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## Clinical indicators to identify neuropathic pain in low back related leg pain: protocol for a modified Delphi study

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# Clinical indicators to identify neuropathic pain in low back related leg pain: protocol for a modified Delphi study

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## Abstract

### Background

Neuropathic low back related leg pain (LBLP) can be a challenge to healthcare providers to diagnose and treat. Accurate diagnosis of neuropathic pain (NP) is fundamental to ensure appropriate intervention is given. However, to date there is no gold standard to diagnose neuropathic LBLP. A Delphi study will therefore be conducted to obtain an expert derived consensus list of clinical indicators to identify a neuropathic component to LBLP.

### Objective

To conduct a three round modified Delphi study to achieve expert consensus on a list of clinical indicators to identify NP in LBLP

### Methods/analysis

Included participants will be considered experts within the field as measured against a pre-defined eligibility criterion. Through an iterative multistage process, participants will rate their agreement with a list of clinical indicators and suggest any missing clinical indicators during each round. Agreement will be measured using the Likert scale. Descriptive statistics will be used to measure agreement; median, IQR and percentage of agreement. Priori consensus criteria will be defined for each round. Data will be collected at the end of round three and a list of clinical indicators will be derived at the end of this study

### Ethics/dissemination

Ethical approval will be approved via the University of Birmingham. On completion of the study findings will be disseminated in a peer-reviewed journal and presented at relevant conferences.

## Keywords

Neuropathic, leg pain, Delphi, diagnosis

## Word count

3126 words

## Article summary

### Strengths and limitations of this study

- This study will develop a list of clinical indicators to identify a neuropathic component to LBLP, which will help to inform clinicians regarding treatment interventions
- This study will use national and international experts in neuropathic pain to inform the list of clinical indicators
- The views of Delphi panellists may differ from those experts who decline participation, and may not fully represent experts in the field of interest.

## Introduction

Neuropathic pain (NP) is defined as pain caused by a lesion or disease of the somatosensory nervous system (Treed et al, 2008). NP is a largely unmet medical need due to ineffective management (Baron et al, 2016). NP is highly prevalent and has been estimated to have a global population prevalence of between 6.9% - 10% (van Hecke et al, 2014). NP is associated with vast economic costs; with total annual costs (including direct and indirect costs) per patient in Europe ranging from £8710 in the UK to €14,446 in Germany (Liedgens et al, 2016). Epidemiological surveys have shown that many patients with NP do not receive appropriate treatment, a common reason for this is misdiagnosis (Torrance et al, 2013). One of the most common presentations of NP is found in those with low back pain (LBP), which is estimated to be at approximately 46.7% (Berger et al, 2012). Up to two thirds of individuals with LBP report concomitant leg pain when presenting in primary and secondary care services (Harrison et al, 2017). Low back related leg pain (LBLP) compared to LBP alone is associated with increased disability, pain, and poorer quality of life (Konstantinou et al, 2013, Hider et al, 2015). LBLP is generally clinically diagnosed as sciatica (lumbar radicular) or referred pain (involving non-neural structures); sciatica is considered neuropathic in nature whereas referred pain is considered nociceptive (Harrison et al, 2017). However, there is evidence to suggest the coexistence of both pain mechanisms in LBLP (Freyenhagen et al, 2008), and evidence for sciatica presenting without NP and referred pain presenting with NP (Mahn et al, 2011).

According to the National Institute for Health and Care Excellence (NICE) recent guidelines, the management of NP differs significantly to the management of LBP without sciatica

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2  
3 (NICE, 2016). Thus the importance of accurate diagnosis of NP in relation to LBLP ensures  
4 that appropriate management is provided. Identification of patients with NP in LBLP is  
5 essential as pharmaceutical intervention, if indicated, may improve patient outcomes  
6 (Harrison et al, 2017). To date, there is no gold standard for diagnosing NP (Smith et al,  
7 2007). Consequently, expert opinion consensus derived lists (Smart et al, 2010) and a  
8 variety of patient reported outcome measures (PROMs) have been developed and used as  
9 methods to determine the presence of NP in research studies (Harrison et al, 2017).  
10 However, there is no uniformity within the literature regarding the best clinical indicators to  
11 use to identify NP in LBLP. The most common clinical indicators utilised to identify NP in  
12 LBLP research include the PainDetect (Beith et al, 2011), The Leeds Assessment of  
13 Neuropathic Symptoms and Signs (LANSS) (Walsh and Hall, 2009), and Douleur  
14 Neuropathique 4 (DN4) (Ouedraogo et al, 2012).

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25 A cross-sectional study by Smart et al (2012) is the one study to identify clinical indicators  
26 predictive of the presence of peripheral NP in low back pain (with or without leg pain),  
27 consisting of a cluster of two symptoms and one sign: '*pain referred in a dermatomal or*  
28 '*cutaneous distribution*', '*history of nerve injury, pathology or mechanical*  
29 '*compromise*' and '*pain/symptom provocation with mechanical/movement tests (e.g.*  
30 '*active/passive, neurodynamic) that move/load/compress neural tissue*'. However, there is  
31 evidence to refute aspects of this cluster. For instance experimental research suggests that  
32 remote immune-inflammatory mechanisms can contribute to the non-dermatomal/cutaneous  
33 innervation spread of symptoms in response to mild sciatic nerve compression in rat models  
34 (Schmid et al, 2013). Furthermore, evidence of non-dermatomal/cutaneous innervation  
35 spread of symptoms in both distal and proximal entrapment neuropathies have been  
36 previously reported (Tampin et al, 2012 & Nora et al, 2004). This highlights the possibility  
37 that pain may not always follow a dermatomal/cutaneous innervation pattern. In addition, an  
38 increasing body of literature highlights the low diagnostic validity of neurodynamic testing  
39 (Nee et al, 2012, Baselgia et al, 2017, Schmid et al, 2018) which consequently questions its  
40 utility as an indicator to detect NP in LBLP. These findings highlight a need for further  
41 consideration of the clinical indicators used to identify NP in LBLP, as clinical uncertainty  
42 exists and there is no established gold standard.

## Objective



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3 To conduct a three round modified Delphi study to achieve expert consensus on a list of  
4 clinical indicators to identify NP in LBLP  
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## 9 **Methods**

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13 This study will be conducted using a modified Delphi method. The Delphi method is an  
14 iterative multistage process used to achieve expert consensus on a given subject (Hasson et  
15 al, 2000). Expert consensus derived criteria obtained through a Delphi method have been  
16 shown to be an effective tool in situations of uncertainty to inform clinical decision making  
17 (Powell, 2003). The Delphi method is a low cost, simple procedure which can be used to  
18 gain information from a large population (Murphy et al, 1998). The Delphi method is  
19 anonymous and participants do not directly interact, instead they receive feedback from their  
20 peers, this minimises the risk of few individuals' opinions dominating (Merlin et al, 2016).  
21 The anonymity has also been linked to higher response rates (Heiko, 2012). This Delphi will  
22 be conducted online which helps to accelerate data collection. Furthermore, geographical  
23 location provides no barrier to participation in the study as it will be conducted electronically  
24 (Merlin et al, 2016).  
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35 This three-round modified Delphi method has been designed with guidance from the  
36 Conducting and Reporting Delphi Studies (CREDES) recommendations (Appendix 1). The  
37 CREDES recommendations are featured on the Equator network and are the only reporting  
38 guidance recommendations for Delphi studies (Jünger et al, 2017). Three rounds of  
39 questionnaires will be administered anonymously through RedCap ([https://www.project-  
40 redcap.org](https://www.project-redcap.org)). All three rounds will use a five-point Likert scale to evaluate the level of  
41 agreement. Between rounds one and three, the results will be analysed and questionnaires  
42 constructed for subsequent rounds. Clinical indicators that do not achieve the consensus will  
43 be removed at each stage. Resultant data at the end of round three will be brought together  
44 to devise a consensus derived list of clinical indicators. The stages of the Delphi and  
45 development of the expert consensus derived list of clinical indicators is summarised in  
46 Figure 1.  
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### Steering committee

The steering committee will be located at the University of Birmingham. The committee will comprise of the lead investigator, a MRes student JM, second investigator a PhD student TN and three senior academics based at the University of Birmingham AR, DF and NH. The three senior academics have considerable experience of using the Delphi technique as well as quantitative and qualitative research methods, and will ensure study quality at each stage.

### Participants

Experts will be defined as individuals with a high level of knowledge within the area of NP in LBLP which will be confirmed against the eligibility criteria outlined below. Recruited experts will be expected to develop a consensus list which will reflect a high degree of content/face validity (McCarthy et al., 2006). Experts will include musculoskeletal/pain specialist physiotherapists, allied healthcare professionals, doctors and academics: all of whom work within a pain setting/have a special interest in NP. JM and TN will review the profiles of potential participants to decide eligibility based on the following criteria:

- International research experts who have  $\geq 2$  peer-reviewed publications relating to NP in LBLP or a related topic (Wiangkham et al, 2016), or
- Working within a pain clinic/musculoskeletal outpatient department for  $\geq 10$  years

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3 Fulfilment of  $\geq 1$  criterion will be required for participant inclusion. There is no clear evidence  
4 to support the use of a pre-defined criteria in ensuring expert participant recruitment into a  
5 Delphi study, but it is consistent with the CREDES recommendations as well as criteria is  
6 used in previous Delphi studies (Wiangkham et al, 2016; Blaschke et al., 2017; Slade et al,  
7 2014). Also, the use of eligibility criteria increases the rigour and transparency of the  
8 recruitment process and minimises the risk of disputes between recruiters.  
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15 The number of participants in Delphi studies varies considerably and there is no clear  
16 indication within the literature of what the ideal number is (Murphy et al., 1998). The aim for  
17 this study will be to recruit a minimum of 30 participants (Sekayi & Kennedy, 2017).  
18 Furthermore, no upper limit will be set as the greater the number of participant, the greater  
19 the data generation. The expectation is that no more than 100 participants will be recruited  
20 based on a previous similar Delphi study (Smart et al, 2010).  
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## 26 27 Recruitment

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31 A snowballing strategy will be used to identify potential participants. JM and TN will review  
32 authorships of published systematic reviews relating to the clinical indicators of NP and  
33 identify national and international profiles. Experts will be invited to participate in the study  
34 and also requested to suggest any peers who fit the eligibility criteria (Slade et al, 2014). Call  
35 for expressions of interest will be posted on social media for participants to be nominated or  
36 self-nominate themselves. Social media platforms will be used due to its high-quality health  
37 care, research, and academic communities (Pezaro et al, 2015).  
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45 Contacted individuals will receive an email with four attached documents. A Participant  
46 Information Sheet will describe the aims and objectives of the Delphi, justification for the  
47 study, eligibility requirements for experts, stages involved in the Delphi process, timeframe  
48 for each stage, assurance on anonymity and the withdrawal process. The second document  
49 will be a consent form, the third a conflict of interest form and the final document will be a  
50 participant information form for participants to detail: age, gender, country of origin, country  
51 of current employment, highest qualification, occupation, professional  
52 background/credentials and working period in NP in LBLP/related field (Wiangkham et al,  
53 2016). Return of the consent form and conflict of interest and participant information form  
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3 signifies agreement to participate. Recruiters will collate/review returned information and  
4 email individuals to confirm participation in the study.  
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### 8 9 Ethical considerations/Quality assurance 10

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13 Ethical approval will be granted by the University of Birmingham. Eligible participants will be  
14 required to return a consent form and conflict of interest form. Participants will be advised at  
15 the start of the study of the withdrawal process should they need it. ID codes will be used  
16 instead of personal information to ensure participants remain anonymous throughout the  
17 process.  
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23 The data obtained in the study will be stored in a password encrypted electronic device  
24 which will only be accessible to the researchers involved in the study. Anonymity will be  
25 ensured throughout the study. Quality assurance will be achieved through three senior  
26 academics (AR, NH, DF) who are part of the steering committee. They share a vast amount  
27 of research methods experience, including the use of the Delphi method, therefore the use  
28 of their expertise in guiding/providing supervision to the lead investigator (JM) will ensure  
29 quality is maintained.  
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### 37 Procedure 38 39 40

41 Figure 2 details the procedure and timeline for the study. Prior to the start of the study, a  
42 pre-notification period of 6 weeks will be allocated to recruit participants.  
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### 47 Round 1 48

49 In the first-round participants will be invited to provide their level of agreement with the list of  
50 clinical indicators suggested by Smart et al (2010) to identify peripheral NP (Appendix 2), for  
51 the purpose of this study, in relation to identifying NP in LBLP. Level of agreement will be  
52 sought using a five-point Likert scale (5 = Strongly agree, 4 = Agree, 3 = No opinion,  
53 2 = Disagree, 1 = Strongly disagree). A five point Likert scale will be used as any number  
54 less than five in a Likert scale has been demonstrated to compromise reliability and validity  
55 (Preston and Colman, 2000). Secondly, through open questions, participants will be invited  
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3 to identify any missing clinical indicators. Participants will be invited to explain their reasons  
4 for their ratings and missing clinical indicators in a free text box. The use of open-ended  
5 questions allows participant freedom to volunteer any clinical indicators considered relevant,  
6 and for a richness in the qualitative data collected (Powell, 2003).  
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10 Participants will be given one month to complete round 1. Reminder emails will be sent to  
11 non-responders at weeks one and three, in this email the withdrawal process will be  
12 highlighted if participants are unable to continue with the study (Zambaldi et al, 2017). Only  
13 those participants who complete round 1 will be invited to round 2, in line with previous  
14 Delphi studies (Slade et al, 2014; Taylor et al, 2016).  
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### 20 *Round 2*

