment process.

9.14.1.5. Strategies to enhance recruitment. Monetary incentives

Monetary incentives such as cash or entry into a prize draw have been found to significantly improve patient recruitment in survey studies. Monetary incentives (RR: 1.39 (95% CI: 1.13–1.64) to RR: 1.53 (95% CI: 1.28–1.84)) have been reported to improve recruitment among RCTs (Caldwell et al., 2010). The lead researcher (MM) received a project grant from the Private Physiotherapy Education Foundation (PPEF) (Charity number: 1005738) to support the delivery of this case-control study. The lead researcher (MM) approached the PPEF during the recruitment phase to determine whether a modification of consumable funding allocated to the project could be used instead for financial incentives. The PPEF was unable to support this request, with the rationale that the PPEF has a UK charity status which does not support financial incentives for research participants. Offering a prize draw or charitable donation as an alternative method might have attracted more participants (Jennings et al., 2015). A RCT investigating the effectiveness of a prize draw on participants' participation reported the prize draw incentive was effective in increasing questionnaire commencement (84.6% vs 75.9%, OR: 1.74, 95% CI: 1.07–2.84) and reducing the delay in completing the questionnaire (19.9 vs 22.6 days, hazard ratio = 1.34, 95% CI : 1.07–1.67) (Morgan et al., 2017). However, it is important to note that this study focused on the response rate for online questionnaires, which may limit the generalisability to this QST study’s reflections.

9.14.1.6. Strategies to enhance recruitment. PPIE consultation

The lead researcher (MM) presented study updates to his research group memberships at the University of Birmingham and King’s College London. The groups included physiotherapists, pre-clinical scientists, individuals with lived experience of spinal pain, and senior trial researchers. The research groups discussed the potential benefits of establishing a therapeutic relationship with potential study participants who share similar cultural backgrounds or languages. It was noted that using eligibility criteria that require sufficient English proficiency may

restrict recruitment. However, the lack of resources available for interpreter services was a common theme discussed across the research group meetings and in this PhD study. Resource limitations have hindered the use of peer recruitment programmes to enhance the recruitment of minority groups. Peer recruitment involves a principal investigator using a community member, known as the peer recruiter, to reach out to potential participants, who often come from minority populations (Manohar et al., 2018). The rationale behind this approach is that potential research participants are more likely to trust a peer than someone who is not part of their community (Manohar et al., 2018). Further exploration of this potential recruitment strategy in radiculopathy research is recommended, as it is crucial to recruit a diverse sample to ensure that research findings can be generalised.

Involving stakeholders in a research study, including PPI, throughout the research process (from research conceptualisation to dissemination) can enhance the research process and outcomes. A systematic review and meta-analysis by Crocker et al., (2018) reported that PPIE in clinical trials was beneficial for both enrolment and retention rates. Recruiting adults with CSR for this PhD study may have required a specific patient and public involvement approach. Various approaches could have been considered, such as advisory boards, stakeholder groups, or patient panels. The lead researcher (MM) regularly communicated study progress to Ascenti, multi-site research groups, and the PhD supervision team. However, formalising a steering group with people who have lived experience of CSR could have improved recruitment for this study. This steering group would have facilitated ideas and discussions for strategies for reaching minority groups and 'hard-to-reach' geographical locations. Nonetheless, there is a lack of comprehensive guidance for recruiting patients, carers, and the public for advisory boards, groups, and panels across different study designs and contexts (Crocker et al., 2018). In future research, more creative approaches that require additional time and resources may be needed to proactively recruit such populations for CSR somatosensory testing studies.

9.14.1.7. Length of study testing

It cannot be ignored that the issue with under-recruitment may, in fact, lie with the QST procedures. As discussed in **Chapter 1**, the current standard to evaluate the presence of a somatosensory dysfunction in clinical pain cohorts is QST. However, from a clinical standpoint, the QST procedure is time consuming (Zhu et al., 2019). This reasons for low recruitment were found in a qualitative interview study of researchers conducting clinical trials investigating the reasons why poor trial recruitment may occur (Briel et al., 2021). From the 49 interview participants, 29 different reasons for recruitment failure were identified (Briel et al., 2021). One notable reason included the high burden for trial participants, which included lengthy testing procedures. The interviewees in Briel et al.'s (2021) study were recruited from Canada, Germany and Switzerland, which may limit the transferability of findings to the UK. Nevertheless, the time-consuming nature of QST is a limitation of clinical studies and should be refined in future research.

9.15. Strengths and limitations

This study has several strengths. Firstly, this was the first case-control study using pragmatic CSR diagnosis criteria to investigate the somatosensory profiles of healthy people and people with CSR. The QST completed was robust and followed the DFNS protocol established for comprehensively assessing the somatosensory nervous system. This enhances the trustworthiness of the results. Secondly, this study was reported according to STROBE guidelines (von Elm et al., 2007) to reduce reporting bias. Thirdly, 25 healthy participants were recruited successfully, meeting the sample target. However, it is acknowledged that there may have been a potential for recruitment bias as all healthy participants were sampled from a university postgraduate student population.

There were limitations to this observational study. Firstly, the low recruitment for the CSR group has already been discussed. This resulted in the hypotheses being unable to be answered. Secondly, the QST was completed in one test site location in each geographical region. Not having multiple test sites across each geographical region (West Midlands and London) may have further exacerbated the low recruitment for the CSR group. Thirdly, the research participant-researcher interaction cannot be ruled out and may influence or bias the patients' perception or

judgement of the outcome (Price and Barrell, 2002). To reduce the likelihood of investigator bias, the lead researcher (MM) (or an additional researcher) could have been blinded to each group. However, this was not practical due to the sole assessor nature of the study design and the funding implications of having additional researchers to complete the somatosensory testing. As a result, there is a risk of investigator bias to these results.

It is acknowledged that Ascenti's patient population with CSR may not be representative of the UK adult general population. The individuals with CSR included in this study accessed Ascenti's physiotherapy services through two different channels: self-paying and private medical insurance (including occupational health services). A UK national survey of 2,003 respondents reported that 41% (n=825) 18-24 age group have personal experience using private healthcare services compared to older age groups (55 years and over; 28%, n=561) (Independent Healthcare Providers Network, 2023). This may be attributed to younger people being more inclined to use digital healthcare services or being covered by their parent's medical insurance policies. However, it is important to acknowledge that approximately 11% of the UK adult population has access to private medical insurance (Laing Buisson, 2022), which is not entirely representative of the UK adult population. This may, therefore, limit the generalisability of any findings. Furthermore, people who use Ascenti's services through self-pay or private medical insurance are more likely to hold higher managerial, administrative, and professional positions (Independent Healthcare Providers Network, 2023) and are also located in two major UK city areas (Birmingham and London). This means they may not fully represent those in semi-skilled and unskilled manual occupations, those who are unemployed or in rural geographical regions. This could result in a sampling bias and may not accurately reflect the broader adult UK population accessing healthcare services.

9.16. Conclusions

This somatosensory case-control study phase of the PhD programme has reported the somatosensory profiles of 25 healthy participants and four people with CSR. Anxiety symptoms were self-reported through questionnaires by the 25 healthy participants. The low recruitment of people with CSR may have been attributed to

the single-site testing location and the length of time required to complete somatosensory testing procedures. As a result, results were descriptively analysed, as completing inferential statistical testing would have resulted in type II error. Further research in establishing portable and time-efficient QST procedures is indicated for people with CSR.

9.17. Next steps

This case-control observational study has reported on the somatosensory profiles of healthy participants and people with CSR. The limitations of study recruitment have been discussed, with future research recommendations made. The final chapter of this thesis (**Chapter 10**) will discuss the main conclusions and implications for clinical practice and research resulting from this PhD programme.

Chapter 10: Overall thesis discussion and conclusions

10.1. Introduction

This chapter summarises the key results and discussion points that have developed from the four studies involved in this research programme. It will discuss the original contributions made to knowledge and understanding of how physiotherapists assess CSR and summarise the challenges associated with this PhD programme.

10.2. Summary of findings

The aim of this PhD programme was to investigate the clinical assessment methods when establishing CSR diagnosis. The PhD thesis included four studies undertaken by the lead researcher (MM) to meet this aim. The subsequent subsections will outline the results from each study.

10.2.1. Chapter 2: epidemiology of cervical spine radiculopathy. A systematic review

This published systematic review was the first known systematic review of research investigating the epidemiology of CSR in an adult population. Incidence ranged between 0.83 to 1.79 per 1000 person-years from three studies. Prevalence values ranged from 1.21 to 5.8 per 1000 from four studies. Prevalence values of 1.1% and 1.3% for males and females, respectively, were reported in one study. These results provided a rationale for investigating assessment practices and reasons underpinning these decisions in subsequent chapters.

10.2.2. The association of mental health symptoms and health outcomes. A systematic review

This published systematic review was the first known systematic review of research investigating the associations between mental health symptoms and diagnosis with health outcomes in people with CSp±R. Twenty-three studies were included in the narrative synthesis. Seven ‘low-quality’ studies measured by GRADE reported that depressive symptoms were linked to poorer health outcomes with CSR and with

non-specific neck pain populations. Distress and anxiety symptoms were also associated with poorer health outcomes in CSR populations and non-specific neck pain in two ‘very low-quality’ cross-sectional studies. Two studies with very low-quality sampling non-specific neck pain populations found that stress and higher job strain were negatively associated with poorer health outcomes. Results provided a rationale for investigating the biopsychosocial assessment practices and reasons underpinning these decisions in subsequent chapters.

10.2.3. Chapters 4 to 8. Cervical spine radiculopathy assessment practice. Mixed methods research

To the lead researcher’s (MM) knowledge, this was the first mixed methods research study to investigate the assessment practices of UK physiotherapists when diagnosing CSR and the reasons underpinning these decisions. Phase 1 of the mixed methods research study was a national online survey. The survey included 63 respondents and found that the most commonly used assessment strategies for diagnosing CSR involved manual muscle strength, light touch dermatomes sensation, and reflex testing. The least commonly used strategies included thermal detection and pain thresholds, pressure detection, and temporal summation somatosensory testing parameters. In addition, pain-screening questionnaires or tools were rarely used in clinical practice to establish CSR diagnosis. Phase 2 of the mixed methods research study included 11 qualitative interviews with Phase 1 participants. Four themes contextualised the reasons that assessment strategies were used to establish CSR diagnosis. These themes were: perception of role, service constraints, minimising risk, and understanding symptoms. Results provided a rationale for investigating the somatosensory assessment of people with CSR in the subsequent chapter.

10.2.4. Chapter 9. Somatosensory profiling healthy participants and people with cervical spine radiculopathy. A case-control study

This case-control study phase reported the somatosensory profiles of 25 healthy participants and four people with CSR. Anxiety symptoms were self-reported through questionnaires by the 25 healthy participants. Moreover, this study

presented a major limitation principally surrounding the lower-than-expected recruitment rates of people with CSR.

10.3. The implications of this PhD programme of research

This PhD programme of research has implications for patients, physiotherapists, healthcare policymakers and researchers.

10.3.1. Implications to physiotherapists

The best available evidence suggests that physiotherapists should use a biopsychosocial approach when establishing a CSR diagnosis. Notwithstanding this, physiotherapists should be aware that the conclusions drawn from published literature on the epidemiology and association of mental health symptoms and health outcomes in people with CSR are limited by a small number of low-quality studies. The systematic reviews indicated that physiotherapists should identify and support people with CSR who are experiencing depression, anxiety and distress as this may negatively impact health outcomes. Assessment methods to support the biopsychosocial approach should include pain-screening tools and questionnaires to support decision-making and appropriate management. However, there are clear gaps in research in this area. Future researchers and physiotherapists should continue to work collaboratively to ensure that assessment practices are informed by robust and contemporary evidence. By increasing awareness of CSR through a national survey, evidence synthesis publications and knowledge transfer activities from this PhD programme, it was hoped that this may stimulate physiotherapists into further considering and evaluating their assessment strategies for this population.

When diagnosing CSR, physiotherapists should continue to clinically reason using both large and small nerve fibre assessment strategies. A contemporary understanding of the underlying pathophysiology of CSR emphasises the importance of somatosensory assessment for both large and small nerve fibres (Schmid et al., 2020). However, it is important to note that somatosensory testing alone cannot establish a diagnosis. **Chapter 9** highlighted the psychosocial and mental health factors that interplay with CSR and, therefore, physiotherapists should adopt a holistic approach to assessment. This approach should ensure that the

physical and mental health and well-being domains are assessed to inform treatment.

It was discussed in this PhD programme that physiotherapists assessing people with CSR are faced with a myriad of different assessment strategies. The choices available to physiotherapists may be based on cost, departmental knowledge and skill or convenience. However, physiotherapists should continue to be evidence-informed practitioners, embracing various and evolving assessment strategies and how they can enhance or change practice. Changing or adapting professional practice can be a complex process (Holopainen et al., 2020). As reported in Phase 2 of the mixed methods research study, physiotherapists often explained that decision-making in practice is based upon individual and organisational barriers. Examples can include time available to complete assessments and expectations from managerial staff in clinical practice. The COM-B system may be a suitable framework for understanding behaviour and the factors required for behaviour to change (Michie et al., 2011). This system acknowledges factors internal to the individual (capability and motivation) and factors that are external to the individual (opportunity), which all interact to generate a desired behaviour (Michie et al., 2011).

It can be challenging for physiotherapists to change their practices or incorporate high-value care evidence practices (Holopainen et al., 2020). An example of this challenge is exemplified by a systematic review that reported that most physiotherapists do not follow the recommendations of the latest evidence-based guidelines in managing people with low back pain (Condon et al., 2016, Fourré et al., 2023, Zadro et al., 2019). Changing behaviour is suggested to have three main components, capability (optimising psychological and physical abilities to enable the behaviour), opportunity (optimising the social and physical environment to enable the behaviour) and motivation (balancing activating and inhibiting mechanisms of the behaviour) (Elven et al., 2015, Michie et al., 2011).

Incorporating the behavioural, psychosocial, and physical elements into somatosensory assessment and analysis in both research and clinical settings requires a diverse range of practical skills and knowledge (Flottorp et al., 2013). It also necessitates the development of new competencies in clinical reasoning when assessing CSR. Additionally, possible barriers such as time constraints, staffing,

financial resources, and support from healthcare management in implementing practice changes will need to be addressed. This raises the need to develop effective and evidence-informed assessment and management decisions to ensure that physiotherapists receive proper training and increase their competency in effectively delivering the healthcare changes as intended (Overmeer et al., 2009). Training or education can be completed through multiple modes such as formalised higher education programmes at pre-registration and post-registration levels or continuing professional development workshops (Dziedzic et al., 2016, Lehane et al., 2018, Overmeer et al., 2009).

10.3.2. Implications for research

The PhD programme has led to three important implications for future research. First, the epidemiology of CSR systematic review identified a low number of 'low-quality' studies and suggested areas of future research to robustly measure the prevalence and incidence of CSR. The second systematic review examined the impact of mental health conditions on health outcomes. Results showed that symptoms of depression and anxiety are negatively associated with poorer health outcomes in people with CSR. As such, future researchers should reflect on how the physical and mental health and well-being components intertwine with one another in a complex condition such as CSR.

Second, the limitations of low recruitment from the online survey and somatosensory profiling studies can better inform future researchers when planning clinical research. The lead researcher (MM) reflected on some important lessons from the survey chapter. The very low response rate to the survey recruitment could potentially lead to selection bias. Additionally, the lead researcher (MM) could not track access to the online survey and the survey recruitment strategy depended on social media and physiotherapist networks, possibly contributing to selection bias. In the observational study chapter (**Chapter 9**), the lead researcher (MM) also learned from the very low recruitment. The length of time to complete the QST procedures and no financial reimbursement for participants' travel and testing time may have contributed to the very low recruitment. These insights can be valuable for future researchers designing similar studies.

Third, the diagnostic criteria for CSR varied among the findings in the systematic reviews and mixed methods. Future researchers should establish agreed diagnostic criteria that reflect contemporary clinical practice across different healthcare professionals and settings. This would consequently enhance the external validity of future studies. From the establishment of an agreed diagnostic criteria of CSR, further research should be conducted that establishes somatosensory phenotypic sub-groups within CSR. This can lead to future research that establishes how these sub-groups may stratify management options and health outcomes for people with CSR.

10.3.3. Implications for healthcare policy

This PhD research programme has two important implications for healthcare policy. Firstly, the integrated mixed methods research results report on how and why physiotherapists establish CSR diagnosis in clinical practice. The reasons identified can provide an estimation of the costs associated with clinical assessment and, therefore, support clinical service development. Furthermore, the mixed methods research study identified that workplace environments modulate the selection, justification and integration of clinical assessment procedures. Survey respondents and interview participants reported how the time available to conduct clinical assessments does, in part, justify the choice of assessment. It is important for clinical service models to consider the amount of time allocated for assessing patients with complex conditions like CSR. The mixed methods research study suggests that providing more time to physiotherapists may help improve their assessment practices. However, it may not always be possible to make such changes in healthcare settings like orthopaedic triage centres. Nevertheless, healthcare policies and employers should prioritise offering time-efficient clinical assessment frameworks to support the delivery of effective healthcare. Secondly, the results from the mixed methods research study provides insights into the barriers and facilitators of continuing professional development of physiotherapists. Physiotherapists reported that working in open environments is more likely to engage in critical reflection, which in turn can enhance clinical reasoning strategies when assessing people with CSR. These insights can support the workforce planning requirements in practice.

10.4. Areas of future research

This PhD programme has identified three main areas for future research. First, the mixed methods research study indicated that physiotherapists adopt a variety of different assessment methods to diagnose CSR. Furthermore, the two systematic reviews showed that there is a significant variation in the clinical assessment criteria used to diagnose CSR. It is crucial to accurately diagnose CSR to distinguish it from any serious spinal condition and to make informed decisions on whether to recommend conservative or invasive management options. Further research is necessary to determine the reliability of somatosensory assessment methods for diagnosing CSR in clinical practice. Additionally, it is necessary to examine how these clinical assessments can predict health outcomes. This will improve the clinical reasoning behind assessment decision-making and support the development of personalised care pathways for people with CSR.

Second, the systematic review in **Chapter 3** identified how mental health conditions or symptoms are negatively associated with health outcomes. Identifying all physical and mental health prognostic indicators could support researchers understand which variables should be stratified in CSR assessment and treatment pathways. These variables can then be examined in relation to their association with treatment to determine their importance. This, in turn, can support the optimal management of this population.

Third, **Chapter 3** identified that health outcome heterogeneity exists in CSR populations. Furthermore, the mixed methods research study (**Chapter 8**) reported that physiotherapists prioritise different assessment measurements to inform management pathways (for example, muscle strength and sensory assessments). Even with outcomes that are commonly assessed, such as muscle strength, there is likely to be variation in how these are measured. Developing a core outcome set for adults with a CSR could be a potential solution. A core outcome set includes a minimum set of outcomes that need to be reported and measured in a health condition (Chiarotto et al., 2017, Williamson et al., 2012). It could enhance the quality of evidence produced by research in CSR by reducing outcome heterogeneity, increasing the relevance of research, and decreasing the scope for outcome bias (Kirkham et al., 2017).

10.5. Strengths and limitations of research

The strengths and limitations of each study are reported in their respective chapters. There were three main overall strengths of this PhD research programme. The first strength of this research was that it was informed by clinical practice based on the experiences of healthcare professionals. The research was developed from the personal experiences of the lead researcher (MM), as well as from discussions with clinicians and researchers in this field. Furthermore, refining clinical assessment practices and enhancing our understanding of complex pain presentations is an identified priority of Versus Arthritis (Versus-Arthritis, 2023). Second, the two systematic reviews (**Chapters 2 and 3**) have reported on and analysed the current research literature and were robustly designed and conducted following best practice guidelines. The findings from both systematic reviews contributed to the justification of overarching research objectives. Furthermore, both reviews have identified gaps in the research that will support future research studies.

