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Original article

Classification criteria for cervical radiculopathy: An international e-Delphi study

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ABSTRACT

Background: Establishing a set of uniform classification criteria (CC) for cervical radiculopathy (CR) is required to aid future recruitment of homogenous populations to clinical trials.
Objectives: To establish expert informed consensus on CC for CR.
Design: A pre-defined four round e-Delphi study in accordance with the guidance on Conducting and Reporting Delphi Studies.
Methods: Individuals with a background in physiotherapy who had authored two or more peer-reviewed publications on CR were invited to participate. The initial round asked opinions on CC for CR. Content analysis was performed on round one output and a list of discrete items were generated forming the round two survey. In rounds two to four, participants were asked to rate the level of importance of each item on a six-point Likert scale. Data were analysed descriptively using median, interquartile range and percentage agreement. Items reaching pre-defined consensus criteria were carried forward to the next round. Items remaining after the fourth round constituted expert consensus on CC for CR.
Results: Twelve participants participated with one drop out. The final round identified one inclusion CC and 12 exclusion CC. The inclusion CC that remained achieved 82% agreement and was 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.
Conclusions: The CC identified can be used to inform eligibility criteria for future CR trials although caution should be practiced as consensus on measurement tools requires further investigation.

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1. Background

Cervical radiculopathy (CR) is often a disabling condition that affects people's physical and psychological quality of life (Daffner et al., 2003), with substantial associated health and socioeconomic costs (Tumialán et al., 2010; Kleinman et al., 2014; Mansfield et al., 2014; Alvin et al., 2016; Rihn et al., 2019). A recent systematic review reported an incidence of CR between 0.83 and 1.79 per 1000 person-years, whilst prevalence ranged from 1.2 to 5.8 per 1000 (Mansfield et al., 2020).

The term CR became progressively more prominent during the 1970s with the aim of avoiding inconsistent terminologies such as radiculitis (Dejerine, 1914), brachialgia (Burt, 1924), and rhizopathy (Frykholm, 1951). However, its use suffered from inconsistency and ambiguity particularly when referring to the presence of neurological deficits, aetiology and pain (Milette et al., 1994). In 1994, the International Association for the Study of Pain (IASP) defined radiculopathy as "objective loss of sensory and/or motor function as a result of conduction block in axons of a spinal nerve or its roots" (Merskey and Bogduk, 1994, p. 17). In 2019, the IASP proposed a classification of chronic pain for the International Classification of Diseases 11 (ICD-11), whereby the term painful radiculopathy was introduced and was classified under chronic neuropathic pain. Painful radiculopathy was defined as "persistent or recurrent pain caused by a lesion or disease involving the cervical, thoracic, lumbar, or sacral nerve roots" (Scholz et al., 2019). Despite the IASP definition of radiculopathy, it has been observed that researchers and clinicians alike often 1) use CR, radicular arm pain, neck and arm pain interchangeably 2) use a variety of definitions for CR or 3) do not provide a case definition of CR at the outset (Bono et al., 2011; Boyles et al., 2011; Eubanks, 2010; Rainville et al., 2019). Moreover, a systematic review found that the presence of neck and/or arm pain was the only consistent selection criteria in randomised controlled trials that evaluated conservative interventions for CR (Thoomes et al., 2012). Other selection criteria such as presence of sensory, motor and reflex disturbances, as well as positive cervical range of motion deficits and Spurling's test were also reported as selection criteria for CR but varied between studies (Thoomes et al., 2012). Since then, numerous authors have advocated the need to establish consensus on classification criteria (CC) for a more uniform diagnosis of CR (Borrella-andrés et al., 2021; Mansfield et al., 2020; Romeo et al., 2018).

Inconsistent CC across CR trials have also resulted in the collation of heterogeneous samples in systematic reviews that compared treatment outcomes. For example, exercise based interventions and exercise combined with traction have statistically significant effects in reducing pain and disability for CR (Liang et al., 2019; Romeo et al., 2018). However, in both studies, the level of evidence was downgraded due to significant heterogeneity of the study population. This affects the validity and clinical utility of results, as well as undermining the overall confidence readers have in the CR literature. There is therefore an urgent need to develop CC to inform future recruitment to clinical trials involving patients with CR. This is the first study aimed at unifying CC for CR. The objective of this study is to develop expert consensus on CC for a diagnosis of CR which can be used to inform eligibility criteria for future CR trials.

2. Methods

2.1. Study design

A pre-defined four-round e-Delphi study was conducted between July 2020 to September 2020. The Delphi method is a consensus development technique which aims to garner opinion from a group of experts using a series of surveys interspersed with controlled feedback (Trevelyan and Robinson, 2015). The advantage of a Delphi consensus over any face to face consensus strategy (like e.g. nominal group techniques) is that it is anonymous (Hohmann et al., 2018). The study is reported in accordance with the Conducting and Reporting Delphi Studies (CREDES) recommendations for transparency (Jünger et al., 2017). Rounds of the e-Delphi study are depicted in Fig. 1. Reminder emails were sent every two days to participants who had not submitted the survey. Ethical approval was granted by the *BLINDED*.

2.2. Steering committee

The steering committee consisted of two Master in Research physiotherapy students (KNL, JM) and three senior researchers (DF, AR, NH) who have experience in participating (Luedtke et al., 2020), conducting (Mistry et al., 2020; Rushton et al., 2014) and supervising (Price et al., 2020; Thoomes et al., 2021; Zambaldi et al., 2017) Delphi studies as well as content expertise in CR (Lam et al., 2021a, 2021b; Liew et al., 2021; Thoomes et al., 2018). The steering committee was responsible for the formulation and refinement of the research question and methodology, design of surveys, execution of the study, data analysis and interpretation.

2.3. Participants

It was estimated that the pool of experts within the field of CR was limited based on our eligibility criteria, therefore the target sample size aimed to recruit ten or more experts in line with previous publications (Maissan et al., 2018; Orhan et al., 2019). Limited evidence suggests reliability will decline drastically with a panel size of below six while a panel size of above 12 would result in plateauing of reliability (Murphy et al., 1998). All participants had to fulfil pre-defined eligibility criteria.