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22 Participants will be issued with the second questionnaire constructed from the results of  
23 round 1. Participants will again be invited to provide level of agreement/disagreement using  
24 the Likert scale for clinical indicators. Participants will be invited to identify any missing  
25 clinical indicators in the format of an open-ended question. Furthermore, participants will  
26 also be given the opportunity to explain the reason for their ratings and addition of any  
27 further clinical indicators.  
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34 Participants will be given one month to complete round 2. Reminder emails will be sent to  
35 non-responders at weeks one and three (Zambaldi et al, 2017). Only those participants who  
36 complete round 2 will be invited to round 3  
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### 41 *Round 3*

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46 The questionnaire for round 3 will be constructed using the clinical indicators which achieved  
47 consensus and any additional information gained from the open-ended question from round  
48 2. Only those who complete round 2 will be invited to round 3. In round 3 participants will be  
49 issued with the third questionnaire constructed from the results of round 2. Participants will  
50 be asked to re-rate their level of agreement with the clinical indicators, presented in  
51 graphical format as per round 2. Participants will also be invited to rank each clinical  
52 indicator for their importance, from highest to lowest. Feedback on round 3 will not be  
53 provided to the participants. Response data will then be re-analysed for levels of agreement  
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3 and consensus (Jones and Hunter, 1995). The steering committee will then use the results  
4 to identify a consensus derived list of clinical indicators.  
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### 9 Data collection

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13 Response data will be collected and quantitative data will be statistically analysed using  
14 SPSS (Version 25.0. Armonk, NY: IBM Corp.) and qualitative data from the open-ended  
15 questions will be inputted into summary tables in a word document for content analysis  
16 (Patton, 2002). Each round will take four weeks with two weeks after each round allocated  
17 for data analysis and formulation of subsequent questionnaire (Zambaldi et al, 2017).  
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### 22 Data analysis

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#### 26 Round 1

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30 Level of agreement with Smart et al's (2010) list will be measured using the Likert scale.  
31 Descriptive statistics including median, Inter-quartile range (IQR) and percentage of  
32 agreement will be gathered using data from each participant (Wiangkham et al, 2016).  
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35 Responses to open questions will be reviewed by JM and TN and a content analysis will be  
36 carried out (Patton, 2002). Results of content analysis will be brought back to the steering  
37 group to ensure quality is maintained, also any disagreements in content analysis will be  
38 presented to the steering group. Content analysis is typically used to identify major themes  
39 in response to qualitative data (Smart et al, 2010). The questionnaire for round 2 will be  
40 constructed using the clinical indicators which achieved consensus from Smart et al's (2010)  
41 list as well as using the missing indicators identified by participants in the open-ended  
42 aspect of the questionnaire.  
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49 Round 1 criteria for consensus include:

- 51 - Median value of participants Likert scale data  $\geq 3$
  - 52 - Percentage of agreement 50% (Wiangkham et al, 2016)
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#### 58 Round 2

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6 Results from round 1 will be presented in a graphical format, with each criterion presented  
7 as a bar chart. Each bar chart will show the number and percentage of respondents  
8 indicating level of agreement/disagreement. Furthermore, a narrative summary finding will  
9 be presented in round 2 of the findings from round 1's open ended question section. This will  
10 provide participants with feedback from round 1.  
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15 Likert scale will be used to assess agreement/disagreement with round 2 questionnaire.  
16 Further content analysis will be conducted from the open-ended free text boxes. Round 3  
17 questionnaire will be constructed using the same method as round 1.  
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21 Round 2 criteria for consensus:

- 22 - Median value of participants Likert scale data  $\geq 3.5$
- 23 - IQR value of participants Likert scale data  $\leq 2$
- 24 - Percentage of agreement 60% (Wiangkham et al, 2016)
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### 31 *Round 3*

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36 As per round 2, graphical depiction of round 2 findings and narrative summaries will be  
37 presented to participants. Participants will use the Likert scale again to suggest  
38 agreement/disagreement with round 3 questionnaire. Participants will rank each clinical  
39 indicator from highest to lowest with respect to importance.  
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44 Round 3 criteria for consensus:

- 45 - Median value of participants Likert scale data  $\geq 4$
- 46 - IQR value of participants Likert scale data  $\leq 3$
- 47 - Percentage of agreement 70% (Wiangkham et al, 2016)
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52 Agreement between participants will also be evaluated across all clinical indicators using  
53 Kendall's *W* coefficient of concordance (Heiko, 2012), statistical significance will be set at  
54  $p < 0.05$ .  
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### 58 *Data Management*

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3 All participant information and feedback will be securely stored on a password-protected  
4 computer throughout the duration of the study. Only members of the research team will be  
5 able to access the information. After completion of the Delphi study, all data will be kept  
6 securely for 10 years in the School of Sport, Exercise and Rehabilitation Sciences,  
7 University of Birmingham before being securely destroyed, in accordance with University  
8 guidelines.  
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### 14 Patient and public involvement

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18 Information from patients and the public has informed the conception and requirement for  
19 this Delphi study as part of an existing programme of research that is centred on lumbar  
20 spinal surgery for back related leg pain and patient outcome.  
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### 23 Dissemination plan

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27 This protocol will be submitted to an open access peer-reviewed journal. On completion the  
28 study findings will be disseminated in a peer-reviewed journal and presented at relevant  
29 conferences.  
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### 33 Conclusion

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39 There is uncertainty within the literature when considering the clinical indicators associated  
40 with identifying NP in LBLP. In order to ascertain a consensus derived set of clinical  
41 indicators, a modified Delphi study has been designed. The clinical implications of this study  
42 will aid clinicians in identifying a neuropathic component to LBLP through a list of clinical  
43 indicators. Assisting in accurate diagnosis will ensure that appropriate treatment is carried  
44 out.  
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### Author contributions

All authors devised the focus of this Delphi study. JM is a MRes student, AR is the lead supervisor, DF and NH are co supervisors and TN is a co-researcher. JM drafted the initial protocol manuscript with lead and co supervisors providing guidance on methodological decisions and proposed analyses. All authors have contributed subject specific expertise. JM and TN will recruit participants into the study. All authors will contribute to data interpretation, conclusions, and dissemination. All authors have read, contributed to, and agreed the final manuscript. AR is the guarantor of the study.

### Funding

It will be conducted as part of a MRes research project through the University of Birmingham.

### Patient consent for publication

Not required.

### Conflict of interest

None.

### Data statement

No further data are available.

## References

- Baron R, Binder A, Attal N, *et al.* Neuropathic low back pain in clinical practice. *European journal of pain* 2016;20: 861–873.
- Baselgia LT, Bennett DL, Silbiger RM, *et al.* Negative neurodynamic tests do not exclude neural dysfunction in patients with entrapment neuropathies. *Archives of Physical Medicine and Rehabilitation* 2017;98: 480 – 486.
- Beith D, Kemp A, Kenyon J, *et al.* Identifying neuropathic back and leg pain: A cross-sectional study. *Pain* 2011;152:1511-6.
- Berger A, Sadosky A, Dukes E, *et al.* Clinical characteristics and patterns of healthcare utilization in patients with painful neuropathic disorders in UK general practice: A retrospective cohort study. *BMC Neurology* 2012;12: 8.
- Blaschke S, O'Callaghan CC, Schofield P. Identifying opportunities for nature engagement in cancer care practice and design: Protocol for four-round modified electronic Delphi. *BMJ Open* 2017;7: 1–9.
- Freyenhagen R, Rolke R, Baron R, *et al.* (2008). Pseudoradicular and radicular low-back pain—a disease continuum rather than different entities? Answers from quantitative sensory testing. *Pain*. 135. 65-74.
- Harrison SA, Stynes S, Dunn KM, *et al.* NP in Low Back-Related Leg Pain Patients: What Is the Evidence of Prevalence, Characteristics, and Prognosis in Primary Care? A Systematic Review of the Literature. *The Journal of Pain* 2017;18: 1295-1312.
- Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing* 2000;32:1008–1015.
- Heiko A. Consensus measurement in Delphi studies: review and implications for future quality assurance. *Technol Forecast Soc Change* 2012;79:1525–36.
- Hider SL, Whitehurst DGT, Thomas E, *et al.* Pain location matters: the impact of leg pain on health care use, work disability and quality of life in patients with low back pain. *European Spine Journal* 2015;24: 444-451.
- Jünger S, Payne SA, Brine J, *et al.* Guidance on Conducting and REporting DElphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review. *Palliative Medicine* 2017;31: 684–706.

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3 Jones J, Hunter D. Qualitative research: consensus methods for medical and health services  
4 research. *British Medical Journal* 1995;31: 376–80.

6  
7 Konstantinou K, Hider L, Jordan L, *et al.* The impact of low back-related leg pain on  
8 outcomes as compared with low back pain alone: A systematic review of the literature. *Clin J*  
9 *Pain* 2013;29: 644-654.

11  
12 Liedgens H, Obradovic M, De Courcy J, *et al.* A burden of illness study for NP in Europe.  
13 *ClinicoEconomics and Outcomes Research* 2016;8:113-126.

15  
16 Mahn F, Hulleman P, Gockel U, *et al.* Sensory symptom profiles and co-morbidities in  
17 painful radiculopathy. *PLoS One* 2011;e18018.

19  
20 McCarthy CJ, Rushton A, Billis V, *et al.* Development of a clinical examination in non-  
21 specific low back pain: a Delphi technique. *Journal of Rehabilitation Medicine* 2006;38: 263-  
22 267.

24  
25 Merlin JS, Young SR, Azari S, *et al.* Management of problematic behaviours among  
26 individuals on long-term opioid therapy: protocol for a Delphi study. *BMJ Open*  
27 2016;6:e011619.

29  
30 Murphy MK, Black NA, Lamping DL, *et al.* Consensus development methods, and their use  
31 in clinical guideline development. *Health Technol Assess* 1998;2: 87–88.

33  
34 NICE (2016). Low back pain and sciatica in over 16s: assessment and management (NICE  
35 Guideline 33). National Institute for Health and Care Excellence. Available  
36 at: <https://www.nice.org.uk/guidance/ng59> [Accessed 10<sup>th</sup> May 2019].

38  
39 Nee RJ, Jull GA, Vicenzino B, *et al.* The validity of upper-limb neurodynamic tests for  
40 detecting peripheral neuropathic pain. *Journal of Orthopaedic Sports Physical Therapy*  
41 2012;42;413-424.

43  
44 Nora DB, Becker J, Ehlers JA, *et al.* Clinical features of 1039 patients with neurophysiologi-  
45 cal diagnosis of carpal tunnel syndrome. *Clin Neurol Neurosurg* 2004;107: 64-69.

47  
48 Ouédraogo DD, Nonguierma N, Napon C, *et al.* Prevalence of NP among black African  
49 patients suffering from common low back pain. *Rheumatol Int* 2012;32. 2149-2153.

51  
52 Patton MQ. Qualitative research methods. Thousand Oaks: Sage Publications. 2002.

54  
55 Pezaro S, Clyne W. Achieving Consensus in the Development of an Online Intervention  
56 Designed to Effectively Support Midwives in Work-Related Psychological Distress: Protocol  
57 for a Delphi Study. *JMIR research protocols* 2015;4:107.

- 1  
2  
3 Powell, C. The Delphi technique: myths and realities. *Journal of Advanced Nursing*  
4 2003;41:376-382.  
5  
6  
7 Preston CC, Colman AM. Optimal number of response categories in rating scales: reliability,  
8 validity, discriminating power, and respondent preferences. *Acta Psychologica* 2000;104:1–  
9 15.  
10  
11 Schmid AB, Hailey L, Tampin B. Entrapment Neuropathies: Challenging common beliefs  
12 with novel evidence. *J Orthop Sports Phys Ther* 2018;48: 58-62.  
13  
14 Schmid AB, Coppieters MW, Ruitenberh MJ, *et al.* Local and remote immune mediated  
15 inflammation after mild peripheral nerve compression in rats. *J Neuropathol Exp Neurol*  
16 2013;72:662-680.  
17  
18  
19 Sekayi D & Kennedy A. Qualitative Delphi method: A four round process with a worked  
20 example. *The Qualitative Report* 2017;22:2755-2763.  
21  
22  
23 Slade SC, Dionne CE, Underwood M, *et al.* Standardised method for reporting exercise  
24 programmes: protocol for a modified Delphi study. *BMJ Open* 2014;4:e006682.  
25  
26  
27  
28 Smart KM, Blake C, Staines A, *et al.* Clinical indicators of ‘nociceptive’, ‘peripheral  
29 neuropathic’ and ‘central’ mechanisms of musculoskeletal pain. A Delphi survey of expert  
30 clinicians. *Manual Therapy* 2010;15:80-7.  
31  
32  
33  
34 Smart KM, Blake C, Staines A, *et al.* Mechanisms-based classifications of musculoskeletal  
35 pain: Part 2 of 3: Symptoms and signs of peripheral NP in patients with low back ( $\pm$ leg) pain.  
36 *Manual Therapy* 2012;17:345-351.  
37  
38  
39 Smith BH, Torrance N, Bennett MI, *et al.* Health and quality of life associated with chronic  
40 pain of predominantly neuropathic origin in the community. *Clin J Pain* 2007;23:43–149.  
41  
42  
43 Tampin B, Slater H, Hall T, *et al.* Quantitative sensory testing somatosensory profiles in  
44 patients with cervical radiculopathy are distinct from those in patients with nonspecific neck-  
45 arm pain. *Pain* 2012;153:2403-2414.  
46  
47  
48 Taylor RM, Feltbower RG, Aslam N, *et al.* Modified international e-Delphi survey to define  
49 healthcare professional competencies for working with teenagers and young adults with  
50 cancer. *BMJ Open* 2016;6:e01136.  
51  
52  
53 Torrance N, Ferguson JA, Afolabi E, *et al.* NP in the community: more under-treated than  
54 refractory? *Pain* 2013;154:690–9.  
55  
56  
57 Treede RD, Jensen S, Campbell JN, *et al.* NP: Redefinition and a grading system for clinical  
58 and research processes. *Neurology* 2008;70:1630-1635.  
59  
60

1  
2  
3 van Hecke O, Austin SK, Khan RA *et al.* Neuropathic pain in the general population: a  
4 systematic review of epidemiological studies. *Pain* 2014;155:654–662.