Third, mixed methods research study has been used in two sequential phases in this PhD programme of research. As discussed in **Chapter 4**, mixed methods research is viewed as a way of addressing complex healthcare issues by using a combination of research approaches (Fetters, 2013). Given that the objectives of this phase of the PhD programme were to investigate the assessment practices of UK physiotherapists when diagnosing CSR and understand the rationale behind these decisions and practices, mixed methods research is justified. Furthermore, the strategies used to ensure the trustworthiness of the qualitative phase in this study are described in detail in **Chapters 6 to 8**. Rigour has been achieved through multiple strategies, for example robust justification of the explanatory sequential design, the consistent use of a personal journal, researcher triangulation when analysing the interviews, and integration of both the survey and qualitative interview phases (**Chapters 5 to 8**).

There are, however, two additional limitations to this PhD programme of research. First, the low response rate to the survey of practice means that the results may not be representative of current physiotherapy practice across the whole of the UK for the assessment of CSR. Second, over a period of 19 months, there was a very low

recruitment of people with CSR to the QST profiling study. Consequently, a comparative analysis between groups was not completed and results were descriptively reported.

10.6. Personal development and reflections as a researcher

This PhD programme is the first step towards achieving my aspiration of becoming an independent researcher. I completed this PhD part-time, over five years, alongside my full-time lectureship position in higher education. A part-time PhD programme of research in combination with the teaching, citizenship and leadership expectations in higher education, has been a challenging balance. However, there were some advantages. The various roles in higher education complement one another. It has been a privilege to facilitate the learning and development of student physiotherapists and postgraduate clinicians. The research questions, development and dissemination have been part of the many teaching sessions and conversations I have had with all students and people with CSR. Working in academia has allowed me to share the knowledge and experiences I have gained through this PhD programme across different platforms, including (but not limited to) scheduled teaching, research project supervision, industry collaborations and public engagement seminars. Moreover, the research knowledge, skills and behaviours I have developed during the PhD programme have provided a strong foundation to address the questions that still remain and have been raised in this research.

10.7. Conclusion

This PhD programme has contributed to the evidence-base to provide an enhanced understanding and evidence when assessing people with CSR. The incidence and prevalence of CSR have been established, and the variance of assessment criteria utilised in the available research has been reported. The association of mental health symptoms, including depression, depressive symptoms, distress and anxiety and their negative impact on health outcomes in people with CSp±R, have been discussed. Findings from the PhD have identified current physiotherapy assessment strategies used and the reasons underpinning the decisions made when establishing CSR. Furthermore, the research began to examine the somatosensory

profiles of people with CSR and healthy control participants. Key limitations relating to the recruitment of people with CSR were identified and should be considered when designing future studies with CSR adult populations. Further studies examining prognosis indicators to develop the stratification of assessment informing how best to treat and evaluate people with CSR are stated.

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Appendices

Appendix 1.1. Search terms adopted for the MEDLINE databases

MEDLINE search strategy 1 – Radiculopathy

1. Cervical spine radiculopathy.tw
2. Radiculopathy/
3. Nerve entrapment.tw
4. Nerve root entrapment.tw
5. terminology/
6. nomenculature.tw.
7. epidemiology/
8. frequency/
9. incidence/
10. prevalence/
11. surveillance/
12. aetiology.tw.
13. etiology/
14. pathogenesis/
15. pathophysiology.tw
16. cause/
17. or/1-4
18. or/5-16
19. and/17,18

MEDLINE search strategy 2 – diagnosis and clinical testing

1. Cervical spine radiculopathy/
2. assess$.tw.
3. assessment, patient outcome/
4. Diagnosis
5. Examination/
6. Physical Examination.tw.
7. Diagnostic Tests/
8. test$.tw.
9. outcome measure$.tw.
10. upper limb tension test.tw.
11. upper limb neurodynamic test.tw
12. spurlings.tw
13. dermatomes.tw
14. myotomes.tw
15. reflex.tw
16. radiograph.tw
17. magnetic resonance imaging/
18. nerve conduction.tw
19. Sensitivity and Specificity/
20. diagnostic test accuracy.tw.

21. or/2-18
22. or/19-20
23. and/1,21,22

MEDLINE search strategy 3– somatosensory profiling

1. *Results from search (17) on search strategy 1*
2. somatosensory/
3. quantitative sensory testing.tw
4. QST.tw
5. Pressure pain threshold.tw
6. Heat pain threshold.tw
7. Thermal detection.tw
8. Cold pain threshold.tw
9. Neuropathic/
10. Nociceptive/
11. warm detection.tw
12. pain tolerance.tw
13. cold pain.tw
14. heat pain.tw
15. temporal summation.tw
16. thermal pain.tw
17. peripheral sensitization.tw
18. central sensitization.tw
19. hypesthesia.tw
20. hyperesthesia.tw
21. hyperalgesia.tw
22. psychophysics.tw
23. sensory threshold.tw
24. sensory detection.tw
25. thermal detection.tw
26. thermal threshold.tw
27. cold detection.tw
28. heat detection.tw
29. pain detection.tw
30. pain threshold.tw
31. sensitivity.tw
32. Quantitative sensory test.tw
33. QST.tw
34. Quantitative sensory.tw
35. or/2-33
36. and/1,35

MEDLINE search strategy 4 – Psychosocial factors

1. *Results from search (17) on search strategy 1*
2. Exp Psychosocial deprivation/
3. Exp Mental health/

4. Exp Psychosomatic Medicine/
5. Exp Anxiety/
6. Exp Stress Disorders, Traumatic, Acute/
7. Exp Stress, Psychological/
8. Exp Depression/
9. Psychosocial.tw
10. Psychological.tw
11. Stress.tw
12. Apprehension.tw
13. Job.tw
14. Social.tw
15. Family.tw
16. Depressive.tw
17. OCD.tw
18. Personality.tw
19. Affective.tw
20. vocation*.tw
21. cognitive.tw
22. distress.tw
23. behavioural.tw
24. OR/2-22.tw
25. AND/1,24

Appendix 1.2. Psychosocial stages of development

Stages of Childhood

Stage 1 – Infancy period: Trust vs. Mistrust

- Virtue: Hope, Maldevelopment: Withdrawal
- Concomitant Freudian stage: oral stage
- Example: Secure environment provided by the caregiver, with regular access to affection and food

Stage 2 – Early Childhood period: Autonomy vs. Shame, doubt

- Virtue: Will, Maldevelopment: Compulsion
- Concomitant Freudian stage: anal stage
- Example: Caregiver promotes self-sufficiency while maintaining a secure environment

Stage 3 – Play Age period: Initiative vs. Guilt

- Virtue: Purpose, Maldevelopment: Inhibition
- Concomitant Freudian stage: genital stage
- Example: Caregiver encourages, supports, and guides the child's own initiatives and interests

Stage 4 – School Age period: Industry vs. Inferiority

- Virtue: Competence, Maldevelopment: Inertia (passivity)
- Concomitant Freudian stage: latency stage
- Example: Reasonable expectations set in school and at home, with praise for their accomplishments

Stage of Adolescence

Stage 5 – Adolescence period: Identity vs. Identity confusion

- Virtue: Fidelity, Maldevelopment: Repudiation
- Example: Individual weighs out their previous experiences, societal expectations, and their aspirations in establishing values and 'finding themselves.'

Stages of Adulthood

Stage 6 – Young Adulthood period: Intimacy vs. Isolation

- Virtue: Love, Maldevelopment: Distantiation

- Example: Individual forms close friendships or long-term partnership

Stage 7 – Adulthood period: Generativity vs. Stagnation/Self-absorption

- Virtue: Care, Maldevelopment: Rejectivity
- Example: Engagement with the next generation through parenting, coaching, or teaching

Stage 8 – Old Age period: Integrity vs. Despair

- Virtue: Wisdom, Maldevelopment: Disdain
- Example: Contemplation and acknowledgment of personal life accomplishments

Appendix 2.1. Search strategy – Medline

Search term	Records retrieved
1) Exp Neck/	**434,786**
2) Exp Neck injuries/	**30,475**
3) Exp Neck Pain/	**39,510**
4) Exp Cervical vertebrae/	**47,635**
5) Cervical spine pain OR cervical pain OR cervicalgia OR cervicodynia or neck adj3 muscles OR neck ache OR occip* OR Odontoid* OR thoracic adj3 spine OR thoracic vertebrae	**138,616**
6) OR/1-5	**558,168**
7) Exp Radiculopathy/	**11,105**
8) Exp Nerve Compression Syndromes/	**24,621**
9) Exp Neuralgia/	**38,251**
10) Nerve* entrapment OR Radicular OR Referred Pain OR (Neck and arm pain) OR Cervical radiculopathy OR Nerve root inflammation OR Nerve root compression	**46,149**
11) OR/7-10	**102,713**
12) Exp Cohort Studies/	**2,617,962**
13) Exp Prognosis/	**2,223,892**
14) Exp Epidemiology/	**2,067,177**
15) Exp Prevalence/	**2,568,526**
16) Exp Incidence/	**2,699,320**
17) OR/14-18	**6,876,453**
18) 6 AND 11 AND 17	**4,224**

Appendix 2.2. Email example to authors

Dear Prof.

I hope that this finds you well.

I am a PhD student at South Bank University, United Kingdom. My research focuses on studying the occurrence and prevalence of cervical spine radiculopathy in adult populations worldwide. Currently, I am conducting a systematic review of existing literature, including both published and unpublished data.

Your primary study titled: “XXX” meets our inclusion criteria for our systematic review.

I am writing to enquire whether you are aware of any pending or planned studies investigating the prevalence or incidence of cervical spine radiculopathy. Additional studies may help strengthen our findings.

Thank you for considering.

Kind regards,
Michael Mansfield

Appendix 2.3. Abstract screening guidance

Lead author	Human participants	Is the age group of participants 18 years and above	Cervical spine radiculopathy	Prevalence or incidence data	Study design: Cohort, case control
	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE

Inclusion criteria

- Report incidence and/or prevalence of carpal tunnel syndrome over any time period and in any adult population (aged 18 years or above).
// It might not be clear from the abstract whether they report male/female separately or combined. If there is uncertainty, keep in at this stage.

- Cervical spine radiculopathy diagnosed by any method, for example, clinical examination, nerve conduction studies, EMG or a medical record code of CSR
// In the review we will need to report separately for the different diagnostic methods.

- Studies must be in the English Language (or can be translated into English with the resources available). The number of non-English language studies excluded will be reported.

If the abstract is not written in English, please include it at this stage – this will allow us to count and see if we can get translated/apply the appropriate exclusion criteria at the next stage.

Also, if there is no abstract text, please include it at this stage unless it is really clear from the title alone that the paper will not report CSR incidence/prevalence data.

Some of the papers report CTS incidence in specific populations e.g. factory workers, athletes etc. We are not looking at risk factors for CSR in this review, but I think we need to include all these papers too. When we report the findings, we will highlight the sample. It may be possible to compare different occupations.

Exclusion criteria
- Paediatric populations or mixed population where those aged <18 years are unable to be distinguished from the sample.

Mixed clinical populations where the incidence/prevalence of CSR is unable to be differentiated from the incidence/prevalence of another condition.
// For example, combined mononeuropathies, widespread polyneuropathies

- Studies reporting incidence/prevalence of CSR surgery only.
// We do not want surgical data, only CSR

- Studies reporting incidence/prevalence of CSR specifically in populations with systemic pathologies, for example, diabetes mellitus, metabolic syndrome, thyroid disorders, rheumatoid arthritis, or other systemic or localised neurological disorders.

Appendix 2.4. Data extraction table with definitions

Lead Author & Date	Population and location	Data Collection Methods	Sample Size (Age, Gender)	Definition of Cervical Spine Radiculopathy (CSR)	Prevalence/Incidence of CSR

Lead Author and date.
State the lead (first) author and year of publication. For example, Mansfield (2021).

Population and location.
State geographical location and population sampled. For example, United Kingdom, primary care patients

Data collection methods.
State how the authors collected epidemiology data. For example, cross-sectional electronic survey.

Sample size.
State the total sample, size, demographics, male:female and age with variance from mean (where available). For example, Total sample 1000, 501 female, Mean age (years) 38.2 (SD 3.4).

Definition of cervical spine radiculopathy.
State the diagnostic criteria used and which criteria is met.

CSR diagnostic criteria:
Definite CSR Diagnosis - *Either (i) or (ii)*

(vi) Acute denervation with EMG studies OR Sensory changes in dermatomal distribution
AND
Weakness, atrophy OR fasciculation in a myotomal distribution *AND*
Unilateral diminished deep tendon reflexes

(vii) Abnormal myelography, CT or MRI correlating with radiculopathy
WITH
Neck pain or combined neck and arm pain
OR
Paraesthesia, hyperesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy

Probable CSR Diagnosis - *Either (iii), (iv) or (v)*

(viii) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy
WITH
Sensory changes in dermatomal distribution or muscle weakness in a myotomal distribution or atrophy or Fasciculation in a myotomal distribution or Unilateral diminished deep tendon reflexes

(ix) Neck pain, neck and arm pain, paraesthesia, hyperaesthesia or dysaesthesia in a nerve root distribution or muscle weakness in a myotomal distribution or atrophy
WITH
Abnormal myelography, CT or MRI correlating with radiculopathy

(x) Neck pain, neck and arm pain with two from:
(v-i) Sensory changes in dermatomal distribution
(v-ii) Muscle weakness in a myotomal distribution or atrophy
(v-iii) Fasciculation in a myotomal distribution
(v-iv) Unilateral diminished deep tendon reflexes

Prevalence/incidence data.
Report incidence and/or prevalence of CSR over any time period and in any adult population (aged 18 years or above).

Appendix 3.1 MEDLINE (PubMed) search strategy

1. Exp Neck/
2. Exp Neck injuries/
3. Exp Neck Pain/
4. Exp Cervical vertebrae/
5. Cervical spine pain OR cervical pain OR cervicalgia OR cervicodynia or neck adj3 muscles OR neck ache OR occip* OR Odontoid* OR thoracic adj3 spine OR thoracic vertebrae
6. OR/1-5

7. Exp Radiculopathy/
8. Exp Nerve Compression Syndromes/
9. Exp Neuralgia/
10. Nerve* entrapment OR Radicular OR Referred Pain OR (Neck and arm pain) OR Cervical radiculopathy OR Nerve root inflammation OR Nerve root compression
11. OR/7-10
12. 6 AND 11
13. 6 OR 11

14. Exp Psychosocial deprivation/
15. Exp Mental health/
16. Exp Psychosomatic Medicine/
17. Exp Anxiety/
18. Exp Stress Disorders, Traumatic, Acute/
19. Exp Stress, Psychological/
20. Exp Depression/
21. Psychosocial OR psychological OR stress OR apprehension OR job OR social OR family OR depressive OR OCD OR personality OR affective OR vocation* OR cognitive OR distress OR behavioural
22. OR/14-21

23. Exp Pain Measurement/
24. Exp Disability evaluation/
25. Exp Health Care Costs/
26. Exp Visual Analogue Scale/
27. Exp Rehabilitation/
28. Disability OR cost OR employment OR healthcare visits OR NDI OR neck disability index OR numeric pain rating score OR NPRS OR recovery
29. OR/23-28

30. Exp Cohort Studies/
31. Exp Prognosis/
32. Exp Morbidity/
33. Exp Epidemiology/
34. Follow up study OR incidence OR logistic OR prognosis OR predict* OR twin control OR time factors OR cox adj3 OR course OR log rank
35. NOT Review OR Single OR Case OR Animal

36. OR/30-35
37. 6 AND 12 AND 13 AND 22 AND 29 AND 36

Appendix 3.2. Email example to authors

Dear Prof.

I hope that this finds you well.

I am a PhD student at the University of East Anglia, United Kingdom. My research investigates the association of psychosocial factors in adults with neck pain with or without radiculopathy. Currently, I am conducting a systematic review of existing literature, including both published and unpublished data.

Your primary study titled: “XXX” meets our inclusion criteria for our systematic review.

I am writing to enquire whether you know of any pending or planned studies investigating health outcomes in this patient population. Additional studies may help strengthen our findings.

Thank you for considering this request.

Kind regards,
Michael Mansfield

Appendix 3.3. Abstract screening guidance

Lead author	Human participants	Is the age group of participants 18 years and above	Cervical spine radiculopathy or cervical spine pain (neck pain)	Mental health exposure	Health outcome measurement
	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE	YES/Unclear NO = STOP/NOT INCLUDE

Inclusion criteria

- Report associative or inference data between mental health symptoms or diagnosis and health outcomes.

// It might not be clear from the abstract whether they report specific associative or inference data. If there is uncertainty, keep in at this stage.

- Mental health symptoms or diagnosis diagnosed by any method, for example, self-reported, clinical assessed, questionnaire/screening tools

// In the review we will need to report separately for the different reported mental health methods.

- Cervical spine radiculopathy or neck pain diagnosed by any method, for example, clinical examination, nerve conduction studies, EMG or a medical record code of CSR

// In the review we will need to report separately for the different diagnostic methods.

- Studies must be in the English Language (or can be translated into English with the resources available). The number of non-English language studies excluded will be reported.

If the abstract is not written in English, please include it at this stage – this will allow us to count and see if we can get translated/apply the appropriate exclusion criteria at the next stage.

Also, if there is no abstract text, please include it at this stage unless it is really clear from the title alone that the paper will not mental health and health outcome data in neck pain and/or cervical spine radiculopathy.

Exclusion criteria

- Paediatric populations or mixed population where those aged <18 years are unable to be distinguished from the sample.

- Studies report neck pain or CSR specifically in populations with systemic pathologies, for example, diabetes mellitus, metabolic syndrome, thyroid disorders, rheumatoid arthritis, or other systemic or localised neurological disorders.

Appendix 3.4. Data extraction table with definitions

Lead Author & Date	Study design	Total population	Male:Female	Age	Spinal diagnosis	Mental health diagnosis	Health outcome	Association or inference data

Lead Author and date.
State the lead (first) author and year of publication.
For example, Mansfield (2021).

Study Design
State the study type.
E.g. Cohort study

Population and location.
State geographical location and population sampled/health care setting.
For example, United Kingdom, primary care patients

Total population and demographics
State the total number in the study's sample. Male: Female ratio and Age (years) with SD data (if present).
For example, 100, 51:49 and 42 years (SD 3.4)

Spinal diagnosis
State verbatim the neck pain and/or radiculopathy diagnosis the authors used in their respective study
For example, 3 month history of non specific neck pain

Mental health diagnosis or symptoms
State the mental health diagnosis or symptoms of the target population
For example, Anxiety

Health outcome
State the health outcome from the study.
For example, Pain measured by numeric pain rating scale; Disability measured by Neck Disability Index; Sick leave measured in days of absence from work

Associative or inference data
State the associative or inference data measure with confidence intervals and/or p-values
For example, OR: 1.4 (95% CI: 0.9-2.1)

Appendix 4.1. Reasons for mixing methods of research. Adapted from Greene et al., (1989, p.259) and Bryman (2006).