Eligibility criteria was:

- Author of two or more peer-reviewed publications on CR within the period of January 2010 to January 2020

2.4. Recruitment

Potentially eligible participants were identified by the lead author (KNL) from scoping searches of the CR literature using Google scholar and PubMed. Invitation emails were sent to individuals who fulfilled the eligibility criteria. Invited individuals were also requested to recommend additional candidates who satisfied the eligibility criteria. Return of the signed consent form, conflict of interest form and professional background form signified confirmation of willingness to participate.

2.5. Procedure

Each stage of the Delphi study involved piloting the survey to ensure comprehensibility of survey questions, correct survey set-up and accurate interpretation and analysis of data. Eleven musculoskeletal physiotherapy masters' students agreed to participate in the pilot Delphi study.

2.5.1. Round 1

Prior to completion of Round 1 questions, participants were requested to read an article endorsed by The American College of Rheumatology titled "Distinctions Between Diagnostic and Classification Criteria?" (Aggarwal et al., 2015). It defined classification as "… standardized definitions that are primarily intended to enable clinical studies to have uniform cohorts for research" (Aggarwal et al., 2015). The intention of this was to ensure that all participants had a unified baseline conception on CR CC, therefore minimising inconsistent interpretation of the research question. Compatible with classic Delphi methodology, the first round comprised an open-ended question with the aim of eliciting the broadest set of ideas from participants (Fig. 1). Participants were requested to consider 1) inclusion and exclusion CC with supporting evidence 2) the clinical examination methods and techniques used to assess the proposed criteria and 3) precise usage of coordinating conjunctions (i.e., AND/OR; OR; AND) and laterality (i.e.

contralateral, ipsilateral, bilateral, unilateral). These considerations were added based on feedback from the piloting phase to improve the clarity of responses. Using an open-ended question, participants were also asked to provide additional free text comments.

Round one data were exported to Microsoft Word and analysed using content analysis (Elo and Kyngäs, 2008). This consisted of a preparation phase where the lead researcher (KNL) read the raw data repeatedly and selected the unit of analysis, typically a word or sentence. Following the familiarisation with data, open coding was performed by placing notes in the margin of the text. All the notes were then extracted and listed separately on a coding sheet. Notes expressing similar meaning were merged. KNL and JM performed the analysis independently. Two sets of results were combined with area of disagreement discussed and resolved through consensus. Results were analysed in a categorisation matrix consisting of three sections (i.e., inclusion CC, exclusion CC and assessment techniques, measurement tools and scoring method) and presented in round 2 as list of items.

2.5.2. Round 2

Participants were asked to rate the level of importance of each item generated in round one using a six-point Likert scale (1 = Not at all important, 2 = Low importance, 3 = Slight importance, 4 = Moderate importance, 5 = Very important, 6 = Extremely important). A six-point Likert scale excludes a mid-point category, and therefore avoids epistemological variance in interpretation of mid-point, often interpreted as neutral, average, and no comment (Tsang, 2012). Ratings of each item were analysed with descriptive statistics including measures of central tendency (median), measure of distribution (IQR) and percentage agreement. Items reaching pre-defined consensus criteria (i.e., median $\geq$3; IQR $\leq$3; percentage agreement $\geq$50%) were taken forward to round three. An open-ended question allowed for additional comments to be added. These qualitative data were imported into Microsoft Word for interpretation and summarisation, with relevant findings as determined by researchers subsequently embedded within the next round survey.

Participants were also asked whether the data they provided in round one was adequately represented in round 2 using a six-point Likert scale (1 = strongly disagree to 6 = strongly agree). Finally, an opportunity for additional comments regarding round two in general was provided in the form of an open-ended question.

2.5.3. Round 3

Participants were asked to rate the level of importance of the items that satisfied round two consensus criteria. For each item, participants were advised to use their previous responses, group statistics (percentage distribution of ratings, median, interquartile range and percentage agreement) and comments from round two to inform their responses. This process allowed participants to realise disparities, to reconsider the evidence and to reflect and re-evaluate on the decision of each item. Data collection and analysis of descriptive statistics and qualitative data were performed as per round two. Items reaching all pre-defined consensus criteria (i.e., median $\geq$4; IQR $\leq$2; percentage agreement $\geq$60%) were taken forwards to round four.

2.5.4. Round 4

Round four was performed as per round three. Items reaching all pre-defined consensus criteria (i.e., median $\geq$5; IQR $\leq$1; percentage agreement $\geq$70%) represented the expert consensus on the CC for CR.

2.5.4.1. Data collection and analysis. The REDCap (Research Electronic Data Capture) (https://www. project-redcap. org) was used for construction, distribution and data collection of survey outputs. Data collection was performed by the lead researcher (KNL) and analysis performed by two researchers (KNL, JM). Statistical analysis was performed using SPSS Version 25.0 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp.). Descriptive statistics for central tendency (median), measure of distribution (IQR) and percentage agreement were used to assess the level of consensus (Mistry et al., 2020). Percentage agreement per item was calculated by dividing the number of responses rated as very important and extremely important (five or above on Likert scale) by the total number of responses (Mistry et al., 2020). Qualitative data from round two to four were imported into Microsoft Word for interpretation and summarisation and were subsequently embedded within the next survey.