5  
6  
7 Walsh J, Hall T. Classification of low back-related leg pain: Do subgroups differ in disability  
8 and psychosocial factors? *J Man Manip Ther* 2009;17:118-123.

9  
10  
11 Wiangkham T, Duda J, Haque MS, *et al.* Development of an active behavioural  
12 physiotherapy intervention (ABPI) for acute whiplash-associated disorder (WAD) II  
13 management: a modified Delphi study. *BMJ Open* 2016;6:e011764.

14  
15  
16 Zambaldi M, Beasley I, Rushton A. Return to play criteria after hamstring muscle injury in  
17 professional football: a Delphi consensus study. *Br J Sports Med* 2017;51;1221–1226.



## Appendix 1

### Rationale for the choice of the Delphi technique

1. *Justification.* The choice of the Delphi technique as a method of systematically collating expert consultation and building consensus needs to be well justified. When selecting the method to answer a particular research question, it is important to keep in mind its constructivist nature

### Planning and design

2. *Planning and process.* The Delphi technique is a flexible method and can be adjusted to the respective research aims and purposes. Any modifications should be justified by a rationale and be applied systematically and rigorously
3. *Definition of consensus.* Unless not reasonable due to the explorative nature of the study, an a priori criterion for consensus should be defined. This includes a clear and transparent guide for action on (a) how to proceed with certain items or topics in the next survey round, (b) the required threshold to terminate the Delphi process and (c) procedures to be followed when consensus is (not) reached after one or more iterations

### Study conduct

4. *Informational input.* All material provided to the expert panel at the outset of the project and throughout the Delphi process should be carefully reviewed and piloted in advance in order to examine the effect on experts' judgements and to prevent bias
5. *Prevention of bias.* Researchers need to take measures to avoid directly or indirectly influencing the experts' judgements. If one or more members of the research team have a conflict of interest, entrusting an independent researcher with the main coordination of the Delphi study is advisable
6. *Interpretation and processing of results.* Consensus does not necessarily imply the 'correct' answer or judgement; (non)consensus and stable disagreement provide informative insights and highlight differences in perspectives concerning the topic in question
7. *External validation.* It is recommended to have the final draft of the resulting guidance on best practice in palliative care reviewed and approved by an external board or authority before publication and dissemination

### Reporting

8. *Purpose and rationale.* The purpose of the study should be clearly defined and demonstrate the appropriateness of the use of the Delphi technique as a method to achieve the research aim. A rationale for the choice of the Delphi technique as the most suitable method needs to be provided
9. *Expert panel.* Criteria for the selection of experts and transparent information on recruitment of the expert panel, socio-demographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported
10. *Description of the methods.* The methods employed need to be comprehensible; this includes information on preparatory steps (How was available evidence on the topic in question synthesised?), piloting of material and survey instruments, design of the survey instrument(s), the number and design of survey rounds, methods of data analysis, processing and synthesis of experts' responses to inform the subsequent survey round and methodological decisions taken by the research team throughout the process
11. *Procedure.* Flow chart to illustrate the stages of the Delphi process, including a preparatory phase, the actual 'Delphi rounds', interim steps of data processing and analysis, and concluding steps
12. *Definition and attainment of consensus.* It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus
13. *Results.* Reporting of results for each round separately is highly advisable in order to make the evolving of consensus over the rounds transparent. This includes figures showing the average group response, changes between rounds, as well as any modifications of the survey instrument such as deletion, addition or modification of survey items based on previous rounds
14. *Discussion of limitations.* Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance
15. *Adequacy of conclusions.* The conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance
16. *Publication and dissemination.* The resulting guidance on good practice in palliative care should be clearly identifiable from the publication, including recommendations for transfer into practice and implementation. If the publication does not allow for a detailed presentation of either the resulting practice guidance or the methodological features of the applied Delphi technique, or both, reference to a more detailed presentation elsewhere should be made (e.g. availability of the full guideline from the authors or online; publication of a separate paper reporting on methodological details and particularities of the process (e.g. persistent disagreement and controversy on certain issues)). A dissemination plan should include endorsement of the guidance by professional associations and health care authorities to facilitate implementation

## Appendix 2

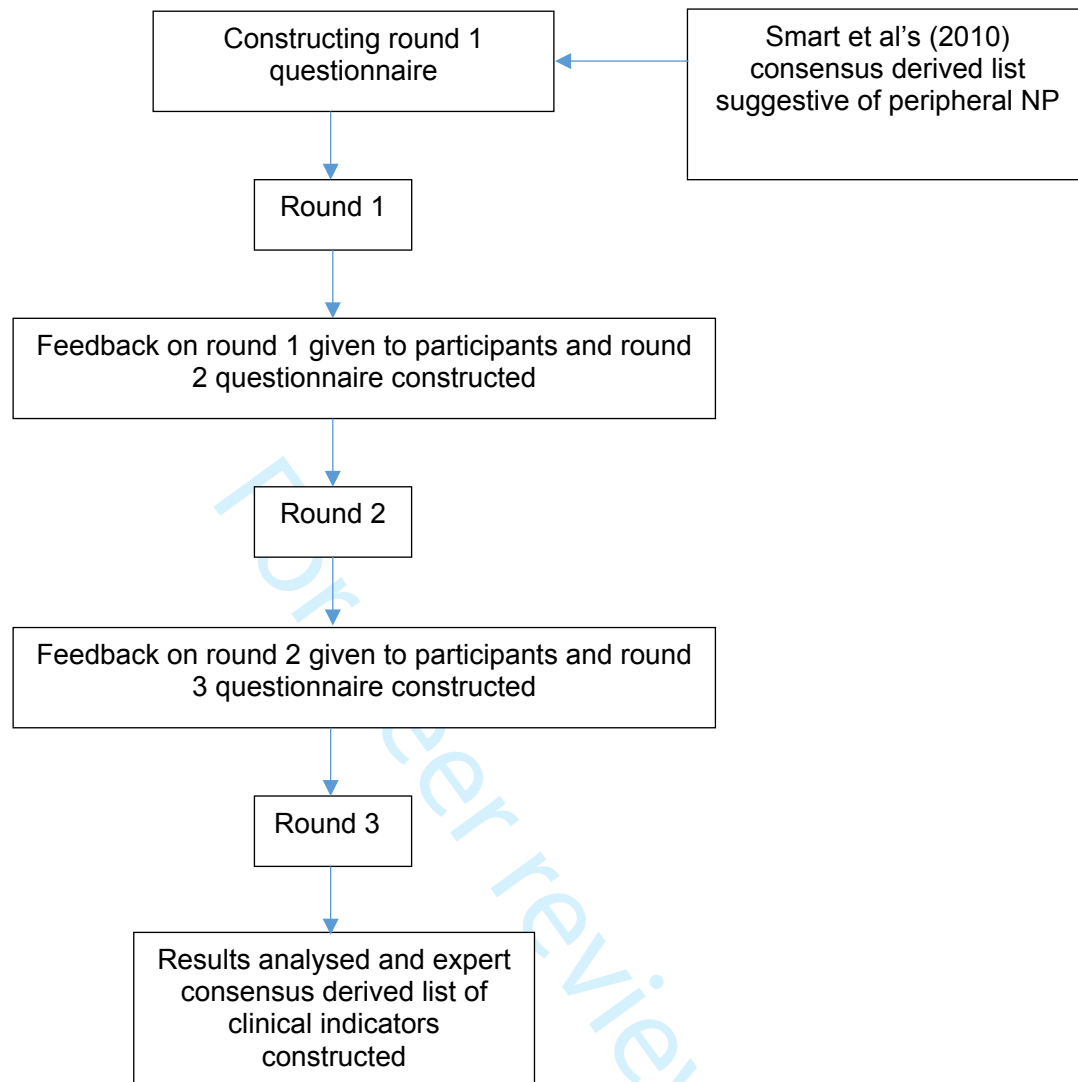
Delphi-derived clinical indicators of 'peripheral neuropathic' pain (Smart et al., 2010).

### **Subjective:**

- Pain variously described as burning, shooting, sharp, aching or electric-shock-like.
- History of nerve injury, pathology or mechanical compromise.
- Pain in association with other neurological symptoms (e.g. pins and needles, numbness, weakness).
- Pain referred in a dermatomal or cutaneous distribution.
- Less responsive to simple analgesia/NSAIDS\* and/or more responsive to anti-epileptic (e.g. Neurontin, Lyrica)/anti-depression (e.g. Amitriptyline) medication.
- Pain of high severity and irritability (i.e. easily provoked, taking longer to settle).
- Mechanical pattern to aggravating and easing factors involving activities/postures associated with movement, loading or compression of neural tissue.
- Pain in association with other dysesthesias (e.g. crawling, electrical, heaviness).
- Reports of spontaneous (i.e. stimulus-independent) pain and/or paroxysmal pain (i.e. sudden recurrences and intensification of pain).

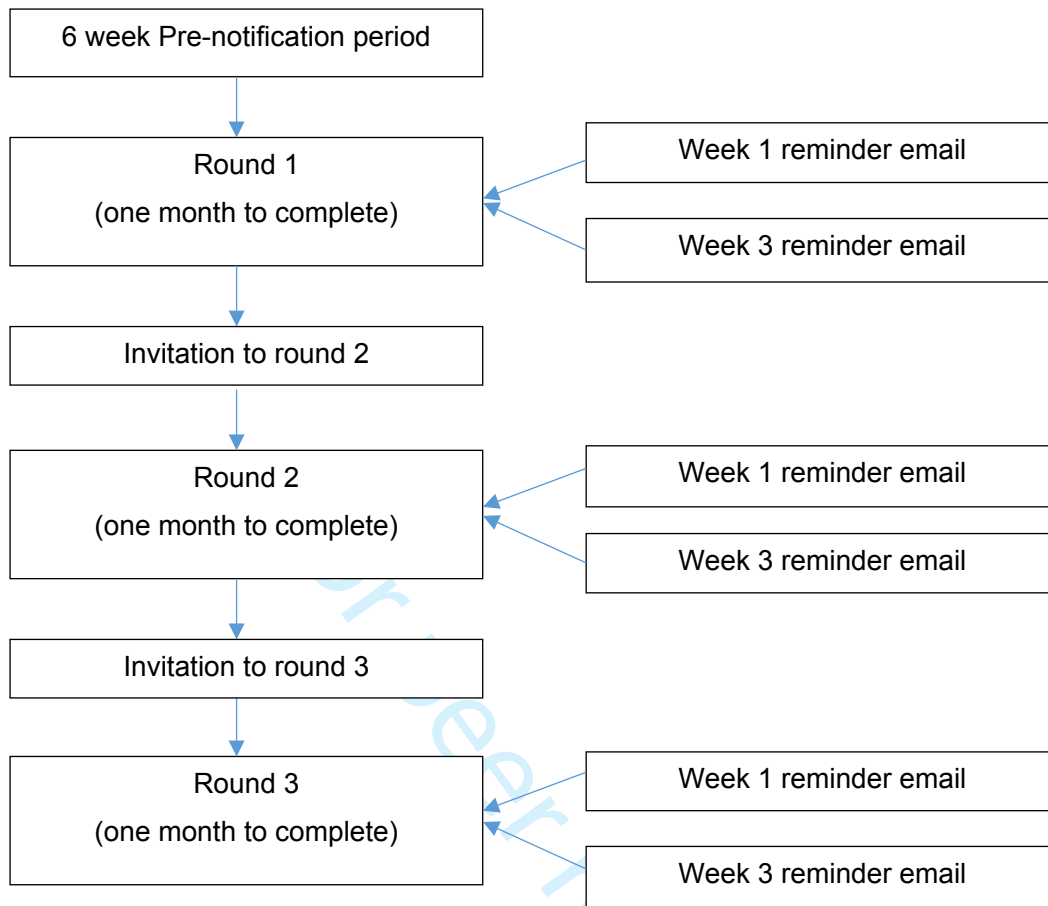
### **Clinical examination:**

- Pain/symptom provocation with mechanical/movement tests (e.g. Active/Passive, Neurodynamic, i.e. SLR<sup>#</sup>, Brachial plexus tension test) that move/load/compress neural tissue.
- Pain/symptom provocation on palpation of relevant neural tissues.
- Positive neurological findings (including altered reflexes, sensation and muscle power in a dermatomal/myotomal or cutaneous nerve distribution).
- Antalgic posturing of the affected limb/body part.
- Positive findings of hyperalgesia (primary or secondary) and/or allodynia and/or hyperpathia within the distribution of pain.



**Figure 1.** Modified Delphi processes to construct list of clinical indicators





**Figure 2.** Procedure and timelines for participants in Delphi study.

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## Clinical indicators to identify neuropathic pain in low back related leg pain: protocol for a modified Delphi study

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# Clinical indicators to identify neuropathic pain in low back related leg pain: protocol for a modified Delphi study

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## Abstract

### Introduction

Neuropathic low back related leg pain (LBLP) can be a challenge to healthcare providers to diagnose and treat. Accurate diagnosis of neuropathic pain (NP) is fundamental to ensure appropriate intervention is given. However, to date there is no gold standard to diagnose neuropathic LBLP. A Delphi study will therefore be conducted to obtain an expert derived consensus list of clinical indicators to identify a neuropathic component to LBLP.

### Methods/analysis

Included participants will be considered experts within the field as measured against a pre-defined eligibility criterion. Through an iterative multistage process, participants will rate their agreement with a list of clinical indicators and suggest any missing clinical indicators during each round. Agreement will be measured using the Likert scale. Descriptive statistics will be used to measure agreement; median, IQR and percentage of agreement. Priori consensus criteria will be defined for each round. Data will be collected at the end of round three and a list of clinical indicators will be derived at the end of this study

### Ethics/dissemination

Ethical approval was gained from the University of Birmingham (ERN\_19-1142). On completion of the study findings will be disseminated in a peer-reviewed journal and presented at relevant conferences.