Greene et al., (1989)	Bryman (2006)
Triangulation aims to achieve agreement, validation, and consistency of findings across various methods.	*Triangulation*. Combining quantitative and qualitative research can produce more reliable findings through triangulation, where methods are cross validated.
Complementarity involves using the results from one method to enhance, clarify, elaborate, and illustrate the results from another method.	*Offset* pertains to the idea that both quantitative and qualitative research methods have their own advantages and disadvantages. By combining these methods, researchers can balance out the weaknesses and utilise the strengths of both approaches.
Development aims to inform one method with results from another method. This includes sampling, implementation, and measurement decisions.	*Completeness*. By using both quantitative and qualitative research, researchers can gain a more complete understanding of their area of inquiry.
Initiation aims to uncover paradoxes and contradictions, explore new perspectives and frameworks, and merge the results and questions from different methods.	*Process* refers to when quantitative research describes social structures, while qualitative research captures the process.
Expansion aims to broaden inquiry using diverse methods for each component.	*Different research questions* can be addressed by quantitative and qualitative research.
	Explanation refers to when one method is used to help explain findings generated by the other.
	Unexpected results occur when quantitative and qualitative research are combined to understand surprising findings.
	Instrument development. Qualitative research is used to develop questionnaire and scale items, improving wording and generating comprehensive closed answers.
	Sampling refers to the process of selecting a subset of individuals or cases from a larger population for research purposes.
	Credibility refers to suggestions that employing both approaches enhances the integrity of findings.
	Context refers to situations where qualitative research provides contextual understanding and

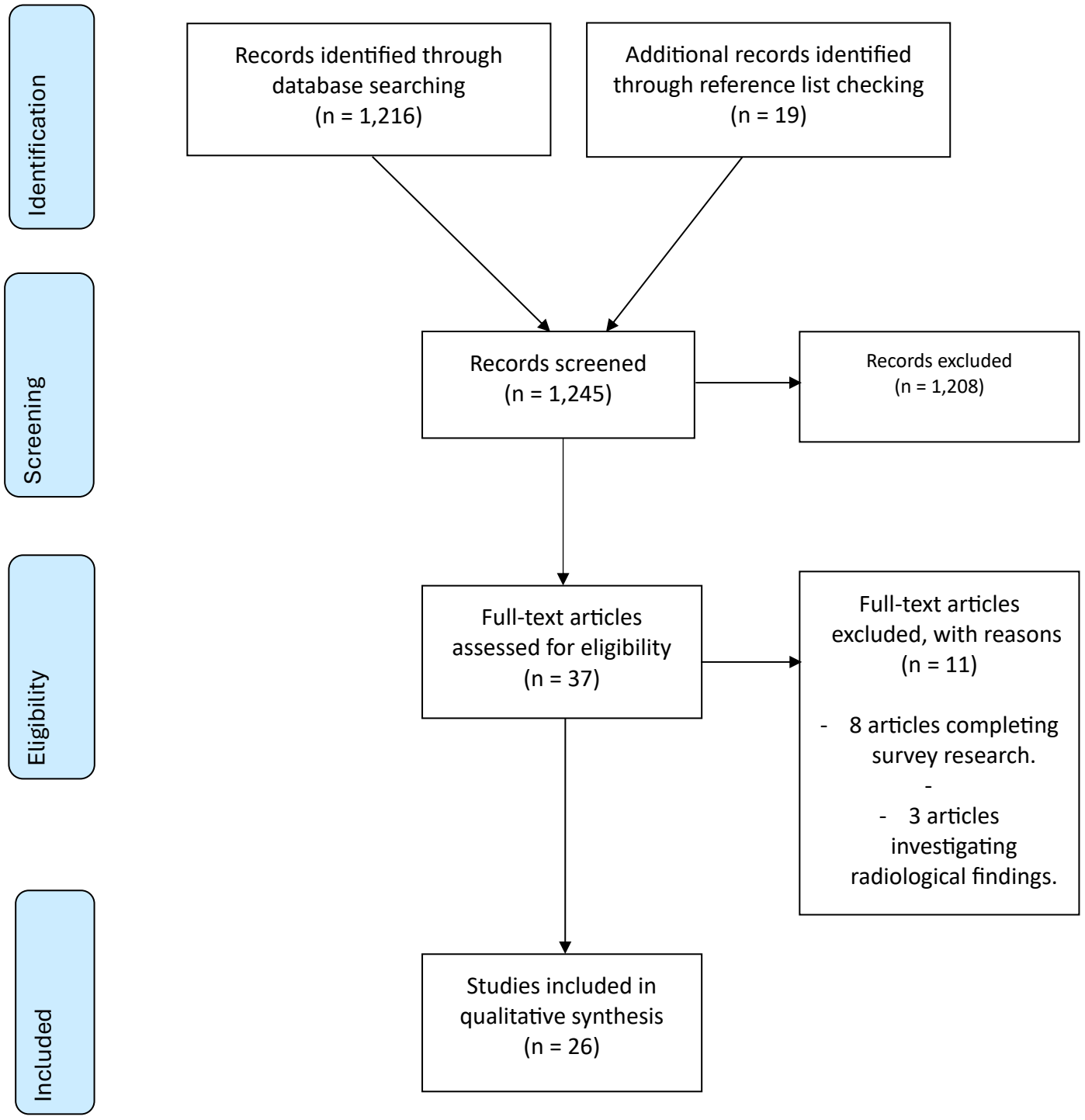
	either generalisable or broad survey-based findings.
	Illustration is the use of qualitative data to explain quantitative findings.
	Utility of findings can be improved by combining theoretical and practical approaches, which is more common in articles with an applied focus.
	Confirm and discover refers to using qualitative data to generate hypotheses and using quantitative research to test them within a single project.
	Diversity of views includes two slightly different rationales. Namely, combining researchers' and participants' perspectives through quantitative and qualitative research respectively and uncovering relationships between variables through quantitative research while also revealing meanings among research participants through qualitative research.
	Enhancement or building upon quantitative and qualitative findings entails a reference to making more of or augmenting either quantitative or qualitative findings by gathering data using a qualitative or quantitative research approach.

Appendix 5.1. Search strategy – Medline

Search conducted on 20th August 2023

Search term (Title and/or abstract)	Records retrieved
1. Neck pain	**12,798**
2. Low back pain	**34,860**
3. Spinal pain	**28,701**
4. Nerve* entrapment OR Radicular OR Referred Pain OR radiculopathy OR Nerve root inflammation OR Nerve root compression	**46,149**
5. OR/1-4	**100,980**
6. Survey	**695,286**
7. Cross sectional	**368,477**
8. Questionnaire	**538,398**
9. OR/6-8	**1,601,751**
10. 5 AND 9	**1,216**

Appendix 5.2. PRISMA (2009) diagram for study selection



Appendix 5.3. List of assessment strategies

Physical assessment

- Myotomes; Manual muscle testing; strength testing
- Dermatomes; Light touch; Light touch sensory assessment
- Reflexes; Biceps/triceps/brachioradialis reflex testing
- Spurling's; Head compression test; Cervical spine axial loading with rotation
- Upper limb tension test; Neurodynamic test: Upper limb tension testing ULTT 1-4

Somatosensory

- Sensory detection
- Pressure pain thresholds; Allodynia/Hyperalgesia; Hypoalgesia
- Thermal detection; Thermal differentiation; Cold pain detection

Screening questionnaires

- Neuropathic pain questionnaire
- Pain Detect survey

Appendix 5.4. List of reasons why assessment is not completed and possible facilitators

Barriers

- Time; Too time consuming; Not sure if useful in clinical practice
- Cost; Financial constraints
- Too many patients; Clinic lists busy
- Space
- Service expects other outcome measures related to the outcome

Facilitators

- More time; Fewer patients
- Free access to tools; Reduce cost of instruments
- Training needs; Understanding scoring systems; Practice

Appendix 5.5. Piloting stages

Stage 1 (Microsoft Word)

- Do the respondents understand a question? It is easy for technical jargon to creep into questions, so we must ensure that it is minimal.
- Have we included any ambiguous questions, double-barrelled questions, loaded or leading questions, or missing instructions?
- Does the survey have any missing answers or double negative/positive phrasing?

	Summary feedback
Physiotherapist 1	Each question clear and easy to read Respondents may not understand some terms such as allodynia but the answers cover this No obvious double-barrelled questions Likert scales useful Free text boxes will be interesting to see what is placed
Physiotherapist 2	All questions clear, no concerns here Imaging may not be available/used by all physiotherapists Pain questionnaires appropriate and contemporary. Again, not all services will have access to these but answers pick up on this All answers expected are present

Stage 2 (Microsoft Forms)

- Can you answer all the questions?
- Are mandatory questions working?
- Can answers be undone once selected?

- Are there any spelling mistakes?
- Can the survey be opened and submitted on multiple devices (desktop, laptop, mobile phone)?
- Record the time taken to complete the questionnaire and decide whether it is reasonable.

	Summary feedback
Physiotherapist 1	Access on Microsoft PC (desktop) and Android phone. Could complete all questions and submit I could click an unclick Likert scales (Only one option could be selected which is what I expected). Thank you for completing the message provides confirmation which is good No obvious spelling mistakes (Not always my strong point though!) Completed survey twice: 1st attempt 17 mins and second attempt 16 mins
Physiotherapist 2	Used Mac laptop and Apple phone. No problems with URL link All questions were mandatory and couldn't progress without answering. MS Forms highlighted areas that required completing Was able to add email address (optional answer) No grammar/spelling errors noted Colour and visuals are neutral. Text size appropriate Completed survey twice: 1st attempt (Phone) 12 mins and second attempt (laptop) 17 mins

Appendix 5.6. Thinking aloud notes (Stage two piloting)

Each meeting was independently conducted over Zoom platform.

	Summary Notes
Physiotherapist 1 (PT 1)	PT1 accessed link via email. Clicked and opened on mobile phone and PC (Windows laptop) with shared screen Read through PIS. We clarified the qualitative stage of the study and not mandatory to provide an email address. Nil queries on the demographics section of the survey. Discussed how PTs may have split roles but answers capture this. Likert questions were logical and flowed as expected. The presentation is intuitive with no obvious discrepancies. Comprehensive list of tests. Discussed that there may be slight variance of the title of tests but this should not cause any problems for qualified PTs.
Physiotherapist 2 (PT2)	Used Mac laptop and Apple phone. No problems with URL link shared screen across Zoom Enquired whether all PIS should be read. Agreed it should be (and understood) before proceeding. Discussed ethics questions and agreement to proceed – clear , concise with no queries. Colour visuals neutral and not glaring Accessed likert scales, order makes sense and able to click relevant frequency Text box useful but all tests are covered therefore unlikely to use this Pain questionnaires and imaging tests all appropriate for practice and was able to select which one used in practice with no errors.

Appendix 5.7. Supervisory team piloting summary feedback

- Both able to open MS Forms link on desktop/laptop devices
- PIS on expected templates
- Check to ensure PIS link can be downloaded
- Ethics questions progressive and have to answer all to progress
- All questions could be answered. Unable to progress without answers being selected.
- Logical sequencing of Likert sequencing
- A larger text box for free text answers on any other testing not listed
- Unable to save and return
- Length of time to complete survey ~18 minutes

Appendix 5.8. Survey questions

What is this study about?

You are invited to take part in a research study about contemporary assessment strategies used by physiotherapists when reaching a cervical spine radiculopathy diagnosis. Identifying contemporary assessment strategies will shape learning and training development areas for qualified clinicians and future research agendas.

You have been invited to participate in this study because you have accessed it via social media. Please read the Participant Information Sheet (link below) carefully, and ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. By giving consent to take part in this study you are telling us that you:

- Understand what you have read
- Agree to take part in the research study as outlined below
- Agree to the use of your personal information as described
- You have downloaded a copy of this Participant Information Sheet to keep

Our Participant Information Sheet can be accessed and downloaded here: https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:28d25181-34a6-47e2-98bd-5f7b3bed68ab

Online Consent Form

School of Health Sciences, University of East Anglia.
Study: Understanding cervical spine radiculopathy assessment practices by UK Physiotherapists: An Online Survey.

Name of Lead Researcher: Mr. Michael Mansfield (michael.mansfield@uea.ac.uk)

Our Participant Information Sheet can be accessed and downloaded here: https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:28d25181-34a6-47e2-98bd-5f7b3bed68ab

1.I confirm that I have read and understood the information sheet for the above project. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction
Yes
No and exit the study

2.I consent voluntarily to be a participant in this project and understand that I can refuse to take part and can withdraw from the project at any time, without having to give a reason
Yes
No and exit the study

3.I consent to the processing of my personal information for the purposes explained to me in the Participation Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018
Yes
No and exit the study

4.I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs
Yes
No and exit the study

5.I agree to take part in the above study
Yes
No and exit the study

Professional Identity
6.Are you a Health Care Profession Council (HCPC) registered physiotherapist practicing in the United Kingdom?
Yes
No

Working practice
7.Please select your professional working area. If you would across multiple areas, please select the working area where you spend most hours
Clinical - Musculoskeletal
Clinical - Orthopaedics
Clinical - Neurology
Clinical - Urgent Care and/or Accident & Emergency
Clinical - Sports
Clinical - Pain management
Clinical - Rheumatology
Clinical - Older adults
None of the above

8.What United Kingdom region do you currently practice in?
England
Northern Ireland
Scotland
Wales

9.Which healthcare sector do you work in (If more than one, please select the sector where you spend most of your working hours)
National Health Service (NHS) - Primary care
National Health Service (NHS) - Secondary care
Charity
Private Practice
Sports
Military
Social enterprise

10.What is your highest educational award?
BSc
Graduate Diploma Physiotherapy
BA
MSc (Pre-registration)
Post Graduate Certificate
Post Graduate Diploma
MSc (Post-registration)
MA
MRes
MPhil
MBA
PhD
Professional Doctorate

11.How many years has it been since you received your highest educational award?

Less than 1 year
1-5 Years
6-10 Years
11-15 Years
16-20 Years
21 Years and above

12.How many years have you worked (as a postgraduate physiotherapist) in a clinical setting assessing and treating people with cervical spine pain with or without radiculopathy?
Less than 1 year
1-5 Years
6-10 Years
11-15 Years
16-20 Years
21 Years and above

13.What proportion of your current working time do you spend assessing and treating people with cervical spine pain with or without radiculopathy?
Less than 10%
10-24%
25-49%
50-74%
75-99%
100%

Diagnosis
14.How confident are you in assessing a person with cervical spine radiculopathy?
Extremely confident
Somewhat confident
Somewhat not confident
Extremely not confident

Diagnostic Methods

15.Do you use these methods when establishing a cervical spine radiculopathy diagnosis?

	Always use	Often use	Sometimes use	Rarely use	Heard of this test, but do not use	Not heard of this test
Pressure Pain Threshold						
Pressure Detection Threshold						
Heat Pain Threshold						
Heat Detection Threshold						
Cold Pain Threshold						
Cold Detection Threshold						
Temporal Summation						
Conditioned Pain Modulation						
Vibration Detection Threshold						
Mechanical Pain Sensitivity						
Dynamic Mechanical Allodynia						
Reflexes						
Myotomes Testing or Manual Muscle Testing						
Spurling's Test Manoeuvre						
"Neural dynamic test" *Examples may include: Upper*						

	Always use	Often use	Sometimes use	Rarely use	Heard of this test, but do not use	Not heard of this test
Limb Tension Test (ULTT) Upper Limb Neural Test (ULNT))						
Light touch test (light touch sensation)						

16.Is there another **physical assessment method** which you have heard of or use when establishing a cervical spine radiculopathy diagnosis which is not listed in the previous question?

(Enter "No" if there is not another physical assessment method)

Possible Barriers, Somatosensory Assessment Methods

17.Why do you think the somatosensory assessment methods listed below are *rarely used or not used* in clinical practice when establishing a cervical spine radiculopathy diagnosis?

(Pressure Pain Threshold; Pressure Detection Threshold; Heat Pain Threshold; Heat Detection Threshold; Cold Pain Threshold; Cold Detection Threshold; Temporal Summation; Conditioned Pain Modulation; Vibration Detection Threshold; Mechanical Pain Sensitivity; Dynamic Mechanical Allodynia)

Select all which apply
Time to collect this data
Cost of equipment
Reduced confidence using the equipment or interpreting data collected
They are more useful for researchers than clinicians in practice
Prioritising other assessment metrics when forming a cervical spine radiculopathy diagnosis
Availability of equipment

Possible Facilitators, Somatosensory Assessment Methods
18.What do you think could improve the use of somatosensory assessment methods listed below when establishing a cervical spine radiculopathy diagnosis?

(Pressure Pain Threshold; Pressure Detection Threshold; Heat Pain Threshold; Heat Detection Threshold; Cold Pain Threshold; Cold Detection

Threshold; Temporal Summation; Conditioned Pain Modulation; Vibration Detection Threshold; Mechanical Pain Sensitivity; Dynamic Mechanical Allodynia)

Select all which apply
Additional time in clinic to complete
Further training on how to use and data interpretation
Further training on when to use
Reduction in equipment costs

Diagnosis Methods - Imaging
19.Do you use these imaging modalities when establishing a cervical spine radiculopathy diagnosis?

	Always use	Often use	Sometimes use	Rarely use	Heard of this imaging modality, but do not use	Not heard of this imaging modality
Magnetic Resonance Imaging (MRI)						
Computed Tomography (CT)						
Nerve Conduction Studies (NCS)						
Plain Radiograph						

Diagnosis, Screening Tools or Questionnaires
20.Do you use these screening tools or questionnaires when making a diagnosis of cervical spine radiculopathy?

	Always use	Often use	Sometimes use	Rarely use	Heard of this but do not use	Not heard of this
Douleure Neuropathique en 4 questions (DN4)						
The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS)						

	Always use	Often use	Sometimes use	Rarely use	Heard of this but do not use	Not heard of this
PainDETECT						
Neuropathic Pain Questionnaire (NPQ)						
ID-Pain						

21.Why do you think these screening tools or questionnaires are *rarely used or not used* in clinical practice when establishing a cervical spine radiculopathy diagnosis

Select all which apply
Reduced time available to collect this data
Confidence using or interpreting data collected in screening tools
They are more useful for researchers than clinicians in practice
Prioritising other assessment metrics when forming a cervical spine radiculopathy diagnosis

Possible Facilitators, Screening Tools or Questionnaires

22.What do you think could improve the usage of **screening tools or questionnaires** when establishing a cervical spine radiculopathy diagnosis?

Select all which apply
Free online access to screening tools
Additional time in clinic to complete
Further training on how to use and data interpretation
Further training on when to use

Completion and Exit Page

Thank you for taking the time to complete this survey.

As the data is anonymised at the point of submission of the survey, you will not be able to withdraw your responses (data) from the study after that point once you submit your survey.

If you have any queries or concerns about this survey, please contact Michael Mansfield (Michael.mansfield@uea.ac.uk)

Please ensure you have clicked the submit button to exit the survey

23.A follow up interview study will be conducted to explore the responses by participants from this survey.

Please provide your email address below if you are happy to be contacted about this interview study:

24.If you are happy to receive a report of the survey results, please enter your email address below:

Appendix 5.9. Ethics decision letter

University of East Anglia

University of East Anglia
Norwich Research Park
Norwich. NR4 7TJ

Email: ethicsmonitor@uea.ac.uk
Web: www.uea.ac.uk

Study title: Retrospective Review - Understanding cervical spine radiculopathy assessment practices among United Kingdom Physiotherapists. A national online survey

Application ID: ETH2122-0455

Dear Michael,

Your application and amendments were considered on 24th January 2022 by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee).

The decision is: **approved**.

You are therefore able to start your project subject to any other necessary approvals being given.

It is a requirement of this ethics approval that you should report any adverse events which occur during your project to the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) as soon as possible. An adverse event is one which was not anticipated in the research design, and which could potentially cause risk or harm to the participants or the researcher, or which reveals potential risks in the treatment under evaluation. For research involving animals, it may be the unintended death of an animal after trapping or carrying out a procedure.

Any amendments to your submitted project in terms of design, sample, data collection, focus etc. should be notified to the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) in advance to ensure ethical compliance. If the amendments are substantial a new application may be required.

Approval by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) should not be taken as evidence that your study is compliant with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. If you need guidance on how to make your study UK GDPR compliant, please contact the UEA Data Protection Officer (dataprotection@uea.ac.uk).

Please can you send your report once your project is completed to the FMH S-REC (fmh.ethics@uea.ac.uk).