Consensus was defined *a priori,* informed by previous studies and was

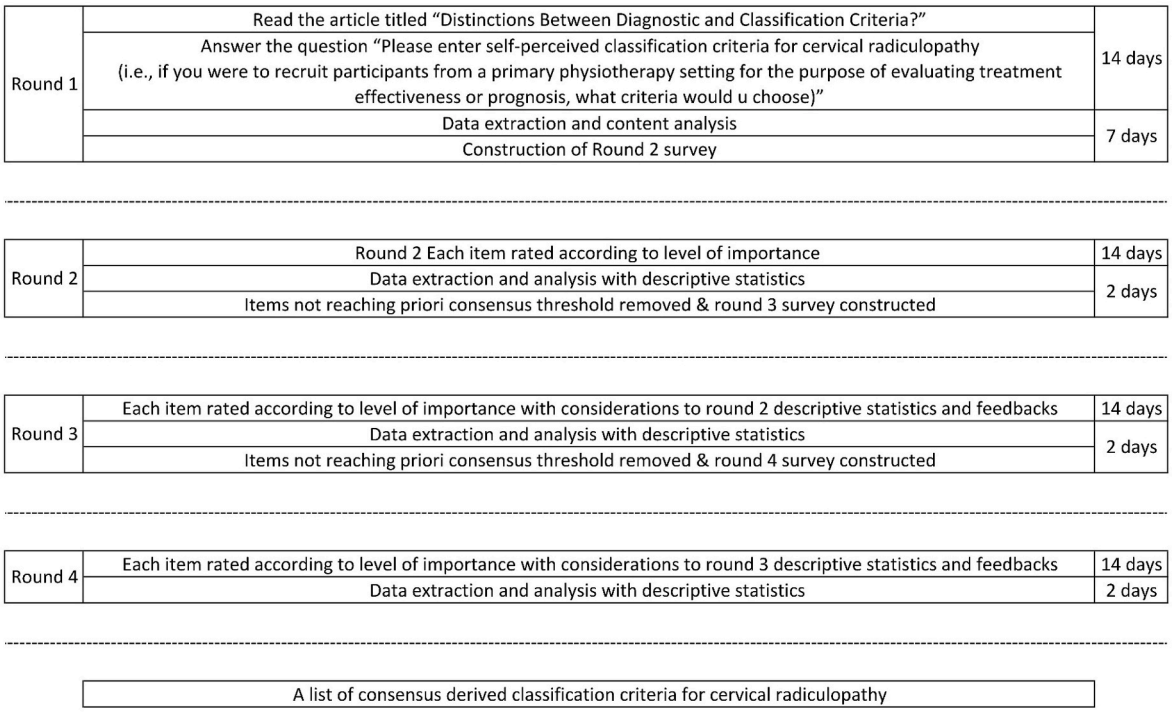

Fig. 1. Flowchart depicting the procedure during each round of the e-Delphi study.

progressively more stringent as rounds progressed to ensure final CC achieved a high level of consensus (Mistry et al., 2020; Wiangkham et al., 2016).

3. Results

3.1. Participants

Of 29 potentially eligible participants identified and invited to participate, 15 failed to respond to the invitation, two replied and declined participation due to a self-perceived lack of expertise and twelve expressed interest. All 12 fulfilled eligibility criteria and consented to participate. Participant characteristics are presented in Table 1. Response rates were 100% for round one, and 91.7% for rounds two, three and four, with an overall attrition rate of 8.3%.

3.2. Round 1

Post content analysis, 66 items were generated with 26, 32 and 8 items representing inclusion CC, exclusion CC and assessment techniques, measurement tools and scoring method respectively. Within the inclusion CC section, numerous themes emerged such as the need for positive clinical tests, presence of neurological deficits, presence of neck and/arm pain, distribution of arm pain and presence of imaging abnormalities. The list of items generated from round one is presented in Appendix I.

3.3. Round 2

In round two, 40 items were generated with 11, 24 and 5 items representing inclusion CC, exclusion CC and assessment techniques, measurement tools and scoring method respectively. Descriptive statistic for round two including percentage agreements is presented in Appendix II.

Four themes emerged after analysis of qualitative data.

- **Clinical test and/or signs and symptoms in isolation are unhelpful.**
  - o *"… no single test taken alone is helpful. Rather a cluster of findings (clinical±imaging as needed) that can exclude serious differential diagnosis and contextualize the clinical findings to understand what it is NOT as well as what the findings suggest the clinical presentation is.*" (Participant 1)
  - o"*As a standalone with no other aligned information, low relevance.*" (Participant 6)
  - o*"it is usual for the level of arm pain to be higher than that of neck pain but the item alone is not consequential*" (Participant 7)
- **Some criteria lacked detail descriptions.**
  - o*"where is the neck pain, where is the arm pain and how is this associated with other findings?"* (Participant 1)
  - o*"Not specific enough. Which type of sensory change? Loss or gain of function? Are weakness and diminished reflexes in the same myotome?"* (Participant 11)
- **The location and onset of certain pathologies should be specified.**
  - oBenign spinal tumors *"Be more specific, which area?*" (Participant 11)
  - oHistory of cervical spine surgery" *Depending on the spinal level"* (Participant 7)
  - oPrevious fracture of cervical spine *"Would depend where the fracture was,* e.g. *fracture of transverse process may not be relevant. Fracture without any signs of radiculopathy/neural compromise may be ok*" (Participant 11)
- **For some exclusion criteria such as metabolic diseases, history of cervical spine surgery and rheumatoid arthritis, it would depend on the aim of the research study**
  - o"Depends on research question/design and aim" (Participant 11)
  - o"Depending on what treatment was being trialed." (Participant 6)

3.4. Round 3

Round three generated 26 items with 8, 15 and 3 items representing inclusion CC, exclusion CC and assessment techniques, measurement tools and scoring method respectively. Descriptive statistics for round three including percentage agreements are available in Appendix III.

One theme emerged after analysis of qualitative data.

- **Clinical presentations are only relevant if related to an affected level**
  - o*"As long as aligned to affected nerve root(s)"* (Participant 1)
  - o*"Motor-, sensory changes and diminished reflexes need to be related to the same nerve root"* (Participant 10)
  - o"*Would need to be specified as motor and/or sensory deficits correlating with the symptomatic nerve root level*" (Participant 11)

3.5. Round 4

In round four, 13 items were generated with 1 and 12 items representing inclusion CC and exclusion CC respectively. This formed the expert consensus on CC of a diagnosis of CR (Table 2). Descriptive statistics for round four including percentage agreements are available in Appendix IV.

One theme emerged after analysis of qualitative data.

Table 1
Participant characteristics (n = 12).