### Keywords

Neuropathic, leg pain, Delphi, diagnosis

## Word count

3126 words

## Article summary

### Strengths and limitations of this study

- This will be the first study to develop a list of clinical indicators to identify a neuropathic component to LBLP, which will help to inform clinicians regarding treatment interventions
- This study will use national and international experts in neuropathic pain to inform the list of clinical indicators
- This study will be reported in line with Conducting and Reporting Delphi Studies recommendations
- This study is a mixed method design and thus utilises quantitative and qualitative data
- The views of Delphi panellists may differ from those experts who decline participation, and may not fully represent experts in the field of interest.

## Introduction

Neuropathic pain (NP) is defined as pain caused by a lesion or disease of the somatosensory nervous system.(1) NP is a largely unmet medical need due to ineffective management.(2) NP is highly prevalent and has been estimated to have a global population prevalence of between 6.9% - 10%.(3) NP is associated with vast economic costs; with total annual costs (including direct and indirect costs) per patient in Europe ranging from £8710 in the UK to €14,446 in Germany.(4) Epidemiological surveys have shown that many patients with NP do not receive appropriate treatment, a common reason for this is misdiagnosis.(5) One of the most common presentations of NP is found in those with low back pain (LBP), which is estimated to be at approximately 46.7%.(6) Up to two thirds of individuals with LBP report concomitant leg pain when presenting in primary and secondary care services.(7) Low back related leg pain (LBLP) compared to LBP alone is associated with increased disability, pain, and poorer quality of life.(8,9) LBLP is generally clinically diagnosed as sciatica (lumbar radicular) or referred pain (involving non-neural structures); sciatica is considered neuropathic in nature whereas referred pain is considered nociceptive.(7) However, there is evidence to suggest the coexistence of both pain mechanisms in LBLP,(10) and evidence for sciatica presenting without NP and referred pain presenting with NP.(11)

According to the National Institute for Health and Care Excellence (NICE) recent guidelines, the management of NP differs significantly to the management of LBP without sciatica.(12) Thus the importance of accurate diagnosis of NP in relation to LBLP ensures that appropriate management is provided. Identification of patients with NP in LBLP is essential as pharmaceutical intervention, if indicated, may improve patient outcomes.(7) To date, there is no gold standard for diagnosing NP.(13) Consequently, expert opinion consensus derived lists and a variety of patient reported outcome measures (PROMs) have been developed and used as methods to determine the presence of NP in research studies.(14,7) However, there is no uniformity within the literature regarding the best clinical indicators to

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2  
3 use to identify NP in LBLP. The most common clinical indicators utilised to identify NP in  
4 LBLP research include the PainDetect,(15) The Leeds Assessment of Neuropathic  
5 Symptoms and Signs (LANSS),(16) and Douleur Neuropathique 4 (DN4).(17)  
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10 A cross-sectional study by Smart et al (2012)(18) is the one study to identify clinical  
11 indicators predictive of the presence of peripheral NP in low back pain (with or without leg  
12 pain), consisting of a cluster of two symptoms and one sign: '*pain referred in a dermatomal*  
13 *or cutaneous distribution*', '*history of nerve injury, pathology or mechanical*  
14 *compromise*' and '*pain/symptom provocation with mechanical/movement tests (e.g.*  
15 *active/passive, neurodynamic) that move/load/compress neural tissue*'. However, there is  
16 evidence to refute aspects of this cluster. For instance experimental research suggests that  
17 remote immune-inflammatory mechanisms can contribute to the non-dermatomal/cutaneous  
18 innervation spread of symptoms in response to mild sciatic nerve compression in rat  
19 models.(19) Furthermore, evidence of non-dermatomal/cutaneous innervation spread of  
20 symptoms in both distal and proximal entrapment neuropathies have been previously  
21 reported.(20,21) This highlights the possibility that pain may not always follow a  
22 dermatomal/cutaneous innervation pattern. In addition, an increasing body of literature  
23 highlights the low diagnostic validity of neurodynamic testing which consequently questions  
24 its utility as an indicator to detect NP in LBLP.(22-24) These findings highlight a need for  
25 further consideration of the clinical indicators used to identify NP in LBLP, as clinical  
26 uncertainty exists and there is no established gold standard.  
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## 40 Objective

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43 To conduct a three round modified Delphi study to achieve expert consensus on a list of  
44 clinical indicators to identify NP in LBLP  
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## 51 Methods

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55 This study will be conducted using a modified Delphi method. The Delphi method is an  
56 iterative multistage process used to achieve expert consensus on a given subject.(25)  
57 Expert consensus derived criteria obtained through a Delphi method have been shown to be  
58 an effective tool in situations of uncertainty to inform clinical decision making.(26) The Delphi  
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3 method is a low cost, simple procedure which can be used to gain information form a large  
4 population.(27) The Delphi method is anonymous and participants do not directly interact,  
5 instead they receive feedback from their peers, this minimises the risk of few individuals'  
6 opinions dominating.(28) The anonymity has also been linked to higher response rates.(29)  
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8 This Delphi will be conducted online which helps to accelerate data collection. Furthermore,  
9 geographical location provides no barrier to participation in the study as it will be conducted  
10 electronically.(28)  
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17 This three-round modified Delphi method has been designed with guidance from the  
18 Conducting and Reporting Delphi Studies (CREDES) recommendations (Appendix 1). The  
19 CREDES recommendations are featured on the Equator network and are the only reporting  
20 guidance recommendations for Delphi studies.(30) Three rounds of questionnaires will be  
21 administered anonymously through RedCap (<https://www.project-redcap.org>). All three  
22 rounds will use a five-point Likert scale to evaluate the level of agreement. Between rounds  
23 one and three, the results will be analysed and questionnaires constructed for subsequent  
24 rounds. Clinical indicators that do not achieve the consensus will be removed at each  
25 stage. Resultant data at the end of round three will be brought together to devise a  
26 consensus derived list of clinical indicators. The stages of the Delphi and development of the  
27 expert consensus derived list of clinical indicators is summarised in Figure 1.  
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### 37 Steering committee

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41 The steering committee will be located at the University of Birmingham. The committee will  
42 comprise of the lead investigator, a MRes student JM, second investigator a PhD student TN  
43 and three senior academics based at the University of Birmingham AR, DF and NH. The  
44 three senior academics have considerable experience of using the Delphi technique as well  
45 as quantitative and qualitative research methods, and will ensure study quality at each  
46 stage.  
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### 53 Participants

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57 Experts will be defined as individuals with a high level of knowledge within the area of NP in  
58 LBLP which will be confirmed against the eligibility criteria outlined below. Recruited experts  
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3 will be expected to develop a consensus list which will reflect a high degree of content/face  
4 validity.(31) Experts will include musculoskeletal/pain specialist physiotherapists, allied  
5 healthcare professionals, doctors and academics: all of whom work within a pain  
6 setting/have a special interest in NP. JM and TN will review the profiles of potential  
7 participants to decide eligibility based on the following criteria:

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11 - International research experts who have  $\geq 2$  peer-reviewed publications relating to NP in  
12 LBLP or a related topic,(32) or  
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14 - Working within a pain clinic/musculoskeletal outpatient department for  $\geq 10$  years  
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19 Fulfilment of  $\geq 1$  criterion will be required for participant inclusion. There is no clear evidence  
20 to support the use of a pre-defined criteria in ensuring expert participant recruitment into a  
21 Delphi study, but it is consistent with the CREDES recommendations as well as criteria is  
22 used in previous Delphi studies.(32-34) Also, the use of eligibility criteria increases the rigour  
23 and transparency of the recruitment process and minimises the risk of disputes between  
24 recruiters.  
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31 The number of participants in Delphi studies varies considerably and there is no clear  
32 indication within the literature of what the ideal number is.(27) The aim for this study will be  
33 to recruit a minimum of 30 participants.(35) Furthermore, no upper limit will be set as the  
34 greater the number of participant, the greater the data generation. The expectation is that no  
35 more than 100 participants will be recruited based on a previous similar Delphi study.(14)  
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## 41 Recruitment

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46 A snowballing strategy will be used to identify potential participants. JM and TN will review  
47 authorships of published systematic reviews relating to the clinical indicators of NP and  
48 identify national and international profiles. Experts will be invited to participate in the study  
49 and also requested to suggest any peers who fit the eligibility criteria.(34) Call for  
50 expressions of interest will be posted on social media for participants to be nominated or  
51 self-nominate themselves. Social media platforms will be used due to its high-quality health  
52 care, research, and academic communities.(36)  
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3 Contacted individuals will receive an email with four attached documents. A Participant  
4 Information Sheet will describe the aims and objectives of the Delphi, justification for the  
5 study, eligibility requirements for experts, stages involved in the Delphi process, timeframe  
6 for each stage, assurance on anonymity and the withdrawal process. The second document  
7 will be a consent form, the third a conflict of interest form and the final document will be a  
8 participant information form for participants to detail: age, gender, country of origin, country  
9 of current employment, highest qualification, occupation, professional  
10 background/credentials and working period in NP in LBLP/related field.(32) Return of the  
11 consent form and conflict of interest and participant information form signifies agreement to  
12 participate. Recruiters will collate/review returned information and email individuals to  
13 confirm participation in the study.  
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### 23 Ethical considerations/Quality assurance

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27 Ethical approval was granted by the University of Birmingham (ERN\_19-1142). Eligible  
28 participants will be required to return a consent form and conflict of interest form.  
29 Participants will be advised at the start of the study of the withdrawal process should they  
30 need it. ID codes will be used instead of personal information to ensure participants remain  
31 anonymous throughout the process.  
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38 The data obtained in the study will be stored in a password encrypted electronic devise  
39 which will only be accessible to the researchers involved in the study. Anonymity will be  
40 ensured throughout the study. Quality assurance will be achieved through three senior  
41 academics (AR, NH, DF) who are part of the steering committee. They share a vast amount  
42 of research methods experience, including the use of the Delphi method, therefore the use  
43 of their expertise in guiding/providing supervision to the lead investigator (JM) will ensure  
44 quality is maintained.  
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### 51 Procedure

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56 Figure 2 details the procedure and timeline for the study. Prior to the start of the study, a  
57 pre-notification period of 6 weeks will be allocated to recruit participants.  
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### Round 1

In the first-round participants will be invited to provide their level of agreement with the list of clinical indicators suggested by Smart et al (2010)(14) to identify peripheral NP (Appendix 2), for the purpose of this study, in relation to identifying NP in LBLP. Level of agreement will be sought using a five-point Likert scale (5 = Strongly agree, 4 = Agree, 3 = No opinion, 2 = Disagree, 1 = Strongly disagree). A five point Likert scale will be used as any number less than five in a Likert scale has been demonstrated to compromise reliability and validity.(37) Secondly, through open questions, participants will be invited to identify any missing clinical indicators. Participants will be invited to explain their reasons for their ratings and missing clinical indicators in a free text box. The use of open-ended questions allows participant freedom to volunteer any clinical indicators considered relevant, and for a richness in the qualitative data collected.(26)

Participants will be given one month to complete round 1. Reminder emails will be sent to non-responders at weeks one and three, in this email the withdrawal process will be highlighted if participants are unable to continue with the study.(38) Only those participants who complete round 1 will be invited to round 2, in line with previous Delphi studies.(34,39)

### Round 2

Participants will be issued with the second questionnaire constructed from the results of round 1. Participants will again be invited to provide level of agreement/disagreement using the Likert scale for clinical indicators. Participants will be invited to identify any missing clinical indicators in the format of an open-ended question. Furthermore, participants will also be given the opportunity to explain the reason for their ratings and addition of any further clinical indicators.

Participants will be given one month to complete round 2. Reminder emails will be sent to non-responders at weeks one and three.(38) Only those participants who complete round 2 will be invited to round 3

### Round 3

The questionnaire for round 3 will be constructed using the clinical indicators which achieved consensus and any additional information gained from the open-ended question from round 2. Only those who complete round 2 will be invited to round 3. In round 3 participants will be

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2  
3 issued with the third questionnaire constructed from the results of round 2. Participants will  
4 be asked to re-rate their level of agreement with the clinical indicators, presented in  
5 graphical format as per round 2. Participants will also be invited to rank each clinical  
6 indicator for their importance, from highest to lowest. Feedback on round 3 will not be  
7 provided to the participants. Response data will then be re-analysed for levels of agreement  
8 and consensus.(40) The steering committee will then use the results to identify a consensus  
9 derived list of clinical indicators.  
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### 17 Data collection

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21 Response data will be collected and quantitative data will be statistically analysed using  
22 SPSS (Version 25.0. Armonk, NY: IBM Corp.) and qualitative data from the open-ended  
23 questions will be inputted into summary tables in a word document for content analysis.(41)  
24 Each round will take four weeks with two weeks after each round allocated for data analysis  
25 and formulation of subsequent questionnaire.(38)  
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### 30 Data analysis

#### 31 Round 1

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34 Level of agreement with Smart et al's (2010)(14) list will be measured using the Likert scale.  
35 Descriptive statistics including median, Inter-quartile range (IQR) and percentage of  
36 agreement will be gathered using data from each participant.(32)  
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41 Responses to open questions will be reviewed by JM and TN and a content analysis will be  
42 carried out.(41) Results of content analysis will be brought back to the steering group to  
43 ensure quality is maintained, also any disagreements in content analysis will be presented to  
44 the steering group. Content analysis is typically used to identify major themes in response to  
45 qualitative data.(14) The questionnaire for round 2 will be constructed using the clinical  
46 indicators which achieved consensus from Smart et al's (2010)(14) list as well as using the  
47 missing indicators identified by participants in the open-ended aspect of the questionnaire.  
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54 Round 1 criteria for consensus include:

- 55 - Median value of participants Likert scale data  $\geq 3$
  - 56 - Percentage of agreement 50%(32)
- 57  
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## Round 2

Results from round 1 will be presented in a graphical format, with each criterion presented as a bar chart. Each bar chart will show the number and percentage of respondents indicating level of agreement/disagreement. Furthermore, a narrative summary finding will be presented in round 2 of the findings from round 1's open ended question section. This will provide participants with feedback from round 1.