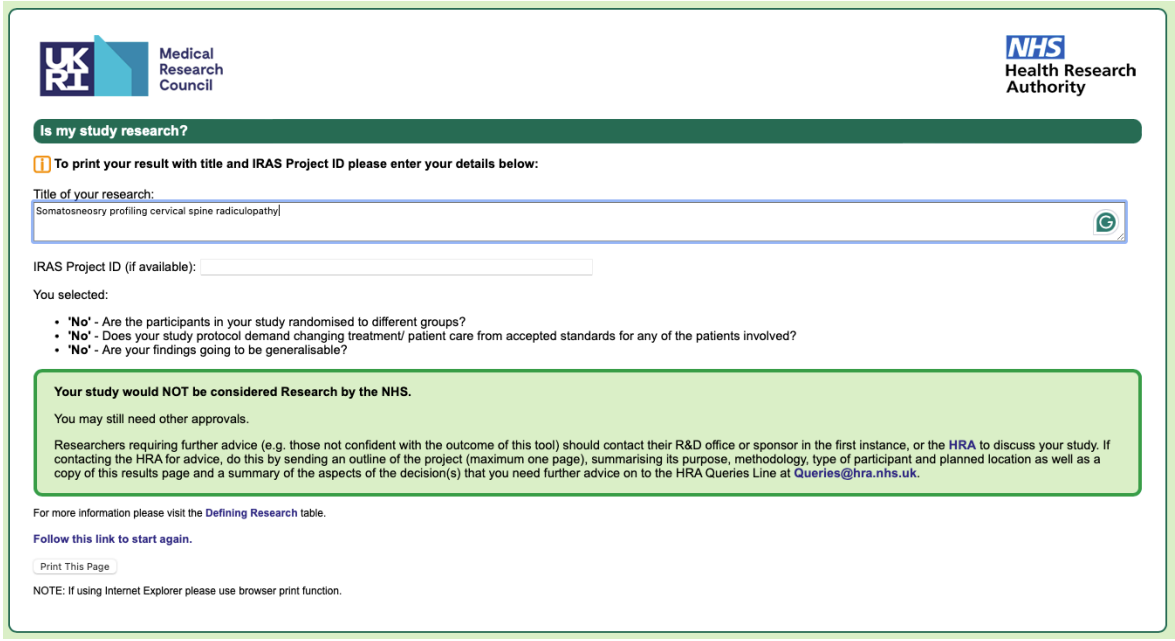
I would like to wish you every success with your project.

On behalf of the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee)

Yours sincerely,

Paul Linsley

Appendix 5.10. Health research authority decision-making tool outcome. Completed on 3rd October 2022



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

Somatosneosry profiling cervical spine radiculopathy

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

For more information please visit the Defining Research table.

Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

Appendix 5.11. Participant information sheet

Participant Information Sheet (PIS)

Michael Mansfield
PhD Student. HSC - Postgraduate Researcher

School of Health Sciences

University of East Anglia
Norwich Research Park
Norwich NR4 7TJ

23rd November 2021

Understanding cervical spine radiculopathy assessment practices among Physiotherapists from the United Kingdom

PARTICIPANT INFORMATION SHEET

(1) What is this study about?

You are invited to take part in a research study about contemporary assessment strategies used by physiotherapists when reaching a cervical spine radiculopathy diagnosis. Identifying contemporary assessment strategies will shape learning and training development areas for qualified clinicians and shape future research agendas.

You have been invited to participate in this study because you have accessed it via social media. The project is entirely voluntary.

This Participant Information Sheet tells you about the research study. Knowing what is involved will help you decide if you want to take part in the study. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about (Email: Michael.mansfield@uea.ac.uk).

Participation in this research study is voluntary. By giving consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.
- ✓ You have received a copy of this Participant Information Sheet to keep.

(2) Who is running the study?

The study is being carried out by the following researcher Mr. Michael Mansfield (Michael.mansfield@uea.ac.uk). This study will take place under the supervision of Dr. Toby Smith (Toby.smith@uea.ac.uk, +44 (0) 1603 593087)

(3) What will the study involve for me?

You will be asked to complete a 20-minute survey online. You will be asked questions about yourself, your current professional role, years of experience and academic qualifications. We will ask you your own perceived confidence in assessing cervical spine radiculopathy. We will also ask you what physical assessment methods and screening questionnaires you use in your clinical practice. We will ask you what the facilitators and barriers using physical assessment, imaging modalities and diagnostic screening tools in practice.

No information provided will be passed to any third parties. Your data will then be analysed by researchers from UEA and will be published in scientific papers and conferences. Nobody will be able to identify you from any materials we publish or present from this study.

If you wish to be considered for further interview and/or receive a report of the survey results we will require your email address. We will not use your email address for any other purpose. We will not share this email address with any other people or organisations.

This study has received approval from the University of East Anglia's Faculty of Medicine and Health Science's Research Ethics Committee.

(4) How much of my time will the study take?

The total time commitment will be 20 minutes.

(5) Do I have to be in the study? Can I withdraw from the study once I have started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of East Anglia now or in the future.

If you decide to take part in the study, you can withdraw your consent up to the point that your data is fully anonymised. You can do this by exiting the online survey without submitting.

(6) What are the consequences if I withdraw from the study?

If you decide to take part in the study and then change your mind, you are free to withdraw at any time before you have submitted the survey. Once you have submitted it, your responses cannot be withdrawn because they are anonymous and therefore, we will not be able to tell which one is yours.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

By participating in this study there will be potential future benefit in enhancing future education implementation strategies in Physiotherapy pre and post registration curriculums

(9) What will happen to information provided by me and data collected during the study?

Your personal data and information will only be used as outlined in this Participant Information Sheet, unless you consent otherwise. Data management will follow the Data Protection Act 2018 (DPA 2018) and UK General Data Protection Regulation (UK GDPR), and the University of East Anglia's Research Data Management Policy.

The information you provide will be stored securely and your identity will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be identified in these publications if you decide to participate in this study. Study data may also be deposited with a repository to allow it to be made available for scholarly and educational purposes. The data will be kept for at least 10 years beyond the last date the data were accessed. The deposited data will not include your name or any identifiable information about you.

(10) What if I would like further information about the study?

When you have read this information, Michael Mansfield (Michael.mansfield@uea.ac.uk) will be available to discuss it with you further and answer any questions you may have about the study.

(11) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can receive feedback from Michael Mansfield (Michael.mansfield@uea.ac.uk). If you wish to receive this report, please click the link at the end of the survey to download a PDF document. We will not use your email address for any other purpose. We will not share this email address with any other people or organisations.

When the survey analysis is completed the UEA research team will email you with the survey report. We anticipate this to be in August 2022.

(12) What if I have a complaint or any concerns about the study?

If there is a problem, please let me know. You can contact me via the University at the following address:

Mr. Michael Mansfield
PhD Student. Postgraduate Researcher.
School of Health Sciences
University of East Anglia
NORWICH NR4 7TJ
Michael.mansfield@uea.ac.uk

If you would like to speak to someone else, you can contact the study research supervisor: Dr. Toby Smith

Toby.smith@uea.ac.uk
+44 (0) 1603 593087

If you are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact:
Prof. Sally Hardy, Dean of Health Sciences
S.hardy@uea.ac.uk

(13) How do I know that this study has been approved to take place?
To protect your safety, rights, wellbeing and dignity, all research in the University of East Anglia is reviewed by a Research Ethics Body. This research was approved by Faculty of Medicine and Health Sciences Research Ethics Committee

(14) What is the general data protection information I need to be informed about? According to data protection legislation, we are required to inform you that the legal basis for processing your data as listed in Article 6(1) of the UK GDPR is because this allows us to process personal data when it is necessary to perform our public tasks as a university.

In addition to the specific information provided above about why your personal data is required and how it will be used, there is also some general information which needs to be provided for you:

The data controller is the University of East Anglia.
For further information, you can contact the University's Data Protection Officer at dataprotection@uea.ac.uk
You can also find out more about your data protection rights at the Information Commissioner's Office (ICO).
If you are unhappy with how your personal data has been used, please contact the University's Data Protection Officer at dataprotection@uea.ac.uk in the first instance.

(15) OK, I want to take part – what do I do next?
If you are happy and consent to take part in the study, simply access the survey at this website https://forms.office.com/r/Vi60hEYLi4 and answer the questions.

By submitting your responses, you are agreeing to the researcher using the data collected for the purposes described above.

(16) Further information
This information was last updated on 23rd November 2021

Appendix 5.12. Online consent form

University of East Anglia
School of Health Sciences

CONSENT FORM

Title of project: Understanding cervical spine radiculopathy assessment practices among United Kingdom Physiotherapists. A national online survey

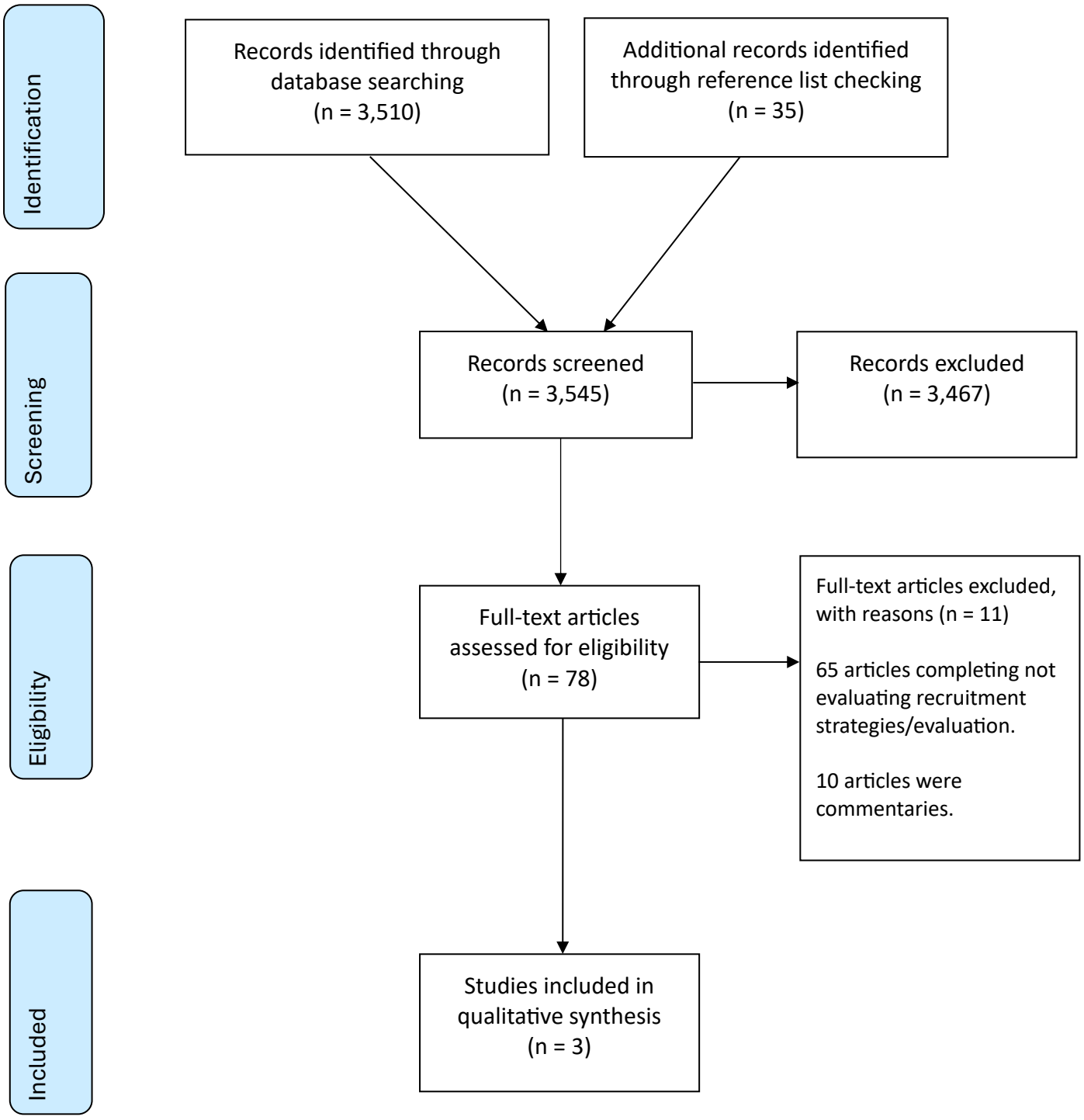
Name of lead researcher: Michael Mansfield (Michael.mansfield@uea.ac.uk)

	YES / NO
I confirm that I have read and understood the information sheet for the above project. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.	
I consent voluntarily to be a participant in this project and understand that I can refuse to take part and can withdraw from the project at any time, without having to give a reason.	
I consent to the processing of my personal information for the purposes explained to me in the Participation Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018.	
I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs	
I agree to take part in the above study	

Appendix 5.13. Search Strategy – Medline

Search term (All free text, Any field, Limited to last 15 years)	Records retrieved
1) Social media	44,743
2) Twitter	9,679
3) Instagram	1,959
4) Facebook	6,605
5) Survey recruitment	52,159
6) Response rate	189,052
7) OR/1-4	51,561
8) OR/5-6	239,073
9) 7 AND 8	3,510

Appendix 5.14. PRISMA (2009) diagram for study selection



Appendix 5.15. iCSP forum advert

We are conducting an online survey from the University of East Anglia to understand the contemporary practices of physiotherapists when assessing and managing people with cervical spine radiculopathy.

We would like to know what physical and somatosensory assessment strategies are used in clinical practice for cervical spine radiculopathy.

The survey will take approximately 20 minutes to complete and is completely confidential (unless you wish to disclose your email address).

If you would like to take part, please access our online survey directly to complete it at https://forms.office.com/r/Vi60hEYLi4 or for further details you can email the lead researcher Mr. Michael Mansfield (Michael.mansfield@uea.ac.uk)

Thank you for considering and all best wishes,

Michael Mansfield

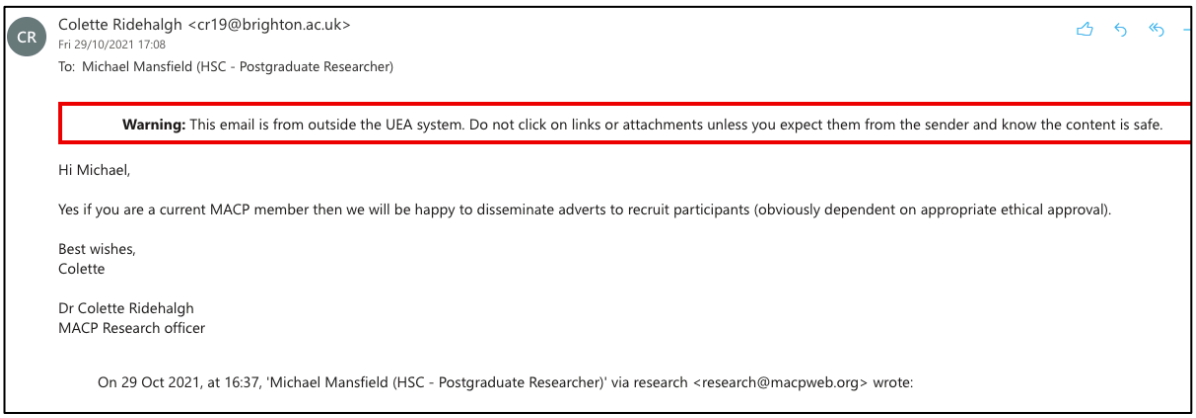
PhD Student

HSC - Postgraduate Researcher

University of East Anglia, Norwich, UK

Appendix 5.16. Evidence of survey dissemination support

Musculoskeletal Association of Chartered Physiotherapists (MACP)



CR

Colette Ridehalgh <cr19@brighton.ac.uk>
Fri 29/10/2021 17:08
To: Michael Mansfield (HSC - Postgraduate Researcher)

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

Hi Michael,

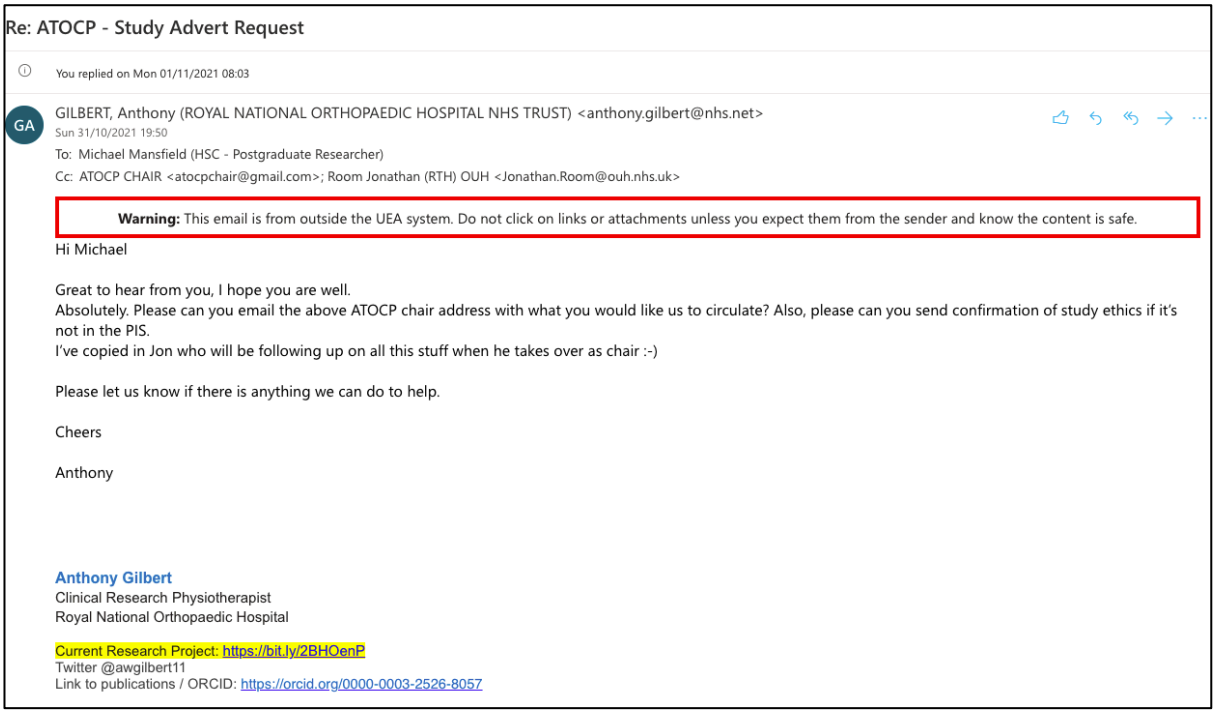
Yes if you are a current MACP member then we will be happy to disseminate adverts to recruit participants (obviously dependent on appropriate ethical approval).

Best wishes,
Colette

Dr Colette Ridehalgh
MACP Research officer

On 29 Oct 2021, at 16:37, 'Michael Mansfield (HSC - Postgraduate Researcher)' via research <research@macpweb.org> wrote:

Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP)



Re: ATOCP - Study Advert Request

You replied on Mon 01/11/2021 08:03

GA

GILBERT, Anthony (ROYAL NATIONAL ORTHOPAEDIC HOSPITAL NHS TRUST) <anthony.gilbert@nhs.net>
Sun 31/10/2021 19:50
To: Michael Mansfield (HSC - Postgraduate Researcher)
Cc: ATOCP CHAIR <atocpchair@gmail.com>; Room Jonathan (RTH) OUH <Jonathan.Room@ouh.nhs.uk>

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

Hi Michael

Great to hear from you, I hope you are well.
Absolutely. Please can you email the above ATOCP chair address with what you would like us to circulate? Also, please can you send confirmation of study ethics if it's not in the PIS.
I've copied in Jon who will be following up on all this stuff when he takes over as chair :-)

Please let us know if there is anything we can do to help.