Gender, n (% female)	8 (67%)
Age years mean (SD)	55.3 (±7.29)
Nationality	
Australia	2
Germany	2
Ireland	1
Nigeria	1
Sweden	2
The Netherlands	4
Country of current employment(s)*	
Australia	7
Germany	1
Guernsey, Channel Islands	1
Nigeria	1
Sweden	2
The Netherlands	2
Highest academic qualification	
MSc	1
PhD	11
Occupation	
Physiotherapist	12
Current roles	
- Emeritus Professor	1
-Professor	3
-Professor and Clinical Physiotherapist	2
-Associate Professor	2
-Adjunct Associate Professor and Clinical Physiotherapist	1
-Research Fellow and Clinical Physiotherapist	1
-Senior Lecturer	1
-PhD candidate and Clinical Physiotherapist	1
Number of CR related peer reviewed publications median (IQR)	5 (4)

*Some participants were employed by multiple institutions from different countries.

Table 2
Final consensus on classification criteria for a diagnosis of cervical radiculopathy.

Inclusion criteria
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 finding
Exclusion criteria
Myelopathy
Pancoast's tumour
Malignancy
Benign spinal tumors
Tuberculosis
Parsonage Turner Syndrome
Spinal cord compression
Spinal infection
History of spondylodiscitis
Upper motor neuron syndrome
Red flag symptoms such as fevers, chills, night pain
Conditions affecting ability to comprehend and adhere to study procedure

- **Medical imaging is not essential because there are concerns regarding its diagnostic accuracy.**
  - o "*Imaging is not essential, but if they have it already it can be useful.*" (Participant 5)
  - o "*Imaging may be false negative*" (Participant 11)

4. Discussion

This is the first study to investigate and establish a consensus on CC for a diagnosis of CR. Twelve physiotherapy academic experts within the field of CR participated with 11 completing all rounds contributing to an overall response rate of 91.7. The quality and level of expertise were reflected by the academic achievements with 11 participants with a doctorate degree, five titled as Professor, five working concurrently as clinical physiotherapist and a median of five peer reviewed articles on CR per participant. Sixty-six criteria were generated in round 1 with 13 reaching consensus in the final round.

Of the initial 26 inclusion CC items, just one reached consensus (i.e., a cluster 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 finding) with 82% agreement between the experts. Our finding shared some similarity with a recent study which performed a content analysis on CC of classification systems containing CR of moderate and high quality (Lam et al., 2021b). For example, neurological deficits such as weakness and altered reflex and arm pain worse than neck pain were criteria for CR in both studies. However, the study by Lam et al. (2021) did not include any imaging findings as criteria for CR but included clinical tests such as Spurling's test and the upper limb neurodynamic test, which are absent from our study. These differences can be explained as CC used in classification systems are aimed at classifying conditions that share similar clinical features with CR in clinical settings. The aim of the present study was however to develop a set of CC to aid selection of individuals with CR in research settings. It is also unclear how the results of this previous work (Lam et al. 2021) could be applied as there were no details as to how many criteria an individual had to satisfy until they can be classified as having CR.

A set of high performing CC should have high diagnostic accuracy, especially specificity, to ensure only individuals with the condition of interest are included. In the absence of evidence on the diagnostic accuracy of this cluster, components of the cluster will be discussed separately.

4.1. Radicular pain with arm pain worse than neck pain

Neck and/or arm pain, rather than radicular pain has previously been identified as an inclusion criterion for CR in clinical trials. From the review of Thoomes et al. (2012), six of the 13 studies reported coexistence of neck and arm pain as a criterion for CR. Our expert panel agreed that radicular pain with arm pain worse than neck pain was one prerequisite for classifying CR. A recent prospective diagnostic accuracy study for CR used a combination of clinical history, physical examination and MRI as reference criteria, and found "arm pain worse than neck pain" to have specificity and sensitivity of 0.81 and 0.58 respectively (Sleijser-Koehorst et al., 2021). However, it was unclear whether the nature of pain was of nociceptive and/or neuropathic and/or mixed origin. In addition, one study had shown only 35% of individuals with CR reported the arm as the maximal pain area (Tampin et al., 2012). In our study, some participants suggested that the decision to include pain should be at the discretion of the researcher and their interest in either patients with painful radiculopathy or non-painful radiculopathy. The criterion of pain alone proved inconsequential as the criteria "Neck and/or arm pain with arm pain exceeding that of neck pain" was unable to reach consensus during round two.

4.2. Paraesthesia or numbness and/or weakness and/or altered reflex

Nine of the initial 26 inclusion CC items contained elements of, or a combination of sensory, motor and reflex abnormalities as criteria. The prevalence of sensory abnormalities, muscle weakness and diminished deep tendon reflexes have been reported as 89.9%, 29.1% and 48.1% respectively in patients diagnosed with CR, based on a neurologist's clinical history and physical examination (Kuijper et al., 2011). A previous systematic review (Thoomes et al., 2012) found that only five out of 13 studies reported the use of sensory symptoms as criteria and only one used the combination of sensory, motor and deep tendon reflex as criteria for CR. The sensory symptoms described in these studies included paraesthesia, numbness, sensory deficits and sensory changes, which corresponded with our study. However, the exact location of the symptoms was rarely given. This too resonated with the comments provided by our experts who suggested that sensory, motor and reflex changes must correlate with the affected nerve root.

Inal et al. (2013), who used needle EMG as a reference standard, found the presence of hypoesthesia and/or motor weakness and/or asymmetry of deep tendon reflex had low specificity and high sensitivity of 0.28 and 0.83 respectively. Another study found similar results (i.e., specificity: 0.31; sensitivity: 0.84) despite a slight difference in criteria i.e., instead of hypoesthesia, sensory abnormalities were expressed as elevated mechanical pain threshold assessed via bedside testing of pinprick and reduced vibration detection threshold assessed via tuning fork (Lauder et al., 2000). Using the clinical presentation confirmed by MRI as a reference standard, subjective paraesthesia and/or numbness as a standalone criterion had a specificity and sensitivity of 0.37 and 0.88 respectively (Sleijser-Koehorst et al., 2021). It seems apparent that the findings of these studies showed a trend towards low specificity and high sensitivity meaning a high level of false positive findings is likely, a scenario that is not ideal for a set of high performing CC. Alternatively, the criteria of "reduced deep tendon reflex AND sensory or motor deficits" showed the reverse with high specificity (0.97–0.98) and low sensitivity (0.09–0.18) (Lauder et al., 2000). Therefore, the specificity of "paraesthesia or numbness and weakness and altered reflex" might be more optimal compared with "paraesthesia or numbness and/or weakness and/or altered reflex". This was reflected by one participant who commented "… a single item is not so important, instead all should be required." This would also eliminate a scenario whereby an individual presents with radicular arm pain and paraesthesia/numbness only which would not be considered as radiculopathy using IASP definition as paraesthesia/numbness is a subjective symptom rather than an objective sign (Merskey and Bogduk, 1994, p. 17). Nevertheless, it would be

impractical to have such stringent criteria as simultaneous occurrence of all three signs and symptoms within an individual are rare, making recruitment a challenge.