Likert scale will be used to assess agreement/disagreement with round 2 questionnaire. Further content analysis will be conducted from the open-ended free text boxes. Round 3 questionnaire will be constructed using the same method as round 1.

Round 2 criteria for consensus:

- Median value of participants Likert scale data  $\geq 3.5$
- IQR value of participants Likert scale data  $\leq 2$
- Percentage of agreement 60%(32)

## Round 3

As per round 2, graphical depiction of round 2 findings and narrative summaries will be presented to participants. Participants will use the Likert scale again to suggest agreement/disagreement with round 3 questionnaire. Participants will rank each clinical indicator from highest to lowest with respect to importance.

Round 3 criteria for consensus:

- Median value of participants Likert scale data  $\geq 4$
- IQR value of participants Likert scale data  $\leq 3$
- Percentage of agreement 70%(32)

Agreement between participants will also be evaluated across all clinical indicators using Kendall's *W* coefficient of concordance,(29) statistical significance will be set at  $p < 0.05$ .

## Data Management

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2  
3 All participant information and feedback will be securely stored on a password-protected  
4 computer throughout the duration of the study. Only members of the research team will be  
5 able to access the information. After completion of the Delphi study, all data will be kept  
6 securely for 10 years in the School of Sport, Exercise and Rehabilitation Sciences,  
7 University of Birmingham before being securely destroyed, in accordance with University  
8 guidelines.  
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### 15 Patient and public involvement

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18 Information from patients and the public has informed the conception and requirement for  
19 this Delphi study as part of an existing programme of research that is centred on lumbar  
20 spinal surgery for back related leg pain and patient outcome.  
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### 26 Dissemination plan

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29 This protocol will be submitted to an open access peer-reviewed journal. On completion, the  
30 study findings will be disseminated in a peer-reviewed journal and presented at relevant  
31 conferences.  
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### 38 Conclusion

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41 There is uncertainty within the literature when considering the clinical indicators associated  
42 with identifying NP in LBLP. In order to ascertain a consensus derived set of clinical  
43 indicators, a modified Delphi study has been designed. The clinical implications of this study  
44 will aid clinicians in identifying a neuropathic component to LBLP through a list of clinical  
45 indicators. Assisting in accurate diagnosis will ensure that appropriate treatment is carried  
46 out.  
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### Author contributions

All authors devised the focus of this Delphi study. JM is a MRes student, AR is the lead supervisor, DF and NH are co supervisors and TN is a co-researcher. JM drafted the initial protocol manuscript with lead and co supervisors providing guidance on methodological decisions and proposed analyses. All authors have contributed subject specific expertise. JM and TN will recruit participants into the study. All authors will contribute to data interpretation, conclusions, and dissemination. All authors have read, contributed to, and agreed the final manuscript. AR is the guarantor of the study.

### Funding

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### Patient consent for publication

Not required.

### Conflict of interest

None.

### Data statement

No further data are available.



## References

1. Treede RD, Jensen S, Campbell JN, *et al.* NP: Redefinition and a grading system for clinical and research processes. *Neurology* 2008;70:1630-1635.
2. Baron R, Binder A, Attal N, *et al.* Neuropathic low back pain in clinical practice. *European journal of pain* 2016;20: 861–873.
3. van Hecke O, Austin SK, Khan RA *et al.* Neuropathic pain in the general population: a systematic review of epidemiological studies. *Pain* 2014;155:654–662.
4. Liedgens H, Obradovic M, De Courcy J, *et al.* A burden of illness study for NP in Europe. *ClinicoEconomics and Outcomes Research* 2016;8:113-126.
5. Torrance N, Ferguson JA, Afolabi E, *et al.* NP in the community: more under-treated than refractory? *Pain* 2013;154:690–9.
6. Berger A, Sadosky A, Dukes E, *et al.* Clinical characteristics and patterns of healthcare utilization in patients with painful neuropathic disorders in UK general practice: A retrospective cohort study. *BMC Neurology* 2012;12: 8.
7. Harrison SA, Stynes S, Dunn KM, *et al.* NP in Low Back-Related Leg Pain Patients: What Is the Evidence of Prevalence, Characteristics, and Prognosis in Primary Care? A Systematic Review of the Literature. *The Journal of Pain* 2017;18: 1295-1312.
8. Konstantinou K, Hider L, Jordan L, *et al.* The impact of low back-related leg pain on outcomes as compared with low back pain alone: A systematic review of the literature. *Clin J Pain* 2013;29: 644-654.
9. Hider SL, Whitehurst DGT, Thomas E, *et al.* Pain location matters: the impact of leg pain on health care use, work disability and quality of life in patients with low back pain. *European Spine Journal* 2015;24: 444-451.
10. Freynhagen R, Rolke R, Baron R, *et al.* (2008). Pseudoradicular and radicular low-back pain—a disease continuum rather than different entities? Answers from quantitative sensory testing. *Pain*. 135. 65-74.
11. Mahn F, Hulleman P, Gockel U, *et al.* Sensory symptom profiles and co-morbidities in painful radiculopathy. *PLoS One* 2011;e18018.

12. NICE (2016). Low back pain and sciatica in over 16s: assessment and management (NICE Guideline 33). National Institute for Health and Care Excellence. Available at: <https://www.nice.org.uk/guidance/ng59> [Accessed 10<sup>th</sup> May 2019].
13. Smith BH, Torrance N, Bennett MI, *et al.* Health and quality of life associated with chronic pain of predominantly neuropathic origin in the community. *Clin J Pain* 2007;23:43–149.
14. Smart KM, Blake C, Staines A, *et al.* Clinical indicators of ‘nociceptive’, ‘peripheral neuropathic’ and ‘central’ mechanisms of musculoskeletal pain. A Delphi survey of expert clinicians. *Manual Therapy* 2010;15:80-7.
15. Beith D, Kemp A, Kenyon J, *et al.* Identifying neuropathic back and leg pain: A cross-sectional study. *Pain* 2011;152:1511-6.
16. Walsh J, Hall T. Classification of low back-related leg pain: Do subgroups differ in disability and psychosocial factors? *J Man Manip Ther* 2009;17:118-123.
17. Ouédraogo DD, Nonguierma N, Napon C, *et al.* Prevalence of NP among black African patients suffering from common low back pain. *Rheumatol Int* 2012;32. 2149-2153.
18. Smart KM, Blake C, Staines A, *et al.* Mechanisms-based classifications of musculoskeletal pain: Part 2 of 3: Symptoms and signs of peripheral NP in patients with low back ( $\pm$ leg) pain. *Manual Therapy* 2012;17:345-351.
19. Schmid AB, Coppieters MW, Ruitenberh MJ, *et al.* Local and remote immune mediated inflammation after mild peripheral nerve compression in rats. *J Neuropathol Exp Neurol* 2013;72:662-680.
20. Tampin B, Slater H, Hall T, *et al.* Quantitative sensory testing somatosensory profiles in patients with cervical radiculopathy are distinct from those in patients with nonspecific neck-arm pain. *Pain* 2012;153:2403-2414.
21. Nora DB, Becker J, Ehlers JA, *et al.* Clinical features of 1039 patients with neurophysiologi- cal diagnosis of carpal tunnel syndrome. *Clin Neurol Neurosurg* 2004;107: 64-69.
22. Nee RJ, Jull GA, Vicenzino B, *et al.* The validity of upper-limb neurodynamic tests for detecting peripheral neuropathic pain. *Journal of Orthopaedic Sports Physical Therapy* 2012;42;413-424.

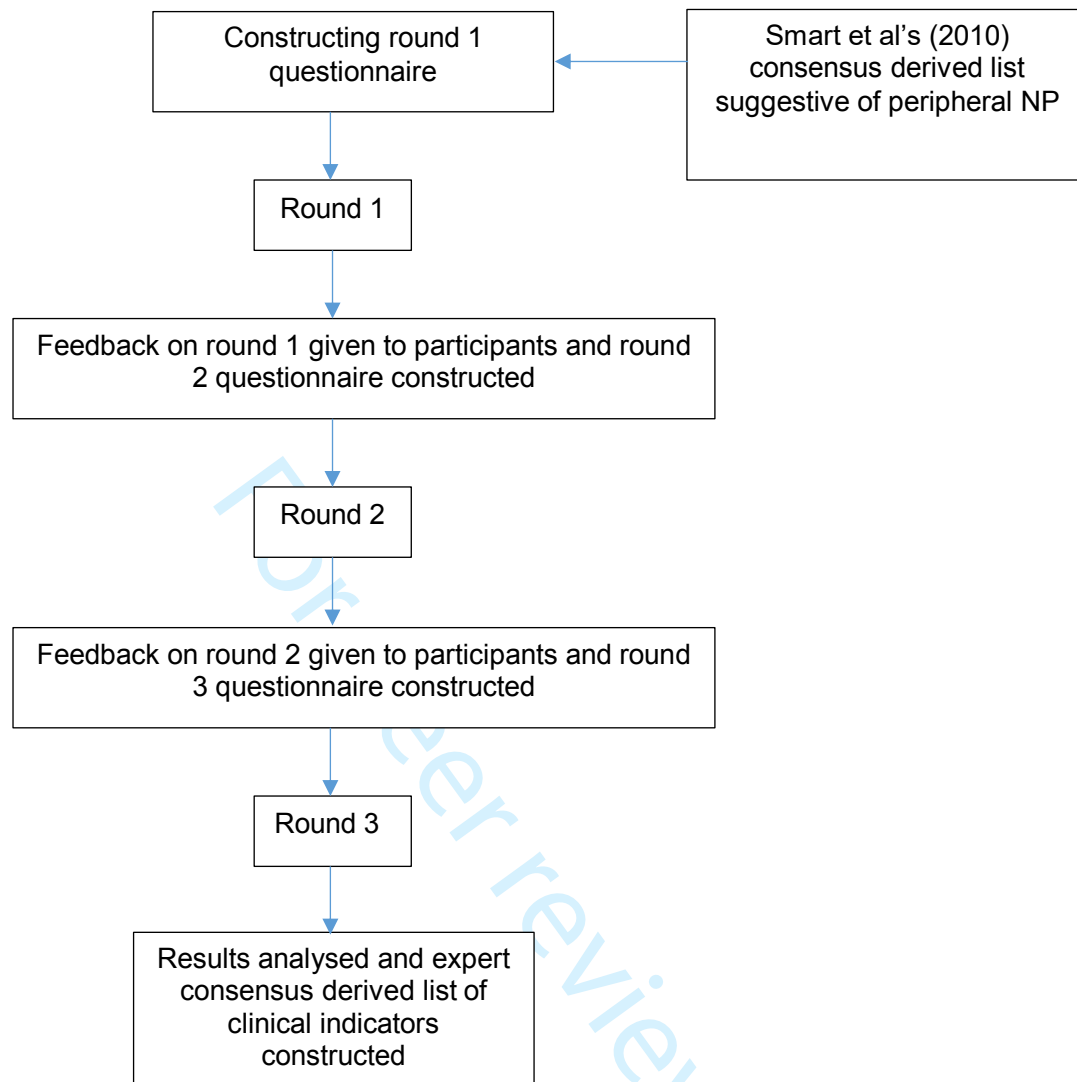
- 1  
2  
3 23. Baselgia LT, Bennett DL, Silbiger RM, *et al.* Negative neurodynamic tests do not exclude  
4 neural dysfunction in patients with entrapment neuropathies. *Archives of Physical Medicine*  
5 *and Rehabilitation* 2017;98: 480 – 486.  
6  
7  
8 24. Schmid AB, Hailey L, Tampin B. Entrapment Neuropathies: Challenging common beliefs  
9 with novel evidence. *J Orthop Sports Phys Ther* 2018;48: 58-62.  
10  
11 25. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique.  
12 *Journal of Advanced Nursing* 2000;32:1008–1015.  
13  
14 26. Powell, C. The Delphi technique: myths and realities. *Journal of Advanced Nursing*  
15 2003;41:376-382.  
16  
17 27. Murphy MK, Black NA, Lamping DL, *et al.* Consensus development methods, and their  
18 use in clinical guideline development. *Health Technol Assess* 1998;2: 87–88.  
19  
20 28. Merlin JS, Young SR, Azari S, *et al.* Management of problematic behaviours among  
21 individuals on long-term opioid therapy: protocol for a Delphi study. *BMJ Open*  
22 2016;6:e011619.  
23  
24 29. Heiko A. Consensus measurement in Delphi studies: review and implications for future  
25 quality assurance. *Technol Forecast Soc Change* 2012;79:1525–36.  
26  
27 30. Jünger S, Payne SA, Brine J, *et al.* Guidance on Conducting and REporting DELphi Studies  
28 (CREDES) in palliative care: Recommendations based on a methodological systematic  
29 review. *Palliative Medicine* 2017;31: 684–706.  
30  
31 31. McCarthy CJ, Rushton A, Billis V, *et al.* Development of a clinical examination in non-  
32 specific low back pain: a Delphi technique. *Journal of Rehabilitation Medicine* 2006;38: 263-  
33 267.  
34  
35 32. Wiangkham T, Duda J, Haque MS, *et al.* Development of an active behavioural  
36 physiotherapy intervention (ABPI) for acute whiplash-associated disorder (WAD) II  
37 management: a modified Delphi study. *BMJ Open* 2016;6:e011764.  
38  
39 33. Blaschke S, O’Callaghan CC, Schofield P. Identifying opportunities for nature engagement  
40 in cancer care practice and design: Protocol for four-round modified electronic Delphi. *BMJ*  
41 *Open* 2017;7: 1–9.  
42  
43 34. Slade SC, Dionne CE, Underwood M, *et al.* Standardised method for reporting exercise  
44 programmes: protocol for a modified Delphi study. *BMJ Open* 2014;4:e006682.  
45  
46 35. Sekayi D & Kennedy A. Qualitative Delphi method: A four round process with a worked  
47 example. *The Qualitative Report* 2017;22:2755-2763.  
48  
49  
50  
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- 1  
2  
3 36. Pezaro S, Clyne W. Achieving Consensus in the Development of an Online Intervention  
4 Designed to Effectively Support Midwives in Work-Related Psychological Distress: Protocol  
5 for a Delphi Study. *JMIR research protocols* 2015;4:107.  
6  
7  
8 37. Preston CC, Colman AM. Optimal number of response categories in rating scales:  
9 reliability, validity, discriminating power, and respondent preferences. *Acta Psychologica*  
10 2000;104:1–15.  
11  
12 38. Zambaldi M, Beasley I, Rushton A. Return to play criteria after hamstring muscle injury in  
13 professional football: a Delphi consensus study. *Br J Sports Med* 2017;51:1221–1226.  
14  
15 39. Taylor RM, Feltbower RG, Aslam N, *et al*. Modified international e-Delphi survey to  
16 define healthcare professional competencies for working with teenagers and young adults  
17 with cancer. *BMJ Open* 2016;6:e01136.  
18  
19 40. Jones J, Hunter D. Qualitative research: consensus methods for medical and health  
20 services research. *British Medical Journal* 1995;31: 376–80.  
21  
22 41. Patton MQ. Qualitative research methods. Thousand Oaks: Sage Publications. 2002.  
23  
24  
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26  
27  
28  
29  
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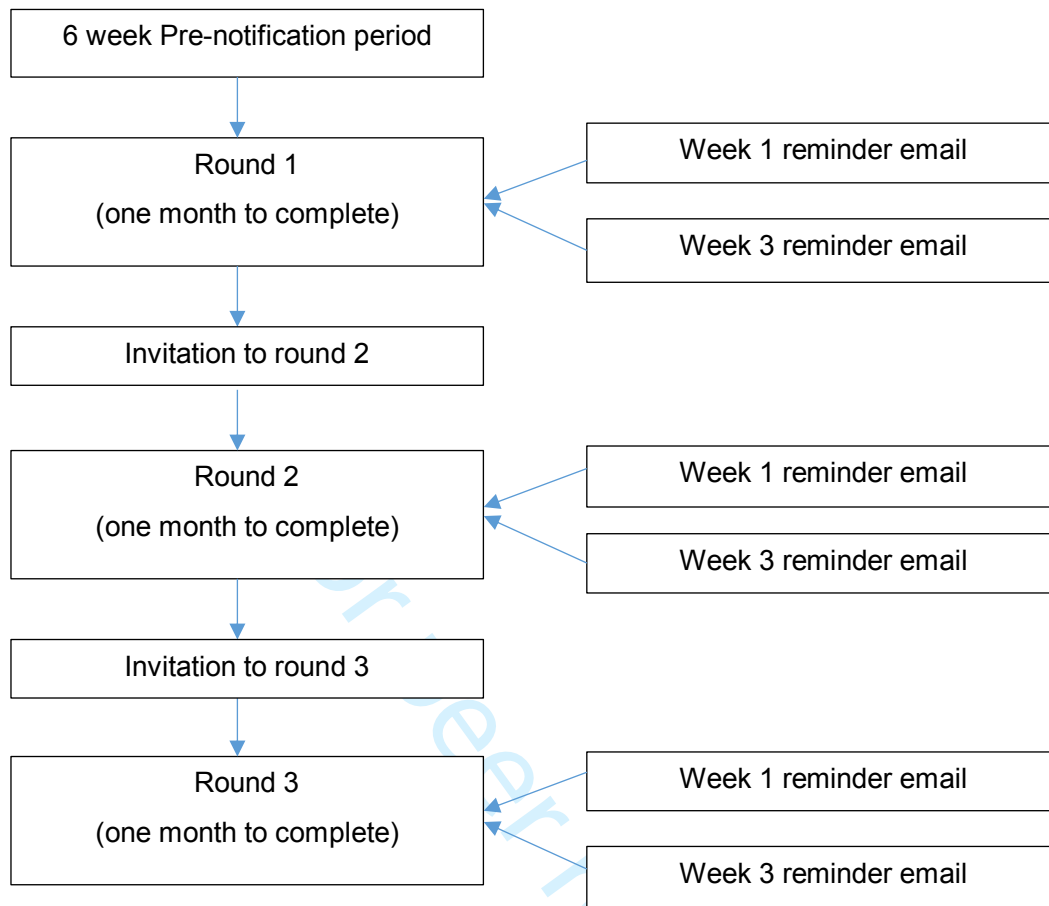
### 31 Figure legends