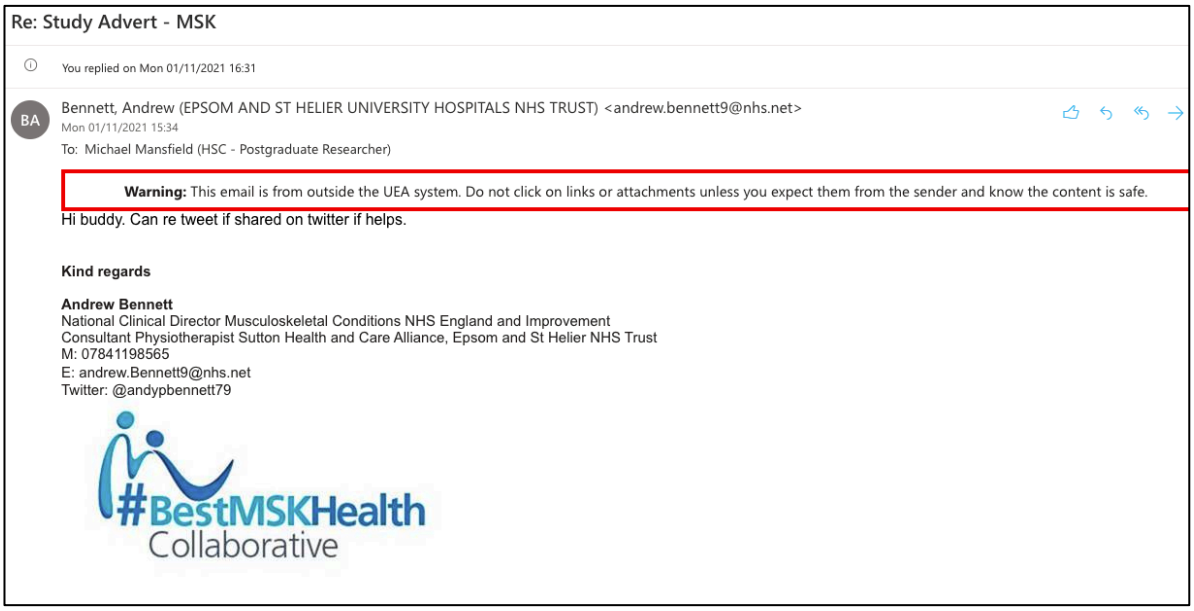
Cheers

Anthony

Anthony Gilbert
Clinical Research Physiotherapist
Royal National Orthopaedic Hospital

Current Research Project: https://bit.ly/2BHOenP
Twitter @awgilbert11
Link to publications / ORCID: https://orcid.org/0000-0003-2526-8057

National Clinical Director of Musculoskeletal Conditions – NHS England



Re: Study Advert - MSK

You replied on Mon 01/11/2021 16:31

BA Bennett, Andrew (EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST) <andrew.bennett9@nhs.net>
Mon 01/11/2021 15:34
To: Michael Mansfield (HSC - Postgraduate Researcher)

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

Hi buddy. Can re tweet if shared on twitter if helps.

Kind regards

Andrew Bennett
National Clinical Director Musculoskeletal Conditions NHS England and Improvement
Consultant Physiotherapist Sutton Health and Care Alliance, Epsom and St Helier NHS Trust
M: 07841198565
E: andrew.Bennett9@nhs.net
Twitter: @andypbennett79

#BestMSKHealth Collaborative

Physiotherapy Research Society (PRS)



Re: Physiotherapy Research Society - Study Advert

You replied on Fri 05/11/2021 11:26

AA Ali Aries <a.m.aries@keele.ac.uk>
Fri 05/11/2021 10:24
To: Michael Mansfield (HSC - Postgraduate Researcher)
Cc: Caroline Belchamber <CBelchamber@aecc.ac.uk>

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

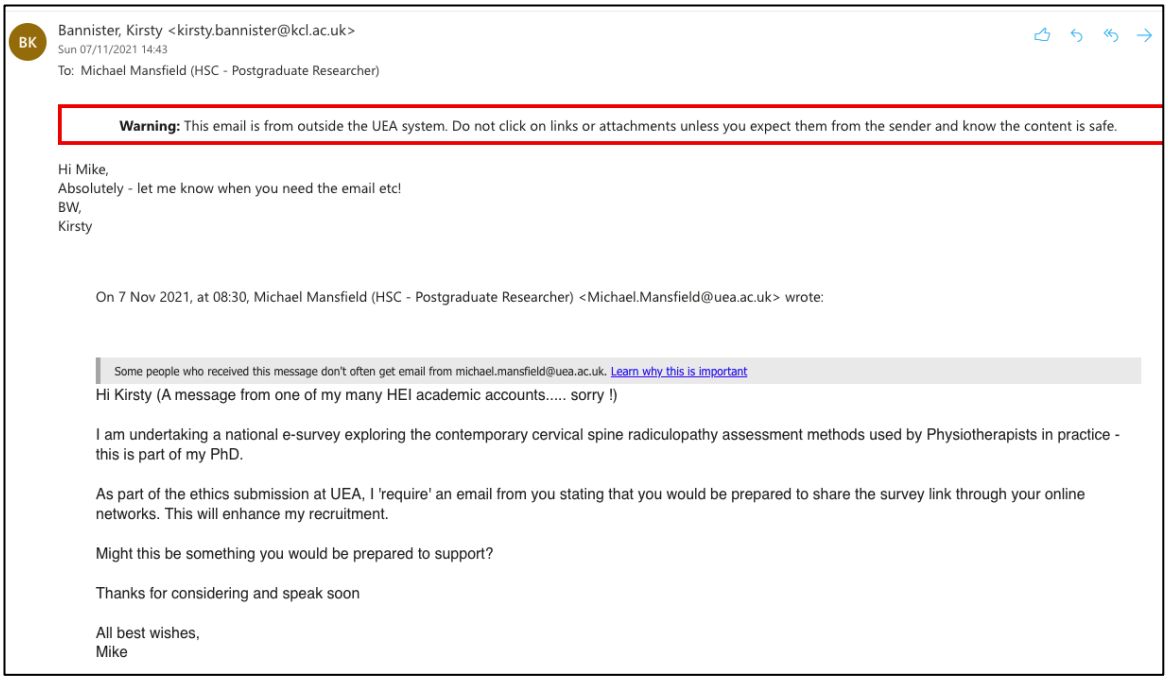
Dear Mike,
If you send the advert Caroline will forward it to our PRS members.
Best wishes
Ali

Dr Alison Aries PhD MCSP
Lecturer/Senior Tutor/Impact Accelerator Unit link/Patient and Public Involvement Advisor for SAHP
School of Allied Health Professions (SAHP), MacKay Building, Keele University, Keele, Staffordshire, UK ST5 5BG
Tel: +44 (0) 1782 734418 | Email: a.m.aries@keele.ac.uk | www.keele.ac.uk

Also,
Clinical Academic (Neurology)
Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road,
Heath Town,
Wolverhampton,
West Midlands, WV10 0QP
Tel: 01902 695597

Chair for the Physiotherapy Research Society (PRS)
Website: https://prs.csp.org.uk
Twitter: @PhysioResSoc

Bannister Lab – Kings College London



Bannister, Kirsty <kirsty.bannister@kcl.ac.uk>
Sun 07/11/2021 14:43
To: Michael Mansfield (HSC - Postgraduate Researcher)

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

Hi Mike,
Absolutely - let me know when you need the email etc!
BW,
Kirsty

On 7 Nov 2021, at 08:30, Michael Mansfield (HSC - Postgraduate Researcher) <Michael.Mansfield@uea.ac.uk> wrote:

Some people who received this message don't often get email from michael.mansfield@uea.ac.uk. Learn why this is important

Hi Kirsty (A message from one of my many HEI academic accounts..... sorry !)

I am undertaking a national e-survey exploring the contemporary cervical spine radiculopathy assessment methods used by Physiotherapists in practice - this is part of my PhD.

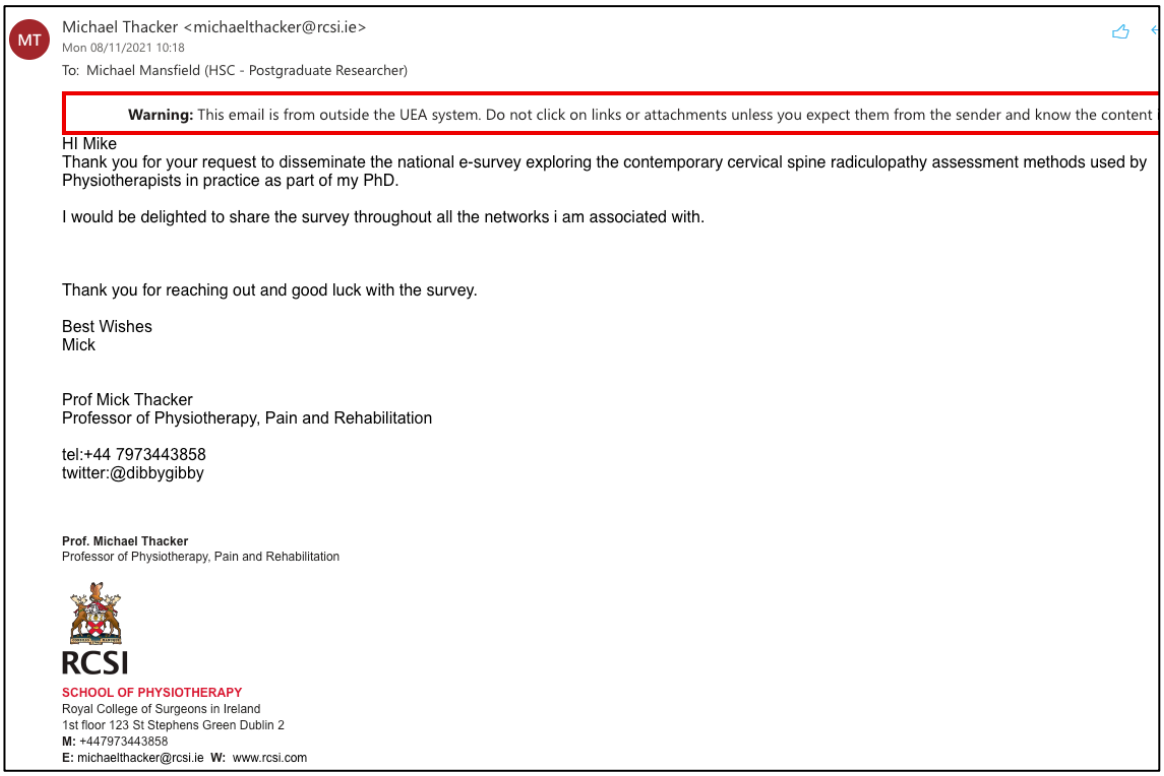
As part of the ethics submission at UEA, I 'require' an email from you stating that you would be prepared to share the survey link through your online networks. This will enhance my recruitment.

Might this be something you would be prepared to support?

Thanks for considering and speak soon

All best wishes,
Mike

Prof. Mick Thacker



Michael Thacker <michaelthacker@rcsi.ie>
Mon 08/11/2021 10:18
To: Michael Mansfield (HSC - Postgraduate Researcher)

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content

HI Mike
Thank you for your request to disseminate the national e-survey exploring the contemporary cervical spine radiculopathy assessment methods used by Physiotherapists in practice as part of my PhD.

I would be delighted to share the survey throughout all the networks i am associated with.

Thank you for reaching out and good luck with the survey.

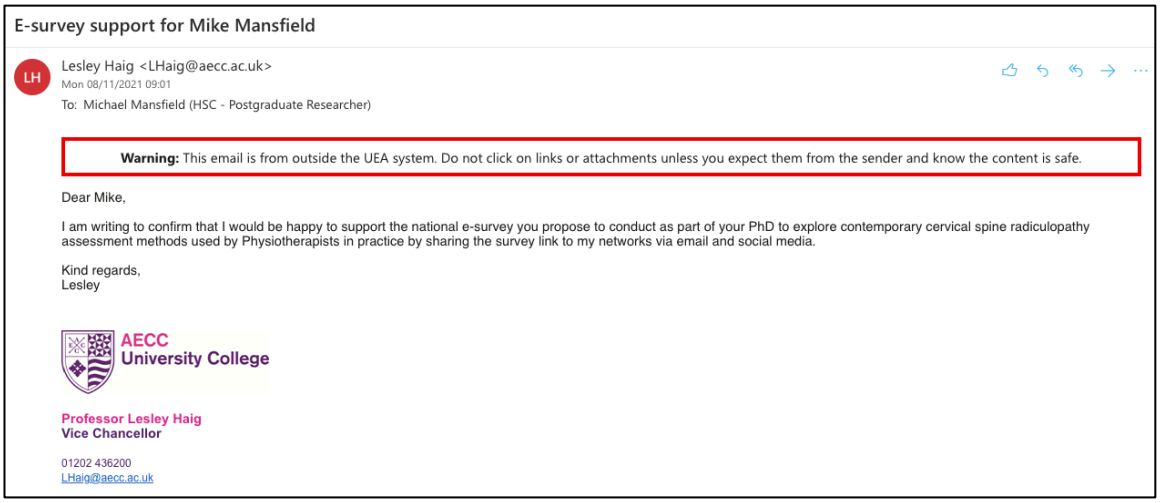
Best Wishes
Mick

Prof Mick Thacker
Professor of Physiotherapy, Pain and Rehabilitation

tel:+44 7973443858
twitter:@dibbygibby

Prof. Michael Thacker
Professor of Physiotherapy, Pain and Rehabilitation

RCSI
SCHOOL OF PHYSIOTHERAPY
Royal College of Surgeons in Ireland
1st floor 123 St Stephens Green Dublin 2
M: +447973443858
E: michaelthacker@rcsi.ie **W:** www.rcsi.com



E-survey support for Mike Mansfield

LH

Lesley Haig <LHaig@aecc.ac.uk>
Mon 08/11/2021 09:01
To: Michael Mansfield (HSC - Postgraduate Researcher)

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

Dear Mike,

I am writing to confirm that I would be happy to support the national e-survey you propose to conduct as part of your PhD to explore contemporary cervical spine radiculopathy assessment methods used by Physiotherapists in practice by sharing the survey link to my networks via email and social media.

Kind regards,
Lesley

AECC
University College

Professor Lesley Haig
Vice Chancellor

01202 436200
LHaig@aecc.ac.uk

Appendix 5.17. Summary of multi-modal recruitment strategy

Parties delivering the survey invitation on behalf of the study team	**Mode of advertisement**	**Relevance to target population**
Musculoskeletal Association of Chartered Physiotherapists	Twitter dissemination, Email mailing list, Online advert posting	Professional network
Physiotherapy Research Society	Twitter dissemination, Email mailing list	Professional network
Association of Trauma and Orthopaedic Chartered Physiotherapists	Twitter dissemination, Email mailing list	Professional network
Interactive Chartered Society of Physiotherapy – iCSP forum	Online advert	Professional membership website
Research group: Bannister Laboratory, Kings College London	Twitter dissemination, In person research group meetings	Targeting professional networks, societies and individuals
Research group: Centre of Precision Rehabilitation for Spinal Pain, University of Birmingham	Twitter dissemination, In person research group meetings	Targeting professional networks, societies and individuals
Individual: Michael Mansfield	Twitter dissemination	Targeting online professional networks, societies and individuals
Individual: Toby Smith	Twitter dissemination	Targeting online professional networks, societies and individuals
Individual: Mick Thacker	Twitter dissemination	Targeting online professional networks, societies and individuals
Individual: Andrew Bennett	Twitter dissemination	Targeting online professional networks, societies and individuals

Individual: Lesley Haig	Twitter dissemination	Targeting online professional networks, societies and individuals

Appendix 6.1. Search strategy – Medline

Search conducted on 20th August 2023

Search term (Title and/or abstract)	Records retrieved
1. Neck pain	**12,798**
2. Low back pain	**34,860**
3. Spinal pain	**28,701**
4. Nerve* entrapment OR Radicular OR Referred Pain OR radiculopathy OR Nerve root inflammation OR Nerve root compression	**46,149**
5. OR/1-4	**100,980**
6. Qualitative	**402,830**
7. Interview	**245,072**
8. OR/6-7	**595,588**
9. 5 AND 8	**2,484**

Appendix 6.2. Piloting feedback

Prompting questions:

- Do the respondents understand each question?
- Is there enough 'blank space' in the interview for pause and reflection?
- How was the interviewer's questioning and listening style?
- Does the interview have any double negative/positive phrasing or repetitive questioning?
- Is there too little/too much time for the interview?

	Summary feedback
Physiotherapist 1	Each question clear and easy to understand. Follow up questions delivered calming generated reflection on current practice. No obvious double-barrelled questions Interview length is just about right. Many clinicians won't give more time if during the day. It felt as if there was enough time to discuss all concepts without being rushed. The bit at the end around anything missed was a good touch and gave opportunity to discuss any more points
Physiotherapist 2	All questions are appropriate for research objectives. Friendly, reflective manner to questioning style Important to provide clarification on specific sensory tests; not all physios will know what they are. Didn't feel as if I was justifying my own practice, felt like a discussion between two peers justifying external findings from survey No obvious unnecessary repetition. I enjoyed the reflection and justification process

Appendix 6.3. Interview questions and topic guide

Key quantitative finding from survey	**Questions**
N/A	*WARM UP STATEMENTS AND QUESTIONS:* Thanking the participant Outlining that there were no right or wrong answers to any of the questions Only interested in their thoughts, experiences and opinions Tell me about your current working clinical environment working as a Physiotherapist. What presentations do you typically see? What age groups do predominantly work with? _____ What is your experience of assessing and/or treating people with cervical spine radiculopathy? Prompt: How often do you assess and/or treat people with cervical spine radiculopathy?
Nearly all UK physiotherapists who completed the	Can you tell me about the assessment strategies you use to diagnose cervical spine radiculopathy (CSR)?

survey indicated they always use myotomes (muscle strength), reflexes and light touch sensation assessment strategies when establishing a CSR diagnosis	- Are there particular clinical signs, symptoms or features that outweigh others in establishing a CSR diagnosis? - **Why are these important?** - Are there any instances when you might adapt this assessment practice?
Pain screening questionnaires are not routinely used in practice when establishing CSR	What is your approach when assessing a person's CSR sensory experience? - What prompts you to complete this? - Have you always done this? Why is that important in forming a CSR diagnosis? Stepping away from your own practice, our survey suggests that UK Physiotherapists do not use pain screening questionnaires when establishing a cervical spine radiculopathy diagnosis. We'd like you to help us unpack why this may be the case. - Prompts if needed: What are your thoughts on this survey finding?
Reasons why physiotherapists do not use pain screening questionnaires when establishing CSR:	Our survey explored the reasons why UK Physiotherapists do not use pain screening questionnaires in clinical practice Again, we'd like you to help us unpack the reasons why physiotherapists do not use pain screening questionnaires. What are your thoughts about this finding?

Time in the clinic; Questionnaire availability; Knowledge around interpreting pain screening questionnaire findings	Does this relate to your clinical practice? - Why? - Tell me more about this
Somatosensory testing parameters are not routinely used in practice when establishing CSR	What is your approach when assessing a person's somatosensory nervous system function/dysfunction? - What prompts you to complete this? - Have you always done this? - Why is that important when establishing a CSR diagnosis? - When do you adapt your somatosensory assessment? Stepping away from your own practice, our survey found that UK Physiotherapists do not use somatosensory testing parameters when establishing a cervical spine radiculopathy diagnosis. What are your thoughts on this survey finding? Is this something you can relate to in your clinical practice?

Reasons why physiotherapists do not use somatosensory tests when establishing CSR: *Time in the clinic; Equipment availability; Knowledge around interpreting somatosensory test parameter findings; Usefulness in clinical setting*	What are your thoughts on the reasons why physiotherapists do not use these test parameters? Does this relate to your clinical practice? - **Why?** - Tell me more about this
Facilitators	
Reasons which might support the use of pain screening tools in clinic: *Free online access; additional time in clinic; further training on how to use and data interpretation*	Our survey explored the reasons why UK Physiotherapists may adopt pain screening questionnaires when establishing CSR What are your thoughts on what could facilitate the use of these pain screening questionnaires in practice? How could these strategies be implemented in clinical practice?

Reasons which might support the use of somatosensory test parameters in clinic: *Free online access; additional time in clinic; further training on how to use and data interpretation*	Our survey explored what might facilitate UK Physiotherapists to adopt somatosensory test parameters when establishing CSR What are your thoughts on might facilitate the use of these somatosensory test parameters in practice? How could these strategies be implemented in clinical practice?

Appendix 6.4. Participant information sheet interviews

Participant Information sheet

Michael Mansfield
PhD Student. HSC
Postgraduate Researcher

School of Health Sciences
University of East Anglia
Norwich Research Park
Norwich NR4 7TJ
United Kingdom

Email: Michael.mansfield@uea.ac.uk

Web: www.uea.ac.uk

Understanding cervical spine radiculopathy assessment practices among Physiotherapists. A qualitative study

PARTICIPANT INFORMATION SHEET

(1) What is this study about?

You are invited to take part in a research study about contemporary assessment strategies used by physiotherapists when reaching a cervical spine radiculopathy diagnosis. Identifying and understanding contemporary assessment strategies will shape learning and training development areas for qualified clinicians and shape future research agendas.