4.3. MRI confirmed nerve root compression compatible with clinical finding

Six of the initial 26 inclusion CC items incorporated imaging and/or neurophysiological findings as criteria for CR. Findings suggest there was consensus that MRI confirmed nerve root compression that are compatible with clinical findings should form part of the CC for CR. This is not reflected by the broader literature (Thoomes et al., 2012) because of concerns over the high rate of false positive and false negative findings when used in isolation (Kuijper et al., 2011). There was a trend indicating that clinical trials involving surgical intervention with or without conservative intervention always included MRI findings as part of inclusion criteria (Engquist et al., 2017; Taso et al., 2020) while trials of conservative management often use criteria based on patient history and physical examination findings alone (Fritz et al., 2014; Keating et al., 2019; Kuijper et al., 2009; Langevin et al., 2015). Furthermore, even when trials included MRI as part of the inclusion criteria, only a few state MRI findings had to be compatible with clinical findings (Peolsson et al., 2019; vanGeest et al., 2014), although what was meant by "compatible with clinical finding" remains unclear. Lack of clarity in criteria are likely to affect inter-rater reliability due to variability in interpretation (Porzsolt et al., 2019).

Exclusion CC are a set of pre-defined items that exclude an individual from participating in the study despite fulfilling inclusion CC (Patino and Ferreira, 2018). These may include specific diseases that share similar clinical presentation to the condition under investigation and features that safeguard the integrity of the trial and safeguard participants (e.g. exclusion of individual who do not understand the purpose and risk of participating, etc.) (Patino and Ferreira, 2018). In our study, 12 of the initial 32 exclusion criteria reached consensus. Ten related to specific diseases and two related to red flag symptoms and conditions that may affect participants' ability to comprehend and adhere to the study procedure. This finding share similarities with a previous systematic review on diagnostic labelling with the exception of previous surgery and trauma (Thoomes et al., 2012). In our study, consensus was not reached on criteria regarding a history of spinal, cervico-thoracic and cervical or thoracic surgery. Participants commented that the decision on exclusion of an individual with a history of surgery should depend on the nature of trial, recency of surgery and the spinal level involved. A history of spinal injury also failed to reach consensus as such a description was deemed too non-specific and it may depend on the spinal level involved. The exclusion of peripheral entrapment neuropathy did not reach consensus although co-occurrence with CR is common. For example, it has been demonstrated that 35 percent of individuals with CR also have carpal tunnel syndrome, also known as double crush syndrome (Lo et al., 2012).

4.4. Strength and limitations

This study was developed and reported in accordance with CREDES recommendations to ensure methodological rigor. Clearly defined eligibility criteria, priori consensus threshold and low attrition were strengths of this study. However, this study was not without limitations. Firstly, all participants were physiotherapists despite attempts to recruit experts from other professions. Therefore, the results cannot be generalised beyond physiotherapy research. Secondly, there is no consensus as to what constitutes an expert therefore the credibility and expertise should be inferred using participant's data such as area of research, years of research experience, number of publications and professional background. The eligibility criteria were selected based on previous Delphi studies however the criteria used, and therefore participants selected, may limit the generalisability of the results. Thirdly, of the 29 individuals identified as potentially eligible, only 12 agreed to participate making non-respondent bias a potential concern. Fourthly, the relatively low sample size may affect representativeness although it has been suggested that representativeness should be assessed against the quality of participants rather than quantity (Powell, 2003). Finally, addition of criteria after round one was not undertaken to minimise participant fatigue and drop-out, although an area for additional comments was provided. Addition of criteria during subsequent rounds might enable refinement of criteria which may have potentially generated different results.

4.5. Future directions and recommendations

In the absence of gold standard and demonstration of good face and content validity for the identified inclusion CC in the present study, we believe this is the best available CC to date. To strengthen the reliability of the criteria, it is recommended that future research should investigate the measurement tools most appropriate to assess the CC.

5. Conclusion

We reached consensus on one inclusion (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 finding) and 12 exclusion CC for CR using expert consensus. This is the first study aimed at unifying CC for CR and can be used to inform eligibility criteria for future CR trials although some caution should be practiced as consensus on measurement tools requires further investigation.

Declaration of competing interest

None.

Appendix I. Items generated from Round 1 and results of Round 2 to 4

	Round 2	Round 3	Round 4
Inclusion criteria			
1. Positive Spurling's test	×	–	–
2. Positive cervical distraction test	×	–	–
3. Positive upper limb neurodynamic test	×	–	–
4. Reduced deep tendon reflex and/or sensation and/or muscle strength of the affected arm	✓	✓	×
5. Sensory changes in a dermatomal distribution	✓	✓	×
AND			
Weakness, atrophy or fasciculation in a myotomal distribution			

(continued on next page)

(*continued*)