32  
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35 Figure 1: Modified Delphi processes to construct list of clinical indicators  
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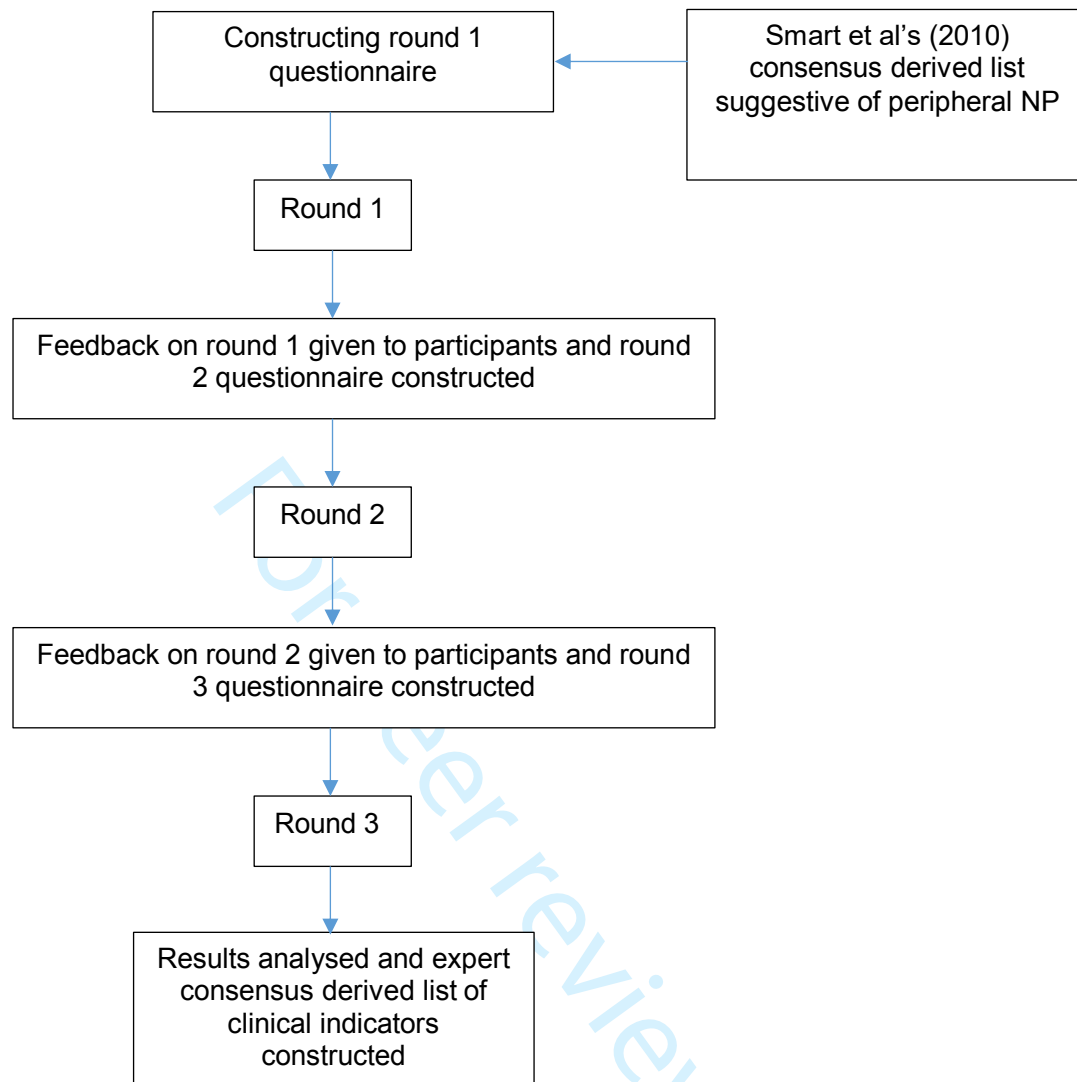
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38 Figure 2: Procedure and timelines for participants in Delphi study  
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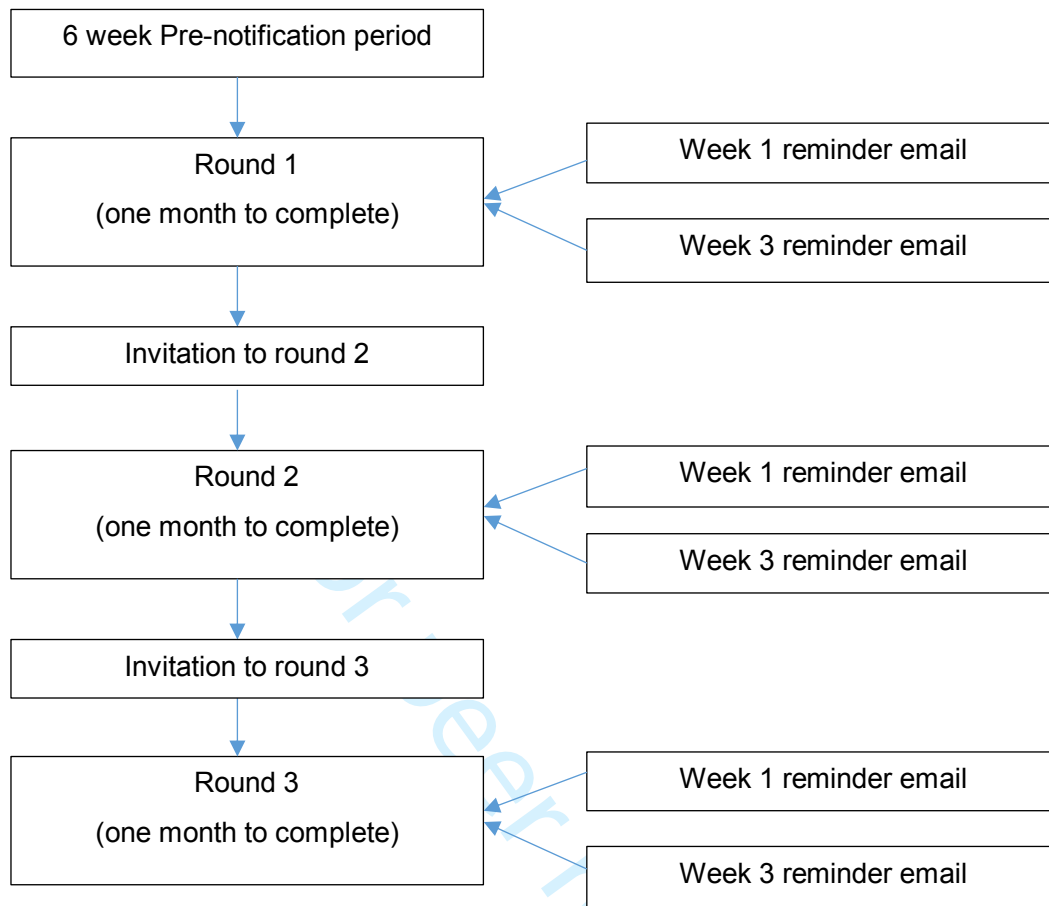
**Figure 1.** Modified Delphi processes to construct list of clinical indicators



**Figure 2.** Procedure and timelines for participants in Delphi study.



**Figure 1.** Modified Delphi processes to construct list of clinical indicators



**Figure 2.** Procedure and timelines for participants in Delphi study.



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## Clinical indicators to identify neuropathic pain in low back related leg pain: protocol for a modified Delphi study

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# Clinical indicators to identify neuropathic pain in low back related leg pain: protocol for a modified Delphi study

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## Abstract

### Introduction

Neuropathic low back related leg pain (LBLP) can be a challenge to healthcare providers to diagnose and treat. Accurate diagnosis of neuropathic pain (NP) is fundamental to ensure appropriate intervention is given. However, to date there is no gold standard to diagnose neuropathic LBLP. A Delphi study will therefore be conducted to obtain an expert derived consensus list of clinical indicators to identify a neuropathic component to LBLP.

### Methods/analysis

Included participants will be considered experts within the field as measured against a pre-defined eligibility criterion. Through an iterative multistage process, participants will rate their agreement with a list of clinical indicators and suggest any missing clinical indicators during each round. Agreement will be measured using the Likert scale. Descriptive statistics will be used to measure agreement; median, IQR and percentage of agreement. Priori consensus criteria will be defined for each round. Data will be collected at the end of round three and a list of clinical indicators will be derived at the end of this study

### Ethics/dissemination

Ethical approval was gained from the University of Birmingham (ERN\_19-1142). On completion of the study findings will be disseminated in a peer-reviewed journal and presented at relevant conferences.

### Keywords

Neuropathic, leg pain, Delphi, diagnosis

## Word count

3126 words

## Article summary

### Strengths and limitations of this study

- This will be the first study to develop a list of clinical indicators to identify a neuropathic component to LBLP, which will help to inform clinicians regarding treatment interventions
- This study will use national and international experts in neuropathic pain to inform the list of clinical indicators
- This study will be reported in line with Conducting and Reporting Delphi Studies recommendations
- This study is a mixed method design and thus utilises quantitative and qualitative data
- The views of Delphi panellists may differ from those experts who decline participation, and may not fully represent experts in the field of interest.