You have been invited to participate in this study because you have previously completed an e-survey and indicated that you are happy to be contacted for the follow up interview study. The project is entirely voluntary. There is no expectation to have read the previous e-survey.

This Participant Information Sheet tells you about the research study. Knowing what is involved will help you decide if you want to take part in the study. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary. By giving consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.
- ✓ You have received a copy of this Participant Information Sheet to keep.

(2) Who is running the study?

The study is being carried out by PhD Student researcher Mr. Michael Mansfield (michael.mansfield@uea.ac.uk).

This study will take place under the supervision of Professor Toby Smith (toby.smith@uea.ac.uk, +44 (0) 1603 593087)

(3) What will the study involve for me?

You will be invited to complete a 45-minute online one-to-one interview with Mr. Michael Mansfield (University of East Anglia PhD Student). We will ask you about your own perceived confidence in assessing cervical spine radiculopathy. We will also ask you what physical assessment methods and screening questionnaires you use in your clinical practice. We will ask you what the barriers and solutions using physical assessment and diagnostic screening tools or questionnaires in practice. An audio and video recording of the interview will be recorded through Microsoft Teams platform.

No information provided will be passed to any third parties. Your data will then be analysed by researchers from UEA and will be published in scientific papers and conferences. You have been invited to participate in this study because you have previously completed an e-survey. The following answers you have provided in the e-survey will be used to characterise the sample of people interviewed in this study, when reporting the results of this qualitative interview:

- Geographical location of work.
- Professional working area.
- Years of experience postgraduation.
- Highest academic qualification.
- Proportion of current working time spent assessing and treating people with cervical spine pain with or without radiculopathy.
- Self-rated confidence assessing a person with cervical spine radiculopathy.

Whilst this will allow us to understand the people included in this interview study, we will ensure that it will not be possible to identify you when reporting these findings in any papers, reports or outputs made from this study. Through this, the interview transcripts will be anonymised so that you cannot be recognised from any of the information we collect from you. Any summary interview content, or direct quotations from the interview, that are made available through academic publication or other academic outlets will be anonymised so that you cannot be identified.

There will be an opportunity for participants to review the interview transcripts for accuracy generated about them prior to publication. If you would like to complete this please provide your email address.

If you wish to receive a report of the interview results we will require your email address. We will not use your email address for any other purpose. We will not share this email address with any other people or organisations.

This study has received approval from the University of East Anglia's Faculty of Medicine and Health Science's Research Ethics Committee.

(4) How much of my time will the study take?

The maximum total time commitment will be 135 minutes. Forty-five minutes will be allocated for the interview and up to 90 minutes to review the interview recording (if you choose to complete this aspect).

(5) Do I have to be in the study? Can I withdraw from the study once I have started?
Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of East Anglia now or in the future.

If you choose not to participate in this study, do not submit a consent form. You can still choose to withdraw your consent up to the point that your data is fully anonymised. This can be completed by informing the lead researcher, Michael Mansfield, by email (Michael.mansfield@uea.ac.uk) that you withdraw your consent.

(6) What are the consequences if I withdraw from the study?

You are free to stop the interview at any time. Unless you say that you want us to keep them, any recordings will be erased and the information you have provided will not be included in the study results. You may also refuse to answer any questions that you do not wish to answer during the interview. If you decide at a later time to withdraw from the study your information will be removed from our records and will not be included in any results, up to the point we have analysed and published the results.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

By participating in this study there will be potential future benefit in enhancing future education implementation strategies in physiotherapy pre and post registration curriculums

(9) What will happen to information provided by me and data collected during the study?

Your personal data and information will only be used as outlined in this Participant Information Sheet, unless you consent otherwise. Data

management will follow the Data Protection Act 2018 (DPA 2018) and UK General Data Protection Regulation (UK GDPR), and the University of East Anglia's Research Data Management Policy.

The information you provide will be stored securely and your identity will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be identified in these publications if you decide to participate in this study.

Study data may also be deposited with secure password protected University of East Anglia OneDrive software repository to allow it to be made available for scholarly and educational purposes. The data will be kept for at least 10 years beyond the last date the data were accessed. The deposited data will not include your name or any identifiable information about you. This will be managed by the research team only which is protected through the UEA password protection system. Once all data has been processed and the findings disseminated, the study data will be stored for 10 years and deleted by the primary supervisor (Prof. Toby Smith).

(10) What if I would like further information about the study?

When you have read this information, Michael Mansfield (Michael.mansfield@uea.ac.uk) will be available to discuss it with you further and answer any questions you may have about the study.

(11) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can receive feedback from PhD Student Michael Mansfield (Michael.mansfield@uea.ac.uk). The interview results and analysis will be emailed to you. If you wish to receive this report, please provide your email address at the end of the interview. We will not use your email address for any other purpose. We will not share this email address with any other people or organisations.

When the survey analysis is completed the UEA research team will email you with the interview report. We anticipate this to be in May 2023.

(12) What if I have a complaint or any concerns about the study?

If there is a problem, please let me know. You can contact me via the University at the following address:
Mr. Michael Mansfield
PhD Student. Postgraduate Researcher.
School of Health Sciences, University of East
Anglia NORWICH NR4 7TJ.
Email: Michael.mansfield@uea.ac.uk

If you would like to speak to someone else, you can contact the study research supervisor:

Prof. Toby Smith (toby.smith@uea.ac.uk, +44 (0) 1603 593087)

If you are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact Prof. Sally Hardy (Dean Health Sciences) s.hardy@uea.ac.uk

(13) How do I know that this study has been approved to take place?

To protect your safety, rights, wellbeing and dignity, all research in the University of East Anglia is reviewed by a Research Ethics Body. This research was approved by Faculty of
Medicine and Health Sciences Research Ethics Committee

(14) What is the general data protection information I need to be informed about?

According to data protection legislation, we are required to inform you that the legal basis for processing your data as listed in Article 6(1) of the UK GDPR is because this allows us to process personal data when it is necessary to perform our public tasks as a university.

In addition to the specific information provided above about why your personal data is required and how it will be used, there is also some general information which needs to be provided for you: The data controller is the University of East Anglia.
For further information, you can contact the University's Data Protection Officer at dataprotection@uea.ac.uk

You can also find out more about your data protection rights at the Information Commissioner's Office (ICO).

If you are unhappy with how your personal data has been used, please contact the University's Data Protection Officer at dataprotection@uea.ac.uk in the first instance.

(15) OK, I want to take part – what do I do next?

If you are happy and consent to take part in the study, simply access the online consent form and answer the questions. By submitting your responses, you are agreeing to the researcher using the data collected for the purposes described above. Please keep the information sheet for your information.

(16) Further information

This information was last updated on 26th October 2022

Appendix 6.5. Online consent form

(https://forms.office.com/r/DPn39Xn0RR)

University of East Anglia
School of Health Sciences

ONLINE CONSENT FORM

Title of project: Understanding cervical spine radiculopathy assessment practices among United Kingdom Physiotherapists: A qualitative study

Name of lead researcher: Michael Mansfield (Michael.mansfield@uea.ac.uk). PhD Student, University of East Anglia.

	Click Yes
A. I confirm that I have read and understood the information sheet for the above project. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.	
B. I consent voluntarily to be a participant in this project and understand that I can refuse to take part and can withdraw from the project at any time, without having to give a reason.	
C. I consent to the processing of my personal information for the purposes explained to me in the Participation Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018.	
D. I understand that the information below has been collected in the e-survey I have previously completed. This information will be used to anonymously characterise my participation in this qualitative interview Geographical location of work. Professional working area. Years of experience post-graduation. Highest academic qualification. Proportion of current working time spent assessing and treating people with cervical spine pain with or without radiculopathy. Self-rated confidence assessing a person with cervical spine radiculopathy.	
E. The lead researcher will respect the confidentiality of all participants' information shared in the interview. I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs.	

F. I understand that the online interview may last up to 45 minutes.	
G. I understand that I may stop the interview at any time if I do not wish to continue, and that unless I indicate otherwise any recordings will then be erased and the information provided will not be included in the study results. I also understand that I may refuse to answer any questions I don't wish to answer.	
H. I understand that the results of this study will be used for a dissertation assessment but that it will not contain my name or any identifiable information about me.	
I. I consent to the interview being audio and video recorded	
J. I consent to my interview transcript being emailed to me	Yes or NO
K. If YES to (I). Please provide your email address here:	

Appendix 6.6. Qualitative interview field note example

Date of interview	4th October 2022
ID Number	001
First Impressions	Quiet individual although confident when discussing own practice. Eye contact made and happy to provide examples from past and present. A good start. Maybe knew what a qualitative interview is—PIS probably provided enough detail.
General Notes	Happy to discuss clinical practice and expectations from service leaders. Happy to discuss "unknown" factors related to diagnosis and challenging patient presentations. Focuses on how diagnosis informs treatment and work up for surgery As the interview progressed more talked and appeared comfortable with different approaches and unknown questionnaires/screening tool. Self-reflected on own practice and recognised gaps in knowledge—this is good! Open body language and head tilt when exploring opinions and reasoning.
Final Comments	Slow start but rapidly grew into the interview. The participant thanked for time and found the line of questioning "interesting".

Appendix 6.7. Excerpts from the lead researcher's reflective diary

Reflective thoughts post initial pilot study interview

I was apprehensive before the start of the pilot interview. The interviewee was experienced in qualitative research. Therefore, I did not want to "show myself up". The interview lasted 50 minutes and was completed electronically. I think I spent too much time ensuring that Wi-Fi connection was stable and there were no room interruptions my end. However, this preparation would be beneficial for the real thing. The opening statement set the scene well and the interviewee seems relaxed. This helped with my own demeanour. The topic guide was like a crib sheet throughout, I was really conscious not to keep looking at this and thinking about interesting follow up questions. Letting the interview be natural seemed to work. Wrapping up seemed a bit of challenge to me, coming to a natural conclusion was apparent but as this was a pilot interview it felt almost "unnatural to "return' to being colleagues again. The feedback provided was very kind and generous. This supported my confidence going forward.

Reflection from main data collection

10th October: Two interview have now been completed. I was pleased to have recruited and get things going. The first interview went well. The interviewee seems comfortable and relaxed throughout. The evening time after a busy clinic for this person probably helped. There were some great reflections around sensory testing going back and forth around education at PG level. I was conscious not to introduce any follow up questions with my own experience as an academic teaching on a programme. Fortunately, I managed to minimise this and

frame discussions back round to the survey. The 2nd interview required some probing in the first 15 minutes, I did have a thought that we may finish much earlier than expected but we seemed to settle into a groove at the 15minute marker. The interviewee was focussed on their own practice when offering explanation, which was ok at first, but I tried to make follow up questions specifically related to the survey and why might this be reported. By the mid-point of the interview this narrative from the interviewee changed and was much more reflective and explored possible reasons why with ease.

28th November. This is moving well, I am getting into a groove with follow up questions and framing them reflectively in a way in which shows I have listened but I would like to understand some more. This facilitated some interviewees to open up some more.

5th December: An interesting interview today. The interviewee had some medico-legal background. Answers were well constructed but almost had a position of defending decision making and exposing “poor” decision making from physiotherapists. We circled around the justification from a legal perspective, which was OK but I suppose I wasn’t entirely expecting this. The interviewee certainly had audio and visual presence throughout the e-interview. I hope I didn’t come across as nervous with this interview. I don’t think so as the interviewee stated at the end how much they enjoyed the conversation and could see real value in the reach I am leading… fascinating! I was not expecting that!

18th December: The interviewee declared without prompting that they were “newly qualified”. This threw me off rhythm because it almost felt like a “cry for help”. Despite this the interviewee had some fascinating insights around culture of departments and importance of research informed practice. I really enjoyed the discussion. The interviewee disclosed that while they did not know every test to diagnose CSR they were happy to learn and understand to support their own practice. Initially I took this as a sign of comfort in the interview process but I was conscious that the interview did not tun into a training session, so I adapted my questions around to focus on physios at different levels of experience to ascertain why practices were present.

3rd January: Last interview completed, what a relief! I reached a recruitment target goal and learnt about myself. An interesting introspective observation about interviewing as a researcher and interviewing as a clinician in practice with a patient. Something to think about with Steph perhaps? Trends in answers were becoming more apparent (for example, time and cost).

1st June: Meeting with Steph today – fantastic! Really got me thinking about developing my codes and themes. I felt a bit vulnerable with my A1 paper, highlighters and pens but this provided me confidence at my own analysis methods and justifying positioning. The drive made me fret a little about how “What if we have completely different viewpoints?” “How will we manage this?”. Having an “external” set of eyes challenged may thought processes and made me think deeper into the “why” question. There were some disagreements with phrasing, for example, the software/ICT item, but the break and follow-up

discussions ensured we reached an acceptable consensus. Furthermore, there was some obvious overlap (In reflection) with external influences from managers, guidelines and peers. This required discussion as there was a debate that they may fit under one theme. We sorted quotations that supported the categories and themes and discussed where this contextual overlap may be. This was an in-depth discussion that I was grateful for, as it supported me to think carefully about the construction and reconstruction of my own ideas and analysis – fruitful!

Appendix 6.8. An example excerpt of the codebook

Theme	Category	Code	Code definition	Example	Reference
Time	Reduced time in clinic	Limited time	Discussions and decision made by physiotherapists is impacted by the time in the clinical diary and patient contact time to select testing	"Most physio's will see 20 patients a day, the clinics are busy and sometimes limited to 20 minutes per patient" (PT 002)	PT 002 Lines 34-45 PT 004 Lines 89-100

Appendix 6.9. An excerpt of the audit decision-making

Individual quotes	MM Notes	Categories emerging	Central theme		MM and SJ Discussion Summary
"… they will describe sharp, stabbing, burning symptoms along their arm" (PT 007)	Describing nerve dysfunction at subjective assessment	Nerve pain descriptors	Understanding symptoms		Agreement. Explanation of nerve symptoms was frequently explained as important when establishing CSR.
"Well, they will do an upper limb tension test; the test result builds a picture for the physio's" (PT 005)	Physical testing to confirm/negate nervous system dysfunction	Neurological testing			Agreement. However, the justification of physical testing relied upon previous education and influences from senior staff/mentors. This may link with external factors and expectations theme.
"Its expected that reflex testing and muscle power would be reduced or gone…. This justifies a radiculopathy diagnosis" (PT 004)	Prediction of symptom response to testing	Mechanical vs neurogenic			Agreement. Interviewees explained how nerves respond to testing provided justification on why these tests were used. Interestingly, they were also explained from the perspective as an "ease" to complete in the clinical setting. Time availability and ease of testing was a frequent explainer when justifying survey findings.

Appendix 7.1. Free text answers (Somatosensory testing parameters)

Question 17 Why do you think the somatosensory assessment methods listed below are rarely used or not used in clinical practice when establishing a cervical spine radiculopathy diagnosis?

Participant ID	Free text response
1, 18	30 minute appointments leave little time Little time in clinic
16	Not useful to form a diagnosis
17	Not enough knowledge about this
24	No training in how to use
25	I'm not sure these tests would add anything to hypotheses formed from the subjective and myotomal, dermatomal and reflex findings
38	Lack of understanding of importance / poor training
42	Familiarity with what each method is designed to assess e.g. what fibres or pain mechanism does cold threshold assess
55	Purpose of current role is to diagnose and manage, and less often to treat, therefore focus on diagnostic. Useful to have baseline somatosensory data to gain whole picture of radiculopathy and track change in these markers with treatment. Somatosensory deficits usually less impacting on the patient than pain and weakness which are therefore treatment focus, and generally, from previous diligent tracking of sensory deficits they improve as pain improves so this reinforces this approach.

59	useful for differential testing or measuring change but other easier tests to complete and too time consuming to do all with each case

Free text answer (Somatosensory testing parameters)

18. What do you think could improve the use of somatosensory assessment methods listed below when establishing a cervical spine radiculopathy diagnosis?

ID	Response
16	Nothing. They are not required
17	Research underpinning these assessment
27	What would be the clinical benefit is this?
42	Exposure on educational courses
55	Research to support tracking this enhances current radiculopathy mgt methods
59	Detailed and clear information on usefulness in clinical practice. e.g. allodynia often associated with neuropathic change and more likely longstanding; vibration more sensitive test to light touch for sensory deficit
60	Further justification that these tests would significantly change prognosis and management

Appendix 9.1. University of Birmingham and Kings College London Ethics approval letters

Dear Mr Mansfield

Re: "Somatosensory profiling in people with neck pain and radicular arm pain"
Application for Ethical Review ERN_21-1404

Thank you for your application for ethical review for the above project, which was reviewed by the Science, Technology, Engineering and Mathematics Ethical Review Committee.

On behalf of the Committee, I confirm that this study now has full ethical approval.

I would like to remind you that any substantive changes to the nature of the study as described in the Application for Ethical Review, and/or any adverse events occurring during the study should be promptly brought to the Committee's attention by the Principal Investigator and may necessitate further ethical review.

Please also ensure that the relevant requirements within the University's Code of Practice for Research and the information and guidance provided on the University's ethics webpages (available at https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Links-and-Resources.aspx) are adhered to and referred to in any future applications for ethical review. It is now a requirement on the revised application form (https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx) to confirm that this guidance has been consulted and is understood, and that it has been taken into account when completing your application for ethical review.

Please be aware that whilst Health and Safety (H&S) issues may be considered during the ethical review process, you are still required to follow the University's guidance on H&S and to ensure that H&S risk assessments have been carried out as appropriate. For further information about this, please contact your School H&S representative or the University's H&S Unit at healthandsafety@contacts.bham.ac.uk.

28/11/2022

Dear Michael

Reference Number: HR/DP-22/23-34421
Study Title: Pain mechanisms in patients with neck and nerve related arm pain using psychophysics

Review Outcome: Approval with Provisos

Ethical Clearance

Thank you for submitting your application for the above project. I am pleased to inform you that your application has now been approved with the provisos indicated at the end of this letter. All changes must be made before data collection commences. The Committee does not need to see evidence of these changes, however supervisors are responsible for ensuring that students implement any requested changes before data collection commences.

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (http://www.kcl.ac.uk/college/policyzone/index.php?id=247).

For your information, ethical approval has been granted for 3 years from 28 November 2022. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed. You will not be sent a reminder when it is due to lapse.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results.

Please ensure that you follow the guidelines for good research practice as laid out in UKRIO's Code of Practice for research: http://ukrio.org/publications/code-of-practice-for-research/.

If you do not start the project within three months of this letter please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study. This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process

https://internal.kcl.ac.uk/innovation/governance-ethics-integrity/research-ethics/applications/modifications

Data Protection Registration

As you have indicated in Section E that personal data will be processed as part of this research project, this letter also confirms that you have also met your requirements for registering this processing activity with King's College London. This is required in line with the College's role as a Data Controller, in accordance with the UK General Data Protection Regulation (UK GDPR).

Please note it is the responsibility of the researcher(s) to ensure compliance with other aspects of the UK GDPR, more information about this can be found here: https://internal.kcl.ac.uk/innovation/governance-ethics-integrity/research-governance-office/data-protection-law-and-research/how-does-uk-dp-law-affect-research

You are required to adhere to all research data/records management and storage procedures agreed to as part of your application. This will be expected even after the completion of the study.

If there are any changes to the project that will impact on how you will you collect, manage or otherwise use your data, these must also be reflected in a modification request as outlined above.