	Round 2	Round 3	Round 4
AND Unilateral diminished deep tendon reflexes			
6. Sensory changes (Paraesthesia and/or dysesthesia and/or hyperaesthesia) in a dermatomal distribution (assessed using light touch, pin prick, thermal hot/cold testing to assess for gain/loss/mixed sensory changes)	✓	×	–
7. Weakness, atrophy, or fasciculation in a myotomal distribution	✓	×	–
8. Unilateral diminished deep tendon reflexes	✓	×	–
9. Neck AND arm pain	✓	✓	×
10. Ipsilateral arm pain with or without neck pain	×	–	–
11. With or without neck and arm pain	×	–	–
12. Unilateral or bilateral arm pain	×	–	–
13. Neck and/or arm pain with arm pain exceeding that of neck pain	×	–	–
14. Arm pain that may or may not follow dermatomal/myotomal distribution	×	–	–
15. Radicular arm pain extending beyond elbow	×	–	–
16. Distribution of arm pain should reside mainly within the relevant dermatome(s) but small proportion may extend outside of that	×	–	–
17. Symptom reproduction with active cervical extension and/or ipsilateral lateral flexion and/or ipsilateral rotation	×	–	–
18. Elicitation of pain with isolated (cervical extension, ipsilateral lateral flexion, ipsilateral rotation) OR combined (cervical extension and ipsilateral lateral flexion and ipsilateral rotation) active movement of the neck	×	–	–
19. Demonstrable abnormality on myelography and/or computed tomography myelography and/or magnetic resonance imaging compatible with clinical findings	✓	✓	×
20. Two or more neurological deficits (i.e., myotomal weakness, diminished or absent deep tendon reflexes and sensory loss) AND Correlating MRI foraminal stenosis and/or positive nerve conduction study	✓	✓	×
21. Motor and/or sensory changes (paraesthesia or hypoesthesia) AND Radiating pain in the arm and/or periscapular region	✓	✓	×
22. 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 finding	✓	✓	✓
23. Pain in the neck and/or arm AND MRI confirmed nerve root compression compatible with clinical findings	×	–	–
24. Demonstrable abnormality on computed tomography scan at the clinically relevant level correlating with cervical radiculopathy with Neck pain, arm pain or combined neck and arm pain AND Paraesthesia, hyperaesthesia, or dysesthesia in a nerve root distribution OR Muscle weakness AND Sensory changes in a dermatomal distribution	✓	✓	×
25. Cervical disc disease (disc herniation with or without osteophytes, or stenosis caused by osteophytes) in one or two cervical segmental levels, confirmed by MRI compatible with clinical findings AND Positive Spurling test	×	–	–
26. Neuropathic pain descriptors and/or features	×	–	–
Exclusion criteria			
1. Myelopathy	✓	✓	✓
2. Pancoast's tumour	✓	✓	✓
3. Malignancy	✓	✓	✓
4. Benign spinal tumors	✓	✓	✓
5. Tuberculosis	✓	✓	✓
6. Parsonage Turner Syndrome	✓	✓	✓
7. Spinal cord compression	✓	✓	✓
8. Spinal infection	✓	✓	✓
9. History of spondylodiscitis	✓	✓	✓
10. Metabolic diseases	×	–	–
11. Red flag symptoms such as fevers, chills, night pain	✓	✓	✓
12. History of cervical spine surgery	✓	×	–
13. History of cervico-thoracic surgery	✓	×	–
14. History of cervical or thoracic surgery	×	–	–
15. Previous fracture of cervical spine	✓	×	–
16. Previous subluxation or dislocation of cervical spine	✓	✓	×
17. Spinal injuries	×	–	–
18. Negative neurodynamic test	×	–	–
19. Peripheral entrapment neuropathies	✓	×	–
20. Other peripheral nerve injury/condition	✓	×	–
21. Diseases that alters normal functioning of nervous system e.g. diabetes	✓	×	–
22. Musculoskeletal disorders affecting sensory or motor function	✓	✓	×
23. Widespread sensory loss with signs of central sensitization	✓	×	–
24. Symptoms affecting bilateral upper extremity	×	–	–
25. Conditions affecting ability to comprehend and adhere to study procedure	✓	✓	✓
26. Psychiatric disorder	×	–	–
27. Known alcohol/drug abuse	✓	✓	×
28. History of cardiovascular disease	×	–	–
29. Organ failure	×	–	–
30. Rheumatoid arthritis	✓	×	–

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	Round 2	Round 3	Round 4
31. Upper motor neuron syndrome	✓	✓	✓
32. Non-specific neck and arm pain with an absence of confirmatory tests that support a cervical radiculopathy	✓	×	–
Assessment techniques, measurement tools and scoring methods			
1. Muscle strength assessed using handheld dynamometer	×	–	–
2. Muscle strength scored using Oxford Scale (also known as Medical Research Council Manual Muscle Testing scale)	✓	×	–
3. Light touch tested with cotton wool in a circumferential manner from arm to hand	×	–	–
4. Sensory changes assessed using light touch AND pin prick AND thermal hot/cold	✓	✓	×
5. Deep tendon reflex assessed with reflex hammer	✓	✓	×
6. Deep tendon reflex applied to trapezius, deltoid, biceps and triceps as appropriate	✓	×	–
7. Criteria for positive neurodynamic test (1) at least partial reproduction of symptoms AND (2) those symptoms can be influenced by sensitising manoeuvres (structural differentiation)	×	–	–
8. Criteria for positive Spurling's test being reduced ROM and reproduction of arm symptom	✓	✓	×

✓ = consensus achieved and were presented in the next round.
× = consensus not achieved and were removed in the next round.