## Introduction

Neuropathic pain (NP) is defined as pain caused by a lesion or disease of the somatosensory nervous system.(1) NP is a largely unmet medical need due to ineffective management.(2) NP is highly prevalent and has been estimated to have a global population prevalence of between 6.9% - 10%.(3) NP is associated with vast economic costs; with total annual costs (including direct and indirect costs) per patient in Europe ranging from £8710 in the UK to €14,446 in Germany.(4) Epidemiological surveys have shown that many patients with NP do not receive appropriate treatment, a common reason for this is misdiagnosis.(5) One of the most common presentations of NP is found in those with low back pain (LBP), which is estimated to be at approximately 46.7%.(6) Up to two thirds of individuals with LBP report concomitant leg pain when presenting in primary and secondary care services.(7) Low back related leg pain (LBLP) compared to LBP alone is associated with increased disability, pain, and poorer quality of life.(8, 9) LBLP is generally clinically diagnosed as sciatica (lumbar radicular) or referred pain (involving non-neural structures); sciatica is considered neuropathic in nature whereas referred pain is considered nociceptive.(7) However, there is evidence to suggest the coexistence of both pain mechanisms in LBLP,(10) and evidence for sciatica presenting without NP and referred pain presenting with NP.(11)

According to the National Institute for Health and Care Excellence (NICE) recent guidelines, the management of NP differs significantly to the management of LBP without sciatica.(12) Thus the importance of accurate diagnosis of NP in relation to LBLP ensures that appropriate management is provided. Identification of patients with NP in LBLP is essential as pharmaceutical intervention, if indicated, may improve patient outcomes.(7) To date, there is no gold standard for diagnosing NP.(13) Consequently, expert opinion consensus derived lists and a variety of patient reported outcome measures (PROMs) have been developed and used as methods to determine the presence of NP in research studies.(14, 7) However, there is no uniformity within the literature regarding the best clinical indicators to

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3 use to identify NP in LBLP. The most common clinical indicators utilised to identify NP in  
4 LBLP research include the PainDetect,(15) The Leeds Assessment of Neuropathic  
5 Symptoms and Signs (LANSS),(16) and Douleur Neuropathique 4 (DN4).(17)  
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10 A cross-sectional study by Smart et al (2012)(18) is the one study to identify clinical  
11 indicators predictive of the presence of peripheral NP in low back pain (with or without leg  
12 pain), consisting of a cluster of two symptoms and one sign: '*pain referred in a dermatomal*  
13 *or cutaneous distribution*', '*history of nerve injury, pathology or mechanical*  
14 *compromise*' and '*pain/symptom provocation with mechanical/movement tests (e.g.*  
15 *active/passive, neurodynamic) that move/load/compress neural tissue*'. However, there is  
16 evidence to refute aspects of this cluster. For instance experimental research suggests that  
17 remote immune-inflammatory mechanisms can contribute to the non-dermatomal/cutaneous  
18 innervation spread of symptoms in response to mild sciatic nerve compression in rat  
19 models.(19) Furthermore, evidence of non-dermatomal/cutaneous innervation spread of  
20 symptoms in both distal and proximal entrapment neuropathies have been previously  
21 reported.(20, 21) This highlights the possibility that pain may not always follow a  
22 dermatomal/cutaneous innervation pattern. In addition, an increasing body of literature  
23 highlights the low diagnostic validity of neurodynamic testing which consequently questions  
24 its utility as an indicator to detect NP in LBLP.(22-24) These findings highlight a need for  
25 further consideration of the clinical indicators used to identify NP in LBLP, as clinical  
26 uncertainty exists and there is no established gold standard.  
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## 40 Objective

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43 To conduct a three round modified Delphi study to achieve expert consensus on a list of  
44 clinical indicators to identify NP in LBLP  
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## 51 Methods

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55 This study will be conducted using a modified Delphi method. The Delphi method is an  
56 iterative multistage process used to achieve expert consensus on a given subject.(25)  
57 Expert consensus derived criteria obtained through a Delphi method have been shown to be  
58 an effective tool in situations of uncertainty to inform clinical decision making.(26) The Delphi  
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3 method is a low cost, simple procedure which can be used to gain information form a large  
4 population.(27) The Delphi method is anonymous and participants do not directly interact,  
5 instead they receive feedback from their peers, this minimises the risk of few individuals'  
6 opinions dominating.(28) The anonymity has also been linked to higher response rates.(29)  
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8 This Delphi will be conducted online which helps to accelerate data collection. Furthermore,  
9 geographical location provides no barrier to participation in the study as it will be conducted  
10 electronically.(28)  
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17 This three-round modified Delphi method has been designed with guidance from the  
18 Conducting and Reporting Delphi Studies (CREDES) recommendations (Appendix 1). The  
19 CREDES recommendations are featured on the Equator network and are the only reporting  
20 guidance recommendations for Delphi studies.(30) Three rounds of questionnaires will be  
21 administered anonymously through RedCap (<https://www.project-redcap.org>). All three  
22 rounds will use a five-point Likert scale to evaluate the level of agreement. Between rounds  
23 one and three, the results will be analysed and questionnaires constructed for subsequent  
24 rounds. Clinical indicators that do not achieve the consensus will be removed at each  
25 stage. Resultant data at the end of round three will be brought together to devise a  
26 consensus derived list of clinical indicators. The stages of the Delphi and development of the  
27 expert consensus derived list of clinical indicators is summarised in Figure 1.  
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### 37 Steering committee

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41 The steering committee will be located at the University of Birmingham. The committee will  
42 comprise of the lead investigator, a MRes student JM, second investigator a PhD student TN  
43 and three senior academics based at the University of Birmingham AR, DF and NH. The  
44 three senior academics have considerable experience of using the Delphi technique as well  
45 as quantitative and qualitative research methods, and will ensure study quality at each  
46 stage.  
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### 53 Participants

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57 Experts will be defined as individuals with a high level of knowledge within the area of NP in  
58 LBLP which will be confirmed against the eligibility criteria outlined below. Recruited experts  
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3 will be expected to develop a consensus list which will reflect a high degree of content/face  
4 validity.(31) Experts will include musculoskeletal/pain specialist physiotherapists, allied  
5 healthcare professionals, doctors and academics: all of whom work within a pain  
6 setting/have a special interest in NP. JM and TN will review the profiles of potential  
7 participants to decide eligibility based on the following criteria:

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11 - International research experts who have  $\geq 2$  peer-reviewed publications relating to NP in  
12 LBLP or a related topic,(32) or  
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14 - Working within a pain clinic/musculoskeletal outpatient department for  $\geq 10$  years  
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19 Fulfilment of  $\geq 1$  criterion will be required for participant inclusion. There is no clear evidence  
20 to support the use of a pre-defined criteria in ensuring expert participant recruitment into a  
21 Delphi study, but it is consistent with the CREDES recommendations as well as criteria is  
22 used in previous Delphi studies.(32-34) Also, the use of eligibility criteria increases the rigour  
23 and transparency of the recruitment process and minimises the risk of disputes between  
24 recruiters.  
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31 The number of participants in Delphi studies varies considerably and there is no clear  
32 indication within the literature of what the ideal number is.(27) The aim for this study will be  
33 to recruit a minimum of 30 participants.(35) Furthermore, no upper limit will be set as the  
34 greater the number of participant, the greater the data generation. The expectation is that no  
35 more than 100 participants will be recruited based on a previous similar Delphi study.(14)  
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## 41 Recruitment

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46 A snowballing strategy will be used to identify potential participants. JM and TN will review  
47 authorships of published systematic reviews relating to the clinical indicators of NP and  
48 identify national and international profiles. Experts will be invited to participate in the study  
49 and also requested to suggest any peers who fit the eligibility criteria.(34) Call for  
50 expressions of interest will be posted on social media for participants to be nominated or  
51 self-nominate themselves. Social media platforms will be used due to its high-quality health  
52 care, research, and academic communities.(36)  
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3 Contacted individuals will receive an email with four attached documents. A Participant  
4 Information Sheet will describe the aims and objectives of the Delphi, justification for the  
5 study, eligibility requirements for experts, stages involved in the Delphi process, timeframe  
6 for each stage, assurance on anonymity and the withdrawal process. The second document  
7 will be a consent form, the third a conflict of interest form and the final document will be a  
8 participant information form for participants to detail: age, gender, country of origin, country  
9 of current employment, highest qualification, occupation, professional  
10 background/credentials and working period in NP in LBLP/related field.(32) Return of the  
11 consent form and conflict of interest and participant information form signifies agreement to  
12 participate. Recruiters will collate/review returned information and email individuals to  
13 confirm participation in the study.  
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### 23 Ethical considerations/Quality assurance

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27 Ethical approval was granted by the University of Birmingham (ERN\_19-1142). Eligible  
28 participants will be required to return a consent form and conflict of interest form.  
29 Participants will be advised at the start of the study of the withdrawal process should they  
30 need it. ID codes will be used instead of personal information to ensure participants remain  
31 anonymous throughout the process.  
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38 The data obtained in the study will be stored in a password encrypted electronic device  
39 which will only be accessible to the researchers involved in the study. Anonymity will be  
40 ensured throughout the study. Quality assurance will be achieved through three senior  
41 academics (AR, NH, DF) who are part of the steering committee. They share a vast amount  
42 of research methods experience, including the use of the Delphi method, therefore the use  
43 of their expertise in guiding/providing supervision to the lead investigator (JM) will ensure  
44 quality is maintained.  
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### 51 Procedure

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56 Figure 2 details the procedure and timeline for the study. Prior to the start of the study, a  
57 pre-notification period of 6 weeks will be allocated to recruit participants.  
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### Round 1

In the first-round participants will be invited to provide their level of agreement with the list of clinical indicators suggested by Smart et al (2010)(14) to identify peripheral NP (Appendix 2), for the purpose of this study, in relation to identifying NP in LBLP. Level of agreement will be sought using a five-point Likert scale (5 = Strongly agree, 4 = Agree, 3 = No opinion, 2 = Disagree, 1 = Strongly disagree). A five point Likert scale will be used as any number less than five in a Likert scale has been demonstrated to compromise reliability and validity.(37) Secondly, through open questions, participants will be invited to identify any missing clinical indicators. Participants will be invited to explain their reasons for their ratings and missing clinical indicators in a free text box. The use of open-ended questions allows participant freedom to volunteer any clinical indicators considered relevant, and for a richness in the qualitative data collected.(26)

Participants will be given one month to complete round 1. Reminder emails will be sent to non-responders at weeks one and three, in this email the withdrawal process will be highlighted if participants are unable to continue with the study.(38) Only those participants who complete round 1 will be invited to round 2, in line with previous Delphi studies.(34, 39)

### Round 2

Participants will be issued with the second questionnaire constructed from the results of round 1. Participants will again be invited to provide level of agreement/disagreement using the Likert scale for clinical indicators. Participants will be invited to identify any missing clinical indicators in the format of an open-ended question. Furthermore, participants will also be given the opportunity to explain the reason for their ratings and addition of any further clinical indicators.

Participants will be given one month to complete round 2. Reminder emails will be sent to non-responders at weeks one and three.(38) Only those participants who complete round 2 will be invited to round 3

### Round 3

The questionnaire for round 3 will be constructed using the clinical indicators which achieved consensus and any additional information gained from the open-ended question from round 2. Only those who complete round 2 will be invited to round 3. In round 3 participants will be

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3 issued with the third questionnaire constructed from the results of round 2. Participants will  
4 be asked to re-rate their level of agreement with the clinical indicators, presented in  
5 graphical format as per round 2. Participants will also be invited to rank each clinical  
6 indicator for their importance, from highest to lowest. Feedback on round 3 will not be  
7 provided to the participants. Response data will then be re-analysed for levels of agreement  
8 and consensus.(40) The steering committee will then use the results to identify a consensus  
9 derived list of clinical indicators.  
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### 17 Data collection

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21 Response data will be collected and quantitative data will be statistically analysed using  
22 SPSS (Version 25.0. Armonk, NY: IBM Corp.) and qualitative data from the open-ended  
23 questions will be inputted into summary tables in a word document for content analysis.(41)  
24 Each round will take four weeks with two weeks after each round allocated for data analysis  
25 and formulation of subsequent questionnaire.(38)  
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### 30 Data analysis

#### 31 Round 1

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34 Level of agreement with Smart et al's (2010)(14) list will be measured using the Likert scale.  
35 Descriptive statistics including median, Inter-quartile range (IQR) and percentage of  
36 agreement will be gathered using data from each participant.(32)  
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41 Responses to open questions will be reviewed by JM and TN and a content analysis will be  
42 carried out.(41) Results of content analysis will be brought back to the steering group to  
43 ensure quality is maintained, also any disagreements in content analysis will be presented to  
44 the steering group. Content analysis is typically used to identify major themes in response to  
45 qualitative data.(14) The questionnaire for round 2 will be constructed using the clinical  
46 indicators which achieved consensus from Smart et al's (2010)(14) list as well as using the  
47 missing indicators identified by participants in the open-ended aspect of the questionnaire.  
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54 Round 1 criteria for consensus include:

- 55 - Median value of participants Likert scale data  $\geq 3$
  - 56 - Percentage of agreement 50%(32)
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## Round 2

Results from round 1 will be presented in a graphical format, with each criterion presented as a bar chart. Each bar chart will show the number and percentage of respondents indicating level of agreement/disagreement. Furthermore, a narrative summary finding will be presented in round 2 of the findings from round 1's open ended question section. This will provide participants with feedback from round 1.

Likert scale will be used to assess agreement/disagreement with round 2 questionnaire. Further content analysis will be conducted from the open-ended free text boxes. Round 3 questionnaire will be constructed using the same method as round 1.

Round 2 criteria for consensus:

- Median value of participants Likert scale data  $\geq 3.5$
- IQR value of participants Likert scale data  $\leq 2$
- Percentage of agreement 60%(32)

## Round 3

As per round 2, graphical depiction of round 2 findings and narrative summaries will be presented to participants. Participants will use the Likert scale again to suggest agreement/disagreement with round 3 questionnaire. Participants will rank each clinical indicator from highest to lowest with respect to importance.