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

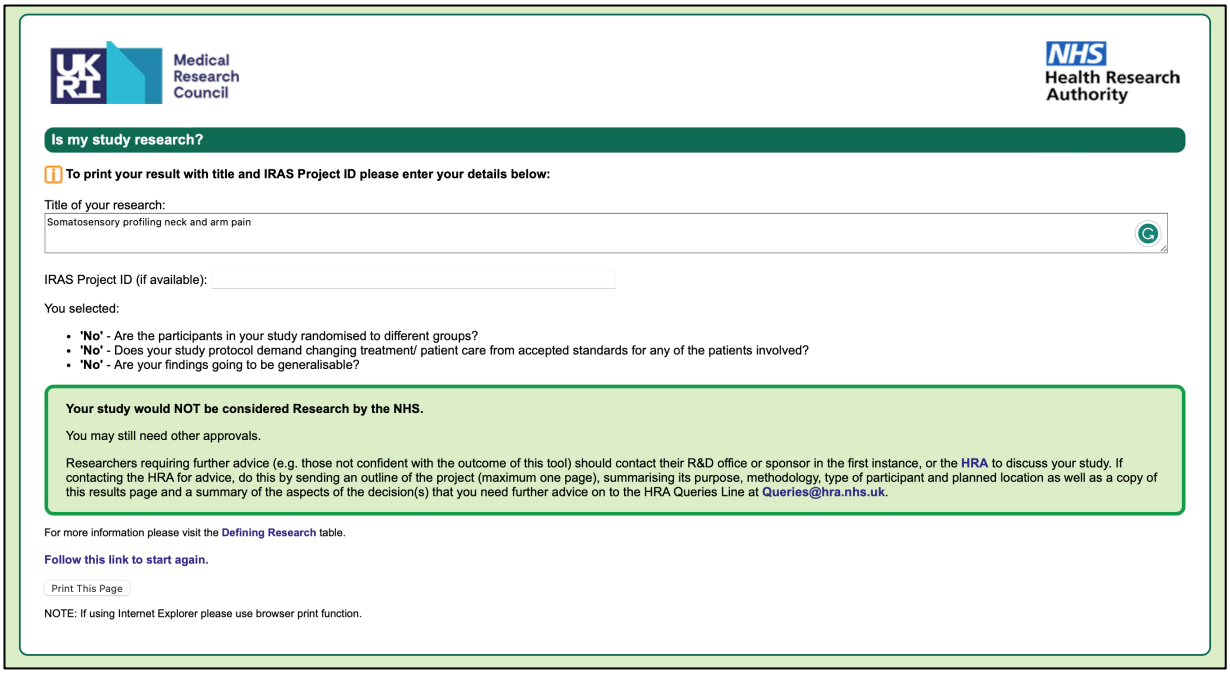
If you have any query about any aspect of this ethical approval, please contact your panel/committee administrator in the first instance (https://internal.kcl.ac.uk/innovation/governance-ethics-integrity/research-ethics/contact)

We wish you every success with this work.

Yours sincerely,

Ms Jessica Adams
Research Ethics Facilitator

Appendix 9.2. Health Research Authority decision making tool



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

Somatosensory profiling neck and arm pain

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

For more information please visit the Defining Research table.

Follow this link to start again.

Print This Page

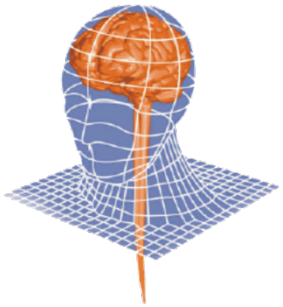
NOTE: If using Internet Explorer please use browser print function.

UMM
UNIVERSITÄTSMEDIZIN
MANNHEIM

Medizinische Fakultät Mannheim
der Universität Heidelberg

Universitätsklinikum Mannheim

DFNS



QST

Certification

for a successful participation of

Mike Mansfield

on 9th-10th of November 2021

in the training on

Quantitative Sensory Testing (QST)

according to the

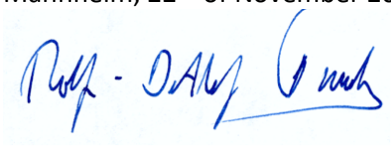
German Research Network on Neuropathic Pain

(DFNS)

at the Department of Neurophysiology

in Mannheim, Germany.

Mannheim, 22nd of November 2021



Prof. Dr. med. Rolf-Detlef Treede
Department of Neurophysiology
Medical Faculty Mannheim
University of Heidelberg
Mannheim Center for Translational Neuroscience (MCTN)
Ludolf-Krehl-Str. 13-17

Appendix 9.4. Study advert

UNIVERSITY OF BIRMINGHAM

Are you a healthy male or female?

Purpose

The purpose of our study is to examine the detection and interpretation of various sensory stimuli (including pain experience) in adult participants without neck pain and radicular arm symptoms. We want to see whether there is a relationship between the tests outlined below, and whether any of the tests can 'predict' for related test outcomes. We are interested in performing sensory testing to assess your baseline pain and touch sensitivity.

Recruitment criteria

- Aged between 18-70 years
- No neck pain and/or upper limb pain in the previous 7 days

You **cannot** participate if you have meet any of the following criteria:

- History of neck trauma or orthopaedic surgery in your neck region
- Neurological conditions (Such as, Multiple Sclerosis, Stroke, Parkinson's Disease)
- Unstable medical, vascular, metabolic or psychological conditions
- History of lumbar surgery and/or 'sciatica'
- Insufficient level of English
- Ongoing medico-legal claims
- Known dermatological condition at the neck, forearm, upper arm and/or hand sites

What do you need to know?

You will be asked to attend one testing session lasting up to 90 minutes with a researcher based at the CPR Spine Research Centre in

the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham.

Firstly, we will invite you to complete some questionnaires related to your general health and pain related thoughts. This should take up to 20 minutes.

During testing the following will be applied to your forearm and/or calf and the responses will be assessed. This testing will last up to 70 minutes.

i) Gradual, graded increase of pressure
ii) Gradual heating and cooling of the skin
iii) Pricking with a series of blunt ended instruments of varying pressure
iv) Touching using a series of thin filaments
v) Vibration detection using a tuning fork

You will be in control of the tests and can stop them at any time. Importantly, these are not pain tolerance tests.

University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee approval number: ERN_21-1404

If you are interested, please contact

Michael Mansfield (Lecturer Musculoskeletal Physiotherapy)

m.mansfield@bham.ac.uk

Appendix 9.5. Telephone screening

Project: Clinical profiling of people with cervical spine radiculopathy
Lead researcher: Michael Mansfield
Telephone Screening

Hello, my name is Michael Mansfield from *King's College London/University of Birmingham*. I am a fully registered Physiotherapist and lead researcher for this project.

As we have discussed via email, I am calling to conduct a screening interview to see if you meet the criteria for taking part in our research study, which is investigating the sensory experiences of people with cervical spine radiculopathy.

I will ask you questions to determine your eligibility to participate in the study. You can decline to answer any of these questions or stop participating in the interview at any time. If you wish to stop, please let me know.

This call should take no longer than 15 minutes. Do I have your permission to continue?

Our ethics agreements require us to ensure that this telephone discussion is used only to determine whether you qualify for this study.

You can choose whether or not to take part in this research screening procedure; it is up to you. If you refuse to answer the questions or stop answering them at any time, you will not be penalized, and it will not negatively impact any current or future assessment or treatment you receive.

The purpose of this telephone call is to determine if you are eligible to take part in the study. The risk of taking part in this telephone screening call is very low. The telephone screening is structured to collect a minimal amount of information, although some individuals may feel uneasy answering these questions to a person they do not know.

Do I have your permission to continue?

Healthy Asymptomatic Controls

Now, I would like to ask you some questions:

	Yes	*No*	*Additional comments*
Are you aged between 18-70 years.			

Have you had any neck pain, arm pain and/or pins and needles/numbness/changes in sensation to touch in the previous seven days.			
Have you had any history of neck trauma, known spinal bony lesion or neck orthopaedic surgery.			
Have you any known neurological condition or diseases (such as Multiple Sclerosis, Stroke, Parkinson's Disease).			
Have you any known clinically significant or unstable medical, metabolic or psychological conditions.			
Have you any known history of lumbar surgery and/or "sciatica" or other musculoskeletal (Joint, muscle bone) pain/disorders that potentially might affect the sensation in the foot.			
Have you any ongoing medico-legal claim(s) related to any symptoms.			
Have you any known dermatological condition impacting skin integrity at the neck, forearm, hand and/or calf sites.			

Cervical Spine Radiculopathy Group

Now, I would like to ask you some questions:

	Yes	*No*	*Additional comments*
Are you aged between 18-70 years.			
Have you had any neck pain, arm pain and pins and needles, numbness or changes in sensation to touch lasting more than one week			
Have you had any history of neck trauma, known spinal bony lesion or neck orthopaedic surgery.			
Have you any known neurological condition or diseases (such as Multiple Sclerosis, Stroke, Parkinson's Disease).			
Have you any known clinically significant or unstable medical, metabolic or psychological conditions.			

Have you any known history of lumbar surgery and/or “sciatica” or other musculoskeletal (Joint, muscle bone) pain/disorders that potentially might affect the sensation in the foot.			
Have you any ongoing medico-legal claim(s) related to any symptoms.			
Are you currently receiving any NHS treatment for your neck and arm symptoms.			
Have you any known dermatological condition impacting skin integrity at the neck, forearm, hand and/or calf sites.			

Closing

Eligible Participant

Based on the information you gave me; it looks like you may be eligible for this study. At this point, you have three choices:

(1) We can schedule a testing appointment over the telephone
(2) I can contact you by email with testing appointment availability
or
(3) If you confirm you are not interested in participating in the study, we can finish the telephone call and not go ahead.

If you have any questions or queries, please email me. Thank you for your time.

OR

Ineligible Participant

Based on the information you gave me, you are not eligible for this study.

If you have any questions or queries, please email me. Thank you for your time.

Appendix 9.6. Participant information sheet – Birmingham

The University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences

Participant Information Form

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Somatosensory profiling people with neck and radicular arm pain

Invitation paragraph

You are being invited to take part in a research study. Before you decide to participate, it is important to know why the research is being done and what it will involve. Please take time to read the following information sheet carefully.
Ask me if there is anything not clear or if you would like more information.

What is the purpose of the project?

The overarching purpose of the project is to quantitatively assess the sensory profile of people with neck pain and arm pain. The purpose of our study is to examine the detection and interpretation of various sensory stimuli (including brief pain experience) in adult participants with neck pain and radicular arm symptoms and healthy control groups. We want to see whether there is a relationship between the tests outlined below, and whether any of the tests have 'predictive power' for related test outcomes. We are interested in performing quantitative sensory testing (QST) to assess your baseline pain and touch sensitivity.

Why have I been invited to take part?

You are being invited to participate in this project because we are interested in testing people aged between 18-70 years of age with neck and arm pain or you are pain free with no previous neck and arm pain symptoms in the last 7 days.

You **cannot** participate if you have any of the following: previous spinal surgery, pregnancy, uncontrolled high blood pressure, known dermatological conditions at the testing sites that alter sensation, rheumatic condition, current or chronic respiratory condition, known neurological conditions, currently receiving National Health Service (NHS) treatment for your neck and arm pain symptoms, or having an ongoing compensation claim related to an injury.

If you do want to take part, you will be given this information sheet to keep and you will be asked to sign a consent form.

What will happen if I take part?

If you choose to take part in the study, you will be asked to experience transient painful sensations.

- The QST will involve some discomfort/transient pain but should not be very painful for any extended amount of time because these are not pain tolerance tests. The increase in discomfort will be brief as you are in control of the tests and can stop them at the point that they first become painful, at which point the test will stop. In fact, most of the QST tests assess mild change in temperature, light touch/stroking of the skin and do not generate painful sensations at all.

None of the methods used in the study are bad for your skin, penetrate the skin's surface or have been known to cause bruising using the methods described here. You might have some small red marks appear on the skin during testing, or some lingering sensitivity to warm water or a cool breeze against the small patch of skin tested. You might also feel mild irritation from the fabric of your sleeve rubbing against the tested area, but like the other sensations, this usually goes away after an hour or so, if it occurs at all.

If you agree, you will take part in the following procedures:

Questionnaires
You will be asked to complete six questionnaires related to your symptoms and daily activities. This will take up to 20 minutes.

Quantitative Sensory Testing
You will be asked to sit in a comfortable chair while the investigator carries out a series of tests using specialised equipment for skin testing. All equipment is tested by the researcher prior to your arrival.

All the tests will be performed on the underside of your forearm of your dominant hand. These tests are designed to measure how sensitive your skin is to warm/hot, cool/cold, touch, pricking, light touch, vibration, and strong pressure sensations. Temperature sensitivity is tested using a machine that circulates water at different temperatures through a 3 cm^2 probe that will be secured lightly to the underside of your forearm with a Velcro strap. The probe will increase and decrease in temperature so we can measure your detection threshold (the point when you first notice the sensation) and pain threshold (the point when the sensation first becomes painful). The tests stop at the first sensation of pain. We will measure how sensitive you are to touch detection by pressing plastic rods of varying stiffness against your skin until it reaches the point where you feel something touching you.

Pricking sensation is measured using blunt-ended metal rods called pinprick stimulators which range in weight from light to heavy and are pressed against your skin. Lighter rods feel like gentle touch, and heavier rods feel like sharp pinpricks. However, these rods do not penetrate the skin or injure it in any way. During this test you will be asked to say whether the rod feels blunt or sharp.

To see how sensitive your skin is to a mixture of stimuli, we will touch your skin with cotton wool, a soft brush, and a cotton bud, combined with pinprick stimulators. Again, you will be asked to rate the painfulness of each touch to your skin. We will also see how sensitive you are to vibration sensations by placing an activated tuning fork on your wrist bone until you no longer feel the vibration, at which point the test stops.

We will see how sensitive you are to strong pressure in two different ways. Firstly, by pressing a pressure algometer with a 1 cm^2 tip into the muscle at the base of your thumb until the pressure first becomes painful, at which point the test will stop. Secondly, though two inflatable pressure cuffs (like those used to measure blood pressure). The cuffs will be secured around the biceps muscle of the upper arm and then inflated at a computer-controlled steady rate using compressed air until the pressure you first detect a painful sensation; the cuff inflation is terminated when it is no longer tolerable.

In total, these tests take up to 70 minutes to perform and are under your control. All the tests can be stopped immediately at any point during testing.

Participation will take place in a quiet and private room at the CPR Spine research laboratories in the School of Sport, Exercise and

Rehabilitation sciences, University of Birmingham. The completion of questionnaires and sensory testing will up to a maximum of 90 minutes.

As part of participation, you will be asked to provide your age and gender because this will be important for how we compare our data with other studies.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

What are the possible risks of taking part?

It is likely you might feel a bit anxious about participating in a pain study, but we hope to be able to explain the tests so that there are no surprises, and you don't feel nervous during the session. We are very experienced in administering these tests and have not had any participants experience adverse effects in previous experiments. We consider these tests to be very low risk and there are no long-term effects associated with the tests. As this is a pain study, you will of course experience painful sensations, but for the most part these are transient or at least very short-term.

In the event of a concern with the project then contact: Susan Cottam (Research Ethics Officer), Tel: 0121 414 8825, Email: s.l.cottam@bham.ac.uk

What are the possible benefits of taking part?

There are no benefits to participating in this study.

Data handling and confidentiality

All information collected on you will be kept strictly confidential. The consent form containing your allocated ID will never be present in electronic form and will be securely stored within CPR Spine and only available to the researchers. All data will be stored on a secure University of Birmingham server for 10 years, managed in accordance

with the EU General Data Protection Regulation 2018 and the University of Birmingham Research Guidelines.

What if I change my mind about taking part?

You are free withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. You are able to withdraw your data from the project up to two weeks following data collection. Any information collated up to this point may be used in our data analysis. After this 2 week period, withdrawal of your data will no longer be possible due to it being anonymised and committed to data analysis. If you withdraw from the project, we will keep the information about you that we have already obtained. safeguard your rights, we will use the minimum personally identifiable information.

How is the project being funded?

This project is being funded by Private Physiotherapy Education Foundation (PPEF).

What will happen to the results of the project?

The results of the project will be summarised in internal presentations, external public engagement activities, higher education teaching and submitted to scientific journals for publication. If you would like to receive a copy of any publications associated with this study, you can indicate this on the consent form. The anonymised data set will not be made publicly available.

Who should I contact for further information?

If you have any questions or require more information about this project, please contact me using the following contact details:

Mr Michael Mansfield
Lecturer Musculoskeletal Physiotherapy

School of Sport, Exercise and Rehabilitation Sciences
College of Life and Environmental Sciences
University of Birmingham
Edgbaston, Birmingham, B15 2TT, UK
e: m.mansfield@bham.ac.uk

Does the study follow ethics procedures?

This study underwent the ethical review processes of the University of Birmingham and received official approval from the University Ethics Committee.

What if I have further questions, or if something goes wrong?

In the event of a complaint/concern with the project then contact:
Susan Cottam (Research Ethics Officer)
Tel: 0121 414 8825
Email: s.l.cottam@bham.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.

Appendix 9.7. Information sheet for participants

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Somatosensory profiling people with neck and radicular arm pain

Invitation Paragraph

You are invited to take part in a research study. Before you decide to participate, it is important to know why the research is being done and what it will involve. Please take time to read the following information sheet carefully. Ask me if there is anything not clear or if you would like more information.

What is the purpose of the project?

The overarching purpose of the project is to quantitatively assess the sensory profile of people with neck pain and arm pain. The purpose of our study is to examine the detection and interpretation of various sensory stimuli (including brief pain experience) in adult participants with neck pain and radicular arm symptoms. We want to see whether there is a relationship between the tests outlined below and whether any of the tests have 'predictive power' for related test outcomes. We are interested in performing quantitative sensory testing (QST) to assess your baseline pain and touch sensitivity.

Why have I been invited to take part?

You are being invited to participate in this project because we are interested in testing people aged between 18-70 years of age with neck and arm pain. You will be given this information sheet to keep, and you will be asked to sign a consent form.

You cannot participate if you have any of the following: previous spinal surgery, pregnancy, uncontrolled high blood pressure, known dermatological conditions at the testing sites that alter sensation, rheumatic condition, current or chronic respiratory condition, known neurological conditions, currently receiving National Health Service (NHS) treatment for your neck and arm pain symptoms, or having an ongoing compensation claim related to an injury.

If you do want to take part, you will be given this information sheet to keep and you will be asked to sign a consent form.

What will happen if I take part?

If you choose to take part in the study, you will be asked to experience transient painful sensations. You will undergo a familiarisation demonstration of the QST

testing before commencing. Images of testing equipment can be found at the end of this document.

The QST will involve some discomfort/transient pain but should not be very painful for any extended amount of time because these are not pain tolerance tests. The increase in discomfort will be brief as you are in control of the tests and can stop them at the point that they first become painful, at which point the test will stop. In fact, most of the QST tests assess mild change in temperature, light touch/stroking of the skin and do not generate painful sensations at all.

None of the methods used in the study are bad for your skin, penetrate the skin's surface or have been known to cause bruising using the methods described here. You might have some small red marks appear on the skin during testing, or some lingering sensitivity to warm water or a cool breeze against the small patch of skin tested. You might also feel mild irritation from the fabric of your sleeve rubbing against the tested area, but like the other sensations, this usually goes away after an hour or so, if it occurs at all. You will be invited to roll up your sleeve to expose the forearm skin but no clothing will be removed.

If you agree, you will take part in the following procedures:

Questionnaires
You will be asked to complete six questionnaires related to your symptoms and daily activities. This will take up to 20 minutes.

None of the methods used in the study are bad for your skin, penetrate the skin's surface or have been known to cause bruising using the methods described here. You might have some small red marks appear on the skin during testing, or some lingering sensitivity to warm water or a cool breeze against the small patch of skin tested. You might also feel mild irritation from the fabric of your sleeve rubbing against the tested area, but like the other sensations, this usually goes away after an hour or so, if it occurs at all.

If you agree, you will take part in the following procedures:

Quantitative Sensory Testing
You will be asked to sit in a comfortable chair while the investigator carries out a series of tests using specialised equipment for skin testing. All equipment is tested by the researcher prior to your arrival. All the tests will be performed on the underside of your forearm of your dominant hand. These tests are designed to measure how sensitive your skin is to warm/hot, cool/cold, touch, pricking, light touch, vibration, and strong pressure sensations. Temperature sensitivity is tested using a machine that circulates water at different temperatures through a 3 cm2 probe that will be secured lightly to the underside of your forearm with a Velcro strap. The probe will increase and decrease in temperature so we can measure your detection threshold (the point when you first notice the sensation) and pain threshold (the point when the sensation first becomes painful). The tests stop at the first sensation of pain by you pressing a stop button. We will measure how sensitive you are to touch detection by pressing plastic rods of varying stiffness against your skin until it reaches the point where you feel something touching you.