Appendix II. Round 2 results

Item	Median	IQR	% Agreement	Consensus achieved
Consensus criteria	≥3	≤3	≥50%	
Inclusion Criteria				
Positive Spurling's test	4	3	45%	×
Positive cervical distraction test	4	2	9%	×
Positive upper limb neurodynamic test	4	1.5	18%	×
Reduced deep tendon reflex and/or sensation and/or muscle strength of the affected arm	6	2	64%	✓
[Sensory changes in a dermatomal distribution] AND [Weakness, atrophy or fasciculation in a myotomal distribution] AND [Unilateral diminished deep tendon reflexes]	5	2	73%	✓
Sensory changes (Paraestheisa and/or dysaesthesia and/or hyperaesthesia) in a dermatomal distribution (assessed using light touch, pin prick, thermal hot/cold testing to assess for gain/loss/mixed sensory changes)	5	1	73%	✓
Weakness, atrophy or fasciculation in a myotomal distribution	5	1.5	73%	✓
Unilateral diminished deep tendon reflexes	5	1	64%	✓
Neck AND arm pain	5	1	64%	✓
Ipsilateral arm pain with or without neck pain	4	2	45%	×
With or without neck and arm pain	2.5	2	13%	×
Unilateral or bilateral arm pain	3	4	33%	×
Neck and/or arm pain with arm pain exceeding that of neck pain	4	2	27%	×
Arm pain that may or may not follow dermatomal/myotomal distribution	3	2	9%	×
Radicular arm pain extending beyond elbow	4	1.5	36%	×
Distribution of arm pain should reside mainly within the relevant dermatome(s) but small proportion may extend outside of that	4	2	45%	×
Symptom reproduction with active cervical extension and/or ipsilateral lateral flexion and/or ipsilateral rotation	4	2.5	36%	×
Elicitation of pain with isolated (cervical extension, ipsilateral lateral flexion, ipsilateral rotation) OR combined (cervical extension and ipsilateral lateral flexion and ipsilateral rotation) active movement of the neck	4	3	36%	×
Demonstrable abnormality on myelography and/or computed tomography myelography and/or magnetic resonance imaging compatible with clinical findings	5	0.5	82%	✓
[Two or more neurological deficits (i.e. myotomal weakness, diminished or absent deep tendon reflexes and sensory loss)] AND [Correlating MRI foraminal stenosis and/or positive nerve conduction study]	5	1.5	73%	✓
[Motor and/or sensory changes (paraesthesia or hypoesthesia)] AND [Radiating pain in the arm and/or periscapular region]	5	1.5	64%	✓
[Radicular pain with arm pain worse than neck pain] AND [paraesthesias or numbness and/or weakness and/or altered reflex] AND [MRI confirmed nerve root compression compatible with clinical findings]	5	2	64%	✓
[Pain in the neck and/or arm] AND [MRI confirmed nerve root compression compatible with clinical findings]	4	3	36%	
[Demonstrable abnormality on computed tomography scan at the clinically relevant level correlating with cervical radiculopathy with Neck pain, arm pain or combined neck and arm pain] AND [Paraesthesia, hyperaesthesia, or dysaesthesia in a nerve root distribution OR Muscle weakness] AND [Sensory changes in a dermatomal distribution]	5	2	64%	✓
[Cervical disc disease (disc herniation with or without osteophytes, or stenosis caused by osteophytes) in one or two cervical segmental levels, confirmed by MRI compatible with clinical findings] AND [Positive Spurling test]	4	2	36%	×
Neuropathic pain descriptors and/or features	4	1.5	36%	×
Exclusion criteria				
Myelopathy	6	0.5	91%	✓
Pancoast's tumor	6	0.5	91%	✓
Malignancy	6	0.5	91%	✓
Benign spinal tumors	5	1	82%	✓
Tuberculosis	6	1	82%	✓
Parsonage Turner Syndrome	6	1.5	73%	✓
Spinal cord compression	6	1	82%	✓
Spinal infection	6	1	82%	✓
History of spondylodiscitis	5	2	64%	✓
Metabolic diseases	4	2.5	45%	×
Red flag symptoms such as fevers, chills, night pain	6	1	82%	✓
History of cervical spine surgery	5	2.5	55%	✓
History of cervico-thoracic surgery	5	2.5	55%	✓
History of cervical or thoracic surgery	4	2	36%	×

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Item	Median	IQR	% Agreement	Consensus achieved
Consensus criteria	≥3	≤3	≥50%	
Previous fracture of cervical spine	5	2.5	55%	✓
Previous subluxation or dislocation of cervical spine	6	2	64%	✓
Spinal injuries	4	1.75	30%	×
Negative neurodynamic test	2	1.5	9%	×
Peripheral entrapment neuropathies	5	2	73%	✓
Other peripheral nerve injury/condition	5	2	73%	✓
Diseases that alters normal functioning of nervous system e.g. diabetes	5	3	64%	✓
Musculoskeletal disorders affecting sensory or motor function	5	3	60%	✓
Widespread sensory loss with signs of central sensitization	5	2	64%	✓
Symptoms affecting bilateral upper extremity	4	3.5	45%	×
Conditions affecting ability to comprehend and adhere to study procedure	6	1.5	73%	✓
Psychiatric disorder	4	1.5	45%	×
Known alcohol/drug abuse	5	1.5	64%	✓
History of cardiovascular disease	3	1.5	27%	×
Organ failure	4	3	36%	×
Rheumatoid arthritis	5	2	73%	✓
Upper motor neuron syndrome	5	2.5	64%	✓
Non-specific neck and arm pain with an absence of confirmatory tests that support a cervical radiculopathy	6	1.5	73%	✓
Assessment techniques, measurement tools and scoring method				
Muscle strength assessed using handheld dynamometer	3	1	9%	×
Muscle strength scored using Oxford Scale (also known as Medical Research Council Manual Muscle Testing scale)	5	2	55%	✓
Light touch tested with cotton wool in a circumferential manner from arm to hand	4	1.5	45%	×
Sensory changes assessed using light touch AND pin prick AND thermal hot/cold	5	1	60%	✓
Deep tendon reflex assessed with reflex hammer	5	2	64%	✓
Deep tendon reflex applied to trapezius, deltoid, biceps and triceps as appropriate	5	1.5	64%	✓
Criteria for positive neurodynamic test (1) at least partial reproduction of symptoms AND (2) those symptoms can be influenced by sensitising manoeuvres (structural differentiation)	4	2	27%	×
Criteria for positive Spurling's test being reduced ROM and reproduction of arm symptom	5	2.5	55%	✓

Appendix III. Round 3 results

Item	Median	IQR	% Agreement	Consensus achieved
Consensus criteria	≥4	≤2	≥60%	
Inclusion Criteria				
Reduced deep tendon reflex and/or sensation and/or muscle strength of the affected arm	5	1.5	70%	✓
[Sensory changes in a dermatomal distribution] AND [Weakness, atrophy or fasciculation in a myotomal distribution] AND [Unilateral diminished deep tendon reflexes]	5	1.75	70%	✓
Sensory changes (Paraestheisa and/or dysaesthesia and/or hyperaesthesia) in a dermatomal distribution (assessed using light touch, pin prick, thermal hot/cold testing to assess for gain/loss/mixed sensory changes)	4.5	2.5	50%	×
Weakness, atrophy or fasciculation in a myotomal distribution	4.5	1	50%	×
Unilateral diminished deep tendon reflexes	4	1	40%	×
Neck AND arm pain	5	1	60%	✓
Demonstrable abnormality on myelography and/or computed tomography myelography and/or magnetic resonance imaging compatible with clinical findings	5	1.75	70%	✓
[Two or more neurological deficits (i.e. myotomal weakness, diminished or absent deep tendon reflexes and sensory loss)] AND [Correlating MRI foraminal stenosis and/or positive nerve conduction study]	6	1	80%	✓
[Motor and/or sensory changes (paraesthesia or hypoesthesia)] AND [Radiating pain in the arm and/or periscapular region]	5	1.75	60%	✓
[Radicular pain with arm pain worse than neck pain] AND [paraesthesias or numbness and/or weakness and/or altered reflex] AND [MRI confirmed nerve root compression compatible with clinical findings]	5	1.5	70%	✓
[Demonstrable abnormality on computed tomography scan at the clinically relevant level correlating with cervical radiculopathy with Neck pain, arm pain or combined neck and arm pain] AND [Paraesthesia, hyperaesthesia, or dysaesthesia in a nerve root distribution OR Muscle weakness] AND [Sensory changes in a dermatomal distribution]	5	1.5	70%	✓
Exclusion criteria				
Myelopathy	6	0.75	90%	✓
Pancoast's tumor	6	1	90%	✓
Malignancy	6	0.75	80%	✓
Benign spinal tumors	5.5	2	60%	✓
Tuberculosis	6	1.5	70%	✓
Parsonage Turner Syndrome	6	1	80%	✓
Spinal cord compression	6	0	80%	✓
Spinal infection	6	0	90%	✓
History of spondylodiscitis	5	1.75	60%	✓
Red flag symptoms such as fevers, chills, night pain	6	1	80%	✓
History of cervical spine surgery	4.5	1.75	50%	×
History of cervico-thoracic surgery	4.5	1	50%	×
Previous fracture of cervical spine	4.5	1	50%	×
Previous subluxation or dislocation of cervical spine	5	2	60%	✓
Peripheral entrapment neuropathies	5	2.75	50%	×

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Item	Median	IQR	% Agreement	Consensus achieved
Consensus criteria	≥4	≤2	≥60%	
Other peripheral nerve injury/condition	4	2.5	40%	×
Diseases that alters normal functioning of nervous system e.g. diabetes	4.5	2	50%	×
Musculoskeletal disorders affecting sensory or motor function	4.5	1	50%	×
Widespread sensory loss with signs of central sensitization	5	1	60%	✓
Conditions affecting ability to comprehend and adhere to study procedure	6	1	80%	✓
Known alcohol/drug abuse	6	2	60%	✓
Rheumatoid arthritis	6	2.5	70%	✓
Upper motor neuron syndrome	6	1	80%	✓
Non-specific neck and arm pain with an absence of confirmatory tests that support a cervical radiculopathy	5	2.5	70%	✓
Assessment techniques, measurement tools and scoring method				
Muscle strength scored using Oxford Scale (also known as Medical Research Council Manual Muscle Testing scale)	4.5	1.75	50%	×
Sensory changes assessed using light touch AND pin prick AND thermal hot/cold	5	1.75	60%	✓
Deep tendon reflex assessed with reflex hammer	5	0.75	80%	✓
Deep tendon reflex applied to trapezius, deltoid, biceps and triceps as appropriate	4.5	1.75	50%	×
Criteria for positive Spurling's test being reduced ROM and reproduction of arm symptom	5	1	60%	✓

Appendix IV. Round 4 results

Item	Median	IQR	% Agreement	Consensus achieved
Consensus criteria	≥5	≤1	≥70%	
Inclusion Criteria				
Reduced deep tendon reflex and/or sensation and/or muscle strength of the affected arm	4	1	45%	×
[Sensory changes in a dermatomal distribution] AND [Weakness, atrophy or fasciculation in a myotomal distribution] AND [Unilateral diminished deep tendon reflexes]	4	1.5	45%	×
Neck AND arm pain	4	1	45%	×
Demonstrable abnormality on myelography and/or computed tomography myelography and/or magnetic resonance imaging compatible with clinical findings	5	1	55%	×
[Two or more neurological deficits (i.e. myotomal weakness, diminished or absent deep tendon reflexes and sensory loss)] AND [Correlating MRI foraminal stenosis and/or positive nerve conduction study]	5	1.5	73%	×
[Motor and/or sensory changes (paraesthesia or hypoesthesia)] AND [Radiating pain in the arm and/or periscapular region]	5	1	55%	×
[Radicular pain with arm pain worse than neck pain] AND [paraesthesias or numbness and/or weakness and/or altered reflex] AND [MRI confirmed nerve root compression compatible with clinical findings]	5	1	82%	✓
[Demonstrable abnormality on computed tomography scan at the clinically relevant level correlating with cervical radiculopathy with Neck pain, arm pain or combined neck and arm pain] AND [Paraesthesia, hyperaesthesia, or dysaesthesia in a nerve root distribution OR Muscle weakness] AND [Sensory changes in a dermatomal distribution]	5	1.5	73%	×
Exclusion criteria				
Myelopathy	6	1	91%	✓
Pancoast's tumor	6	1	91%	✓
Malignancy	6	1	91%	✓
Benign spinal tumors	5	1	82%	✓
Tuberculosis	6	1	91%	✓
Parsonage Turner Syndrome	6	1	82%	✓
Spinal cord compression	6	1	82%	✓
Spinal infection	6	1	91%	✓
History of spondylodiscitis	5	0.5	73%	✓
Red flag symptoms such as fevers, chills, night pain	6	1	82%	✓
Previous subluxation or dislocation of cervical spine	5	2.5	70%	×
Widespread sensory loss with signs of central sensitization	5	1.5	55%	×
Conditions affecting ability to comprehend and adhere to study procedure	5	1	91%	✓
Known alcohol/drug abuse	5	1.5	73%	×
Upper motor neuron syndrome	5	1	91%	✓
Assessment techniques, measurement tools and scoring method				
Sensory changes assessed using light touch AND pin prick AND thermal hot/cold	5	1	55%	×
Deep tendon reflex assessed with reflex hammer	5	1	64%	×
Criteria for positive Spurling's test being reduced ROM and reproduction of arm symptom	4	2	36%	×

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Further reading

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