Pricking sensation is measured using blunt-ended metal rods called pinprick stimulators which range in weight from light to heavy and are pressed against your

skin. Lighter rods feel like gentle touch, and heavier rods feel like sharp pinpricks. However, these rods do not penetrate the skin or injure it in any way. During this test you will be asked to say whether the rod feels blunt or sharp.

To see how sensitive your skin is to a mixture of stimuli, we will touch your skin with cotton wool, a soft brush, and a cotton bud, combined with pinprick stimulators. Again, you will be asked to rate the painfulness of each touch to your skin. We will also see how sensitive you are to vibration sensations by placing an activated tuning fork on your wrist bone until you no longer feel the vibration, you will verbally inform the researcher and at which point the test stops.

We will see how sensitive you are to strong pressure in two different ways. Firstly, by pressing a pressure algometer with a 1 cm2 tip into the muscle at the base of your thumb until the pressure first becomes painful, at which point the test will stop. Secondly, though two inflatable pressure cuffs (like those used to measure blood pressure). The cuffs will be secured around the upper arm (biceps muscle) and then inflated at a computer-controlled steady rate using compressed air until the pressure you first detect a painful sensation; the cuff inflation is terminated when it is no longer tolerable by you pressing a stop button.

Conditioned pain modulation and temporal summation using cuff pressure
We will ask you to lie down on a medical bench with a pillow under your head and another under your knees to create a bend at the knee. We will attach a cuff device – like those used to measure your blood pressure - to each upper arm (biceps) muscle. You will have a series of four tests, each separated by 5-minutes. You will first experience slow increasing pressure on your dominant arm and will be asked to rate the painfulness of it up until it reaches your pain tolerance level. You will then have a series of ten strong pressure stimulations (1-second cuff inflations separated by one-second) and will be asked to continuously rate the painfulness of how it feels. You will have another slow increase in pressure on your other arm, again rating the pain up until your tolerance level. Finally, you will have both cuffs inflating at the same and will be asked to focus on the sensation of your dominant arm and again rate the painfulness of it. You will be in control of the tests and can stop the inflation of the cuff once it reaches your pain tolerance threshold. Any pain sensations will disappear as soon as you stop the test. It is very unlikely that you will have any lingering pain sensations that last outside of the test session, but you may feel ‘aware’ that you have had a squeezing sensation on your muscles after the test ends.

In total, these tests take up to 70 minutes to perform and are under your control. All the tests can be stopped immediately at any point during testing.

Participation will take place in a quiet and private room at the CPR Spine research laboratories in the Wolfson CARD Building, Guy’s Campus, King’s College London. The completion of questionnaires and sensory testing will up to a maximum of 90 minutes.

As part of participation, you will be asked to provide your age, gender and how long you have had your symptoms because this will be important for how we compare our data with other studies.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

What are the possible risks of taking part?

It is likely you might feel a bit anxious about participating in a pain study, but we hope to be able to explain the tests so that there are no surprises, and you don't feel nervous during the session. We are very experienced in administering these tests and have not had any participants experience adverse effects in previous experiments. We consider these tests to be very low risk and there are no long-term effects associated with the tests. As this is a pain study, you will of course experience painful sensations, but for the most part these are transient or at least very short-term.

What are the possible benefits of taking part?

While there are no direct benefits to participation, your participation may assist in our understanding of pain

Data handling and confidentiality

All information collected on you will be kept strictly confidential. The consent form containing your allocated ID will never be present in electronic form and will be securely stored within CPR Spine and only available to the researchers. All data will be stored on a secure King's College London server for 10 years, managed in accordance with the EU General Data Protection Regulation 2018 and the King's College London Research Guidelines. Your data will remain anonymised and will be retained and archived for future analyses within the research team up until 01/06/2023. Your data will not be shared with third parties.

Data Protection Statement

Your data will be processed in accordance with the UK Data Protection Act 2018 and UK GDPR. If you would like more information about how your data will be processed in accordance with GDPR please visit the link below:

https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research

Alternatively, you can be provided a hard copy of the statement. Please feel free to ask for this.

What if I change my mind about taking part?

You are free withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. You are able to withdraw your data from the project up to two weeks following data collection. Any

information collated up to this point will not be used in our data analysis. After this 2 week period, withdrawal of your data will no longer be possible due to it being anonymised and committed to data analysis. If you withdraw from the project, we will keep the information about you that we have already obtained. safeguard your rights, we will use the minimum personally identifiable information.

How is the project being funded?

The research equipment in this project is part-funded by the Private Physiotherapy Education Foundation (PPEF) charity.

What will happen to the results of the project?

The results of the project will be summarised in internal presentations, external public engagement activities, higher education teaching, thesis and research outputs and submitted to scientific journals for publication. If you would like to receive a copy of any publications associated with this study, you can indicate this on the consent form. The anonymised data set will not be made publicly available.

Who should I contact for further information?

If you have any questions or require more information about this project, please contact me using the following contact details:

Mr. Michael Mansfield (Research Associate – Bannister Laboratory) Wolfson Centre for Age-Related Diseases, Wolfson Wing, Hodgkin Building, King's College London, Guy's Campus, London SE1 1UL
Email: mike.mansfield@kcl.ac.uk
Tel.: +44 2078488378

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

Chair of the Health RESC
Franklin Wilkins Building
5.9 Waterloo Bridge Wing
Waterloo Road
London SE1 9NH

Telephone: 020 7848 4020
Email: rec@kcl.ac.uk

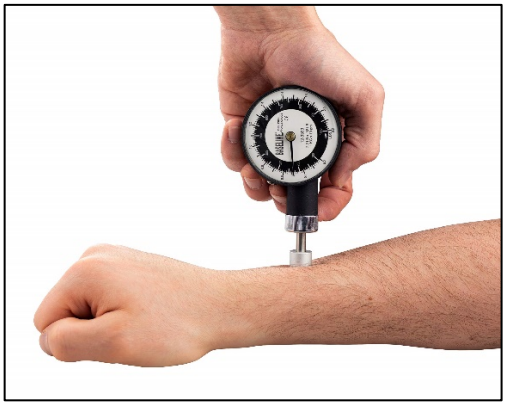
Thank you for reading this information sheet and for considering taking part in this research.

Example images of testing equipment

Vibration tuning fork equipment:



Mechanical touch equipment:



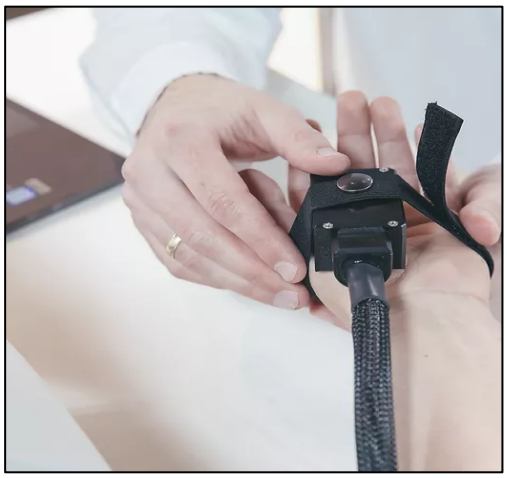
Light touch equipment:



Pressure cuffs equipment:



<u>Thermal (hot/cold) equipment:</u>



Appendix 9.8. Consent form KCL

CONSENT FORM FOR PARTICIPANTS IN RESEARCH PROJECTS

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research

Title of project: Somatosensory profiling people with neck and radicular arm pain		
Ethical review reference number:	**Version number:** 21/10/2022	
		Initials
1. I confirm that I have read and understood the information sheet dated 21/10/2022 Version 1 for the above project. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.		
2. I consent voluntarily to be a participant in this project and understand that I can refuse to take part and can withdraw from the project at any time, without having to give a reason, up two weeks following data collection.		
3. I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018.		
4. I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.		
5. I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs		
6. I agree that my data will be archived for future use by the research team, and they may use my data for future research. I understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would not be identifiable in any report).		
7. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher.		

8. I understand that the information I have submitted will be published as a report	
9. I wish to receive a copy of the final report.	
10. I agree to take part in this study	

Name of Participant	**Date**	**Signature**

Name of Researcher	**Date**	**Signature**

Appendix 9.9. Consent form University of Birmingham

The University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences

Participant Identification number:

CONSENT FORM

Title of Project: Somatosensory profiling people with neck and radicular arm pain

Name of Researchers: Michael Mansfield

	Initials
1. I confirm that I have read and understood the information sheet for the above project. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.	
2. I consent voluntarily to be a participant in this project and understand that I can refuse to take part and can withdraw from the project at any time, without having to give a reason, up two weeks following data collection.	
3. I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018.	
4. I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs	
5. I agree to take part in the above study	

_____ _____

Name of Participant Date Signature

_____ _____

Name of Researcher Date Signature

(Copies of consent for: participant and researcher)

Appendix 9.10. The standardised script of the German Neuropathic Pain Network quantitative sensory testing procedure

Cold detection threshold (CDT)
First we will test your ability to perceive cold sensations. Please press the stop button immediately once you perceive a change in temperature to cool/cooler for the first time.

Subsequently, the thermode will warm up again, until it reaches the baseline temperature. This procedure will start in a few seconds.

Warm detection threshold (WDT)
Now we will test your ability to perceive warm sensations. Please press the stop button immediately once you perceive a change in temperature to warm/warmer for the first time. Subsequently, the thermode will cool down again, until it reaches the baseline temperature. This procedure will start in a few seconds.

Thermal sensory limen (TSL) / Paradoxical heat sensations (PHS)
Now we will test how well you are able to discern between successive temperature changes. Please press the stop button immediately once you feel a temperature change towards “warm” or “cold” sensations, and tell us explicitly whether you felt the temperature change as “warm” or “cold”. It may well be that some of the temperature changes are felt as “hot” or “painfully hot”.

Cold pain threshold (CPT)
Now we will test as to when you perceive the cooling of the thermode as painful. Your skin will be slowly cooled. At some point in time you will feel a second sensation on top of the “cold” sensation. The impression of “cold” will change its quality towards an additional impression of a “burning”, “stinging”, “drilling” or “aching” sensation.

Please press the stop button immediately once you perceive such a change.

Please DO NOT wait to press the stop button until the sensation has become unbearably painful. Subsequently, the thermode will warm up again, until it reaches the baseline temperature. This procedure will start in a few seconds.

Heat pain threshold (HPT)
Now we will test as to when you perceive the warming of the thermode as painful. Your skin will be slowly warmed. At some point in time you will feel a second sensation on top of the “warm” or “hot” sensation. The impression of “warmth” or “heat” will change its quality towards an additional impression of a “burning”, “stinging”, “drilling” or “aching” sensation. Please press the stop button immediately once you perceive such a change.

Please DO NOT wait to press the stop button until the sensation has become unbearably painful. Subsequently, the thermode will cool down again, until it reaches the baseline temperature. This procedure will start in a few seconds.

Mechanical detection threshold (MDT)
This is a test of your ability to detect light touch. Please do not look at the skin area we are testing at any time during the test procedures. I will now touch your skin with these thin hairs. Please say “yes” as soon as you perceive a touch sensation

Mechanical pain threshold (MPT)

This is a test of your ability to perceive “sharp”, “pricking” or “stinging” stimuli. Various fine metal rods that are able to exert different pressure intensities will be carefully placed onto your skin. Please say “sharp” as soon as you no longer perceive only a touching sensation on your skin, but experience an additional “sharp”, “pricking” or “stinging” sensation. Please say “blunt” when you only perceive a touching sensation. Under no circumstances, you should look at the skin area we are testing during the test procedure

Mechanical pain sensitivity (MPS) / Dynamic mechanical allodynia (DMA)

As in the test before, blunt fine metal rods will be carefully pressed against your skin with varying pressure. In between these punctual stimuli your skin will occasionally be touched by a cotton wisp, a Q-tip, and a brush. Some of these stimuli may be accompanied by a “sharp”, “pricking”, “stinging” or “burning” sensation. Other stimuli may only be perceived as a touching sensation, others may not be perceived at all. Please rate the painfulness of each stimulus by giving a number between “0” and “100”. Any “sharp”, “pricking”, “stinging” or “burning” sensation should be defined as being painful and given a rating value above “0”. You may also use decimals. “0” meaning: No pain, no “sharp”, “pricking”, “stinging” or “burning” sensation. “100” meaning: Most intense pain sensation imaginable. Under no circumstances, you should look at the skin area we are testing during the test procedure.

Wind-Up-Ratio (WUR)

Like the previous test I will now press a single fine metal rod against your skin. Please rate the painfulness of this single stimulus by giving a number between “0” and “100”. Any sharp, pricking, stinging or burning sensation should be defined as painful and given a rating. You may use decimals. “0” mean no pain, no sharp, pricking, stinging or burning sensation. “100” means most intense pain sensation imaginable.

Now I will apply a series of 10 stimulations with the same metal rod at 1 second intervals on your skin. Once the entire series is over, please rate it’s average painfulness between “0” and “100”

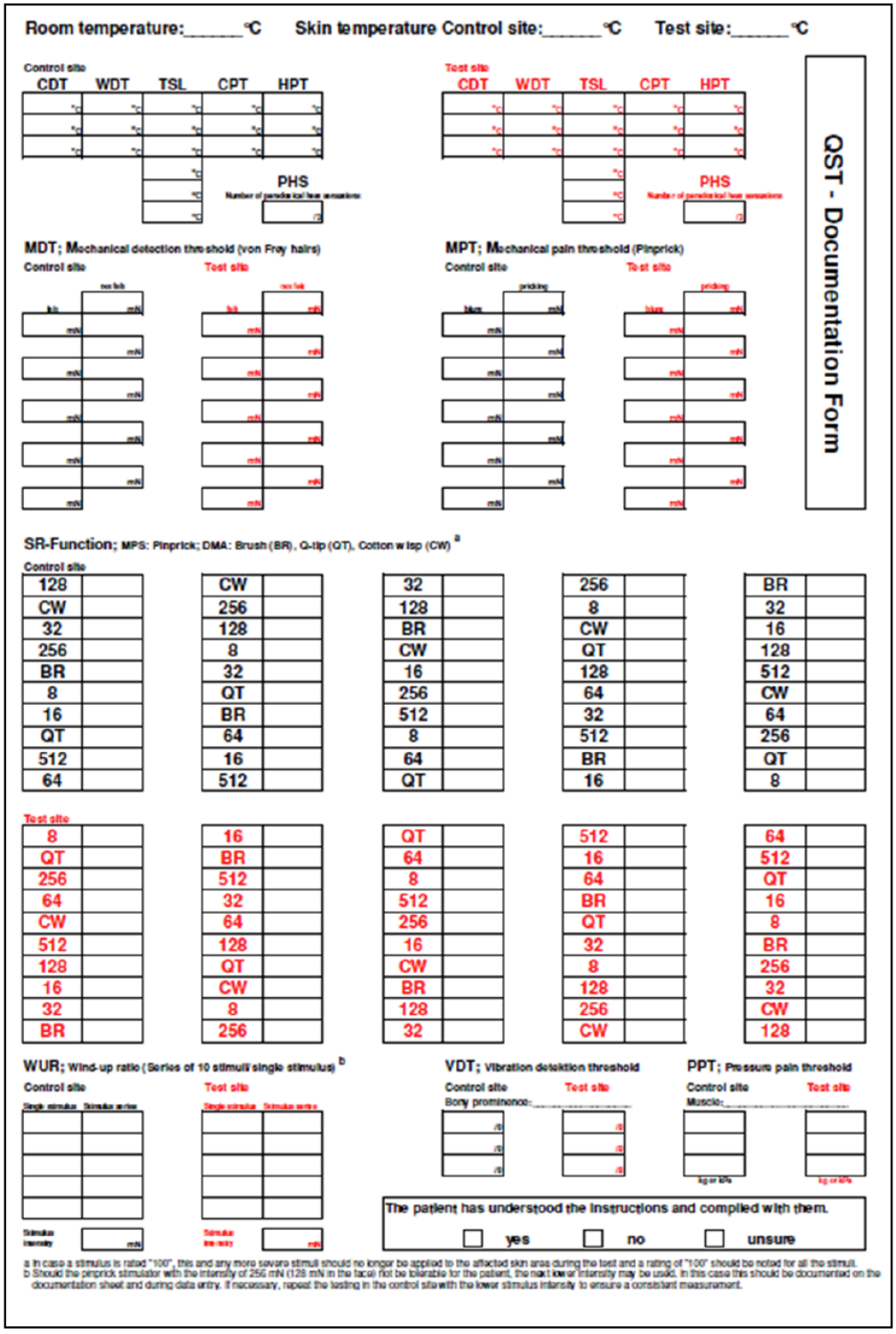
Vibration detection threshold (VDT)

This procedure tests your ability to perceive “vibrations”. I will now place this vibrating tuning fork on your skin. Please tell me if you are able to feel the vibrations? Please immediately say “NOW” as soon as you are no longer able to feel any further vibrations! You may hear the vibrations of the tuning fork as a sound. Please try to pay attention only to the vibration, and not to the sound.

Pressure Pain Threshold (PPT)

This tests your ability to feel pressure pain above muscles. I will press this device against one of your muscles. Please immediately say “Now” as soon as the usual sensation of pressure changes an additional sensation of burning, stinging, drilling or aching.

Appendix 9.11. Documentation form for quantitative sensory testing



Room temperature:_____°C **Skin temperature Control site:_____°C** **Test site:_____°C**

QST - Documentation Form

Control site

CDT	WDT	TSL	CPT	HPT
°C	°C	°C	°C	°C
°C	°C	°C	°C	°C
°C	°C	°C	°C	°C
		°C		
		°C		
		°C		
		PHS		
		/3		

Test site

CDT	WDT	TSL	CPT	HPT
°C	°C	°C	°C	°C
°C	°C	°C	°C	°C
°C	°C	°C	°C	°C
		°C		
		°C		
		°C		
		PHS		
		/3		

MDT; Mechanical detection threshold (von Frey hairs)

Control site / Test site

not felt	mN
felt	mN
mN	mN
mN	mN
mN	mN
mN	mN
mN	mN
mN	mN

MPT; Mechanical pain threshold (Pinprick)

Control site / Test site

pricking	mN
blunt	mN
mN	mN
mN	mN
mN	mN
mN	mN
mN	mN
mN	mN

SR-Function; MPS: Pinprick; DMA: Brush (BR), Q-tip (QT), Cotton wisp (CW) [a]

Control site

128		CW		32		256		BR	
CW		256		128		8		32	
32		128		BR		CW		16	
256		8		CW		QT		128	
BR		32		16		128		512	
8		QT		256		64		CW	
16		BR		512		32		64	
QT		64		8		512		256	
512		16		64		BR		QT	
64		512		QT		16		8	

Test site

8		16		QT		512		64	
QT		BR		64		16		512	
256		512		8		64		QT	
64		32		512		BR		16	
CW		64		256		QT		8	
512		128		16		32		BR	
128		QT		CW		8		256	
16		CW		BR		128		32	
32		8		128		256		CW	
BR		256		32		CW		128	

WUR; Wind-up ratio (Series of 10 stimuli/single stimulus) [b]

Control site / Test site

Single stimulus	Stimulus series
Stimulus intensity	mN

Single stimulus	Stimulus series
Stimulus intensity	mN

VDT; Vibration detektion threshold

Control site / Test site

Bony prominence:_____

/8	/8
/8	/8
/8	/8

PPT; Pressure pain threshold

Control site / Test site

Muscle:_____

kg or kPa	kg or kPa

The patient has understood the instructions and complied with them.

☐ yes ☐ no ☐ unsure

a In case a stimulus is rated "100", this and any more severe stimuli should no longer be applied to the affected skin area during the test and a rating of "100" should be noted for all the stimuli.
b Should the pinprick stimulator with the intensity of 256 mN (128 mN in the face) not be tolerable for the patient, the next lower intensity may be used. In this case this should be documented on the documentation sheet and during data entry. If necessary, repeat the testing in the control site with the lower stimulus intensity to ensure a consistent measurement.

Appendix 9.12. People with cervical spine radiculopathy recruitment tracker