Round 3 criteria for consensus:

- Median value of participants Likert scale data  $\geq 4$
- IQR value of participants Likert scale data  $\leq 3$
- Percentage of agreement 70%(32)

Agreement between participants will also be evaluated across all clinical indicators using Kendall's *W* coefficient of concordance,(29) statistical significance will be set at  $p < 0.05$ .

## Data Management

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3 All participant information and feedback will be securely stored on a password-protected  
4 computer throughout the duration of the study. Only members of the research team will be  
5 able to access the information. After completion of the Delphi study, all data will be kept  
6 securely for 10 years in the School of Sport, Exercise and Rehabilitation Sciences,  
7 University of Birmingham before being securely destroyed, in accordance with University  
8 guidelines.  
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### 15 Patient and public involvement

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18 Information from patients and the public has informed the conception and requirement for  
19 this Delphi study as part of an existing programme of research that is centred on lumbar  
20 spinal surgery for back related leg pain and patient outcome.  
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### 26 Dissemination plan

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29 This protocol will be submitted to an open access peer-reviewed journal. On completion the  
30 study findings will be disseminated in a peer-reviewed journal and presented at relevant  
31 conferences.  
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### 36 Discussion

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39 The results from this study will assist both clinicians and researchers in establishing a clear  
40 reference standard for diagnosing NP in LBLP. By establishing a uniformly recognised  
41 reference standard, timely and accurate diagnosis to inform precision management of  
42 patients with NP in LBLP will be possible. In turn, timely and accurate diagnosis will enable  
43 an improved prognosis and reduce the risk of patients developing chronicity. It will be  
44 possible to use the list of clinical indicators derived from this study in combination with  
45 guidelines(12) to further inform clinicians regarding the identification of NP in LBLP, thus  
46 affording greater confidence in their clinical judgement. The results from this study will  
47 provide the first list of clinical indicators specific to identifying NP in LBLP, and therefore will  
48 serve a need both clinically and within the contemporary literature to inform further research.  
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### 56 Conclusion

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3 There is uncertainty within the literature when considering the clinical indicators associated  
4 with identifying NP in LBLP. In order to ascertain a consensus derived set of clinical  
5 indicators, a modified Delphi study has been designed. The clinical implications of this study  
6 will aid clinicians in identifying a neuropathic component to LBLP through a list of clinical  
7 indicators. Assisting in accurate diagnosis will ensure that appropriate treatment is carried  
8 out.  
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For peer review only

### Author contributions

All authors devised the focus of this Delphi study. JM is a MRes student, AR is the lead supervisor, DF and NH are co supervisors and TN is a co-researcher. JM drafted the initial protocol manuscript with lead and co supervisors providing guidance on methodological decisions and proposed analyses. All authors have contributed subject specific expertise. JM and TN will recruit participants into the study. All authors will contribute to data interpretation, conclusions, and dissemination. All authors have read, contributed to, and agreed the final manuscript. AR is the guarantor of the study.

### Funding

It will be conducted as part of a MRes research project through the University of Birmingham.

### Patient consent for publication

Not required.

### Conflict of interest

None.

### Data statement

No further data are available.



## References

1. Treede RD, Jensen S, Campbell JN, *et al.* NP: Redefinition and a grading system for clinical and research processes. *Neurology* 2008;70:1630-1635.
2. Baron R, Binder A, Attal N, *et al.* Neuropathic low back pain in clinical practice. *European journal of pain* 2016;20: 861–873.
3. van Hecke O, Austin SK, Khan RA *et al.* Neuropathic pain in the general population: a systematic review of epidemiological studies. *Pain* 2014;155:654–662.
4. Liedgens H, Obradovic M, De Courcy J, *et al.* A burden of illness study for NP in Europe. *ClinicoEconomics and Outcomes Research* 2016;8:113-126.
5. Torrance N, Ferguson JA, Afolabi E, *et al.* NP in the community: more under-treated than refractory? *Pain* 2013;154:690–9.
6. Berger A, Sadosky A, Dukes E, *et al.* Clinical characteristics and patterns of healthcare utilization in patients with painful neuropathic disorders in UK general practice: A retrospective cohort study. *BMC Neurology* 2012;12: 8.
7. Harrison SA, Stynes S, Dunn KM, *et al.* NP in Low Back-Related Leg Pain Patients: What Is the Evidence of Prevalence, Characteristics, and Prognosis in Primary Care? A Systematic Review of the Literature. *The Journal of Pain* 2017;18: 1295-1312.
8. Konstantinou K, Hider L, Jordan L, *et al.* The impact of low back-related leg pain on outcomes as compared with low back pain alone: A systematic review of the literature. *Clin J Pain* 2013;29: 644-654.
9. Hider SL, Whitehurst DGT, Thomas E, *et al.* Pain location matters: the impact of leg pain on health care use, work disability and quality of life in patients with low back pain. *European Spine Journal* 2015;24: 444-451.
10. Freynhagen R, Rolke R, Baron R, *et al.* (2008). Pseudoradicular and radicular low-back pain—a disease continuum rather than different entities? Answers from quantitative sensory testing. *Pain*. 135. 65-74.
11. Mahn F, Hulleman P, Gockel U, *et al.* Sensory symptom profiles and co-morbidities in painful radiculopathy. *PLoS One* 2011;e18018.

12. NICE (2016). Low back pain and sciatica in over 16s: assessment and management (NICE Guideline 33). National Institute for Health and Care Excellence. Available at: <https://www.nice.org.uk/guidance/ng59> [Accessed 10<sup>th</sup> May 2019].
13. Smith BH, Torrance N, Bennett MI, *et al.* Health and quality of life associated with chronic pain of predominantly neuropathic origin in the community. *Clin J Pain* 2007;23:43–149.
14. Smart KM, Blake C, Staines A, *et al.* Clinical indicators of ‘nociceptive’, ‘peripheral neuropathic’ and ‘central’ mechanisms of musculoskeletal pain. A Delphi survey of expert clinicians. *Manual Therapy* 2010;15:80-7.
15. Beith D, Kemp A, Kenyon J, *et al.* Identifying neuropathic back and leg pain: A cross-sectional study. *Pain* 2011;152:1511-6.
16. Walsh J, Hall T. Classification of low back-related leg pain: Do subgroups differ in disability and psychosocial factors? *J Man Manip Ther* 2009;17:118-123.
17. Ouédraogo DD, Nonguierma N, Napon C, *et al.* Prevalence of NP among black African patients suffering from common low back pain. *Rheumatol Int* 2012;32. 2149-2153.
18. Smart KM, Blake C, Staines A, *et al.* Mechanisms-based classifications of musculoskeletal pain: Part 2 of 3: Symptoms and signs of peripheral NP in patients with low back ( $\pm$ leg) pain. *Manual Therapy* 2012;17:345-351.
19. Schmid AB, Coppieters MW, Ruitenberh MJ, *et al.* Local and remote immune mediated inflammation after mild peripheral nerve compression in rats. *J Neuropathol Exp Neurol* 2013;72:662-680.
20. Tampin B, Slater H, Hall T, *et al.* Quantitative sensory testing somatosensory profiles in patients with cervical radiculopathy are distinct from those in patients with nonspecific neck-arm pain. *Pain* 2012;153:2403-2414.
21. Nora DB, Becker J, Ehlers JA, *et al.* Clinical features of 1039 patients with neurophysiological diagnosis of carpal tunnel syndrome. *Clin Neurol Neurosurg* 2004;107: 64-69.
22. Nee RJ, Jull GA, Vicenzino B, *et al.* The validity of upper-limb neurodynamic tests for detecting peripheral neuropathic pain. *Journal of Orthopaedic Sports Physical Therapy* 2012;42:413-424.

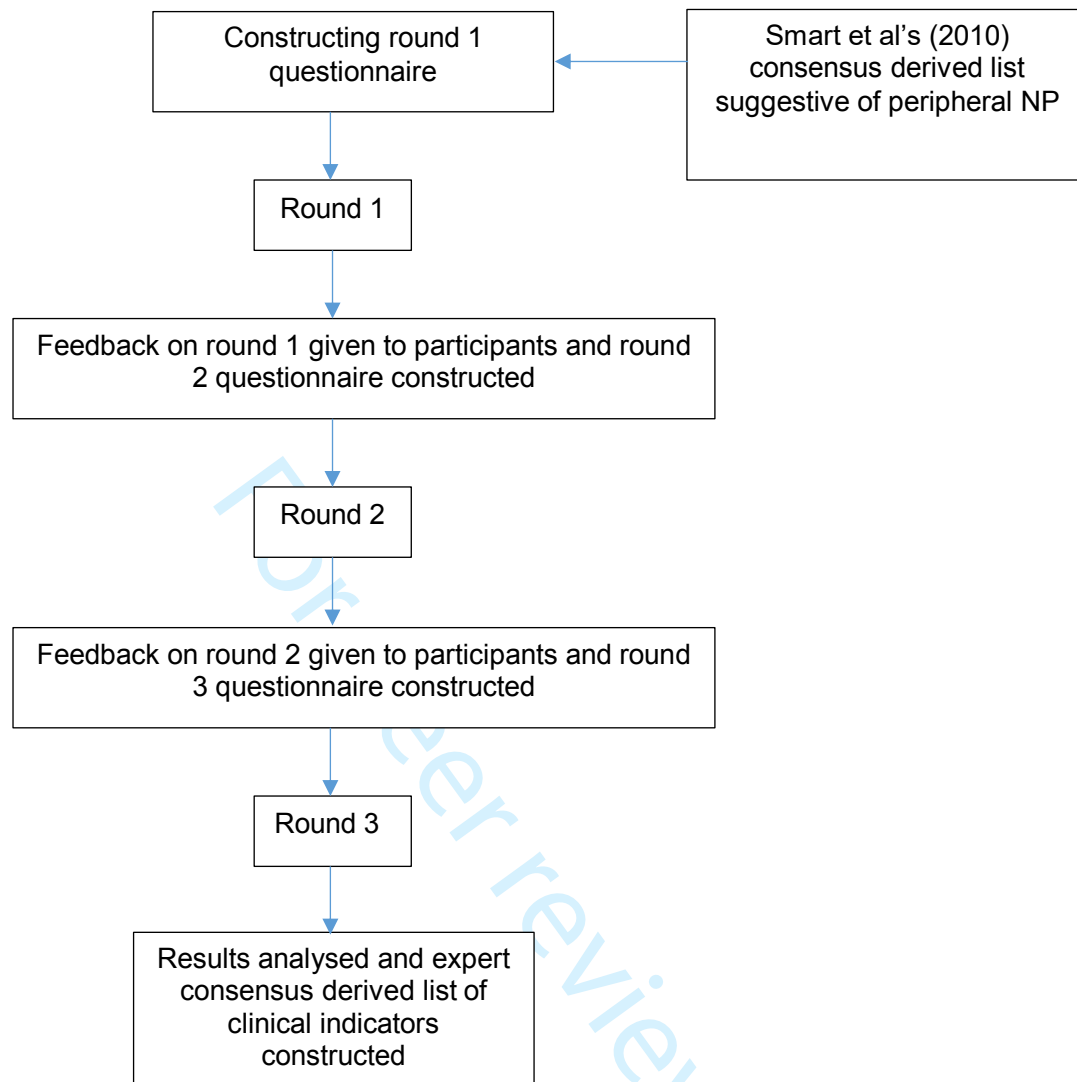
23. Baselgia LT, Bennett DL, Silbiger RM, *et al.* Negative neurodynamic tests do not exclude neural dysfunction in patients with entrapment neuropathies. *Archives of Physical Medicine and Rehabilitation* 2017;98: 480 – 486.
24. Schmid AB, Hailey L, Tampin B. Entrapment Neuropathies: Challenging common beliefs with novel evidence. *J Orthop Sports Phys Ther* 2018;48: 58-62.
25. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing* 2000;32:1008–1015.
26. Powell, C. The Delphi technique: myths and realities. *Journal of Advanced Nursing* 2003;41:376-382.
27. Murphy MK, Black NA, Lamping DL, *et al.* Consensus development methods, and their use in clinical guideline development. *Health Technol Assess* 1998;2: 87–88.
28. Merlin JS, Young SR, Azari S, *et al.* Management of problematic behaviours among individuals on long-term opioid therapy: protocol for a Delphi study. *BMJ Open* 2016;6:e011619.
29. Heiko A. Consensus measurement in Delphi studies: review and implications for future quality assurance. *Technol Forecast Soc Change* 2012;79:1525–36.
30. Jünger S, Payne SA, Brine J, *et al.* Guidance on Conducting and REporting DELphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review. *Palliative Medicine* 2017;31: 684–706.
31. McCarthy CJ, Rushton A, Billis V, *et al.* Development of a clinical examination in non-specific low back pain: a Delphi technique. *Journal of Rehabilitation Medicine* 2006;38: 263-267.
32. Wiangkham T, Duda J, Haque MS, *et al.* Development of an active behavioural physiotherapy intervention (ABPI) for acute whiplash-associated disorder (WAD) II management: a modified Delphi study. *BMJ Open* 2016;6:e011764.
33. Blaschke S, O’Callaghan CC, Schofield P. Identifying opportunities for nature engagement in cancer care practice and design: Protocol for four-round modified electronic Delphi. *BMJ Open* 2017;7: 1–9.
34. Slade SC, Dionne CE, Underwood M, *et al.* Standardised method for reporting exercise programmes: protocol for a modified Delphi study. *BMJ Open* 2014;4:e006682.
35. Sekayi D & Kennedy A. Qualitative Delphi method: A four round process with a worked example. *The Qualitative Report* 2017;22:2755-2763.

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2  
3 36. Pezaro S, Clyne W. Achieving Consensus in the Development of an Online Intervention  
4 Designed to Effectively Support Midwives in Work-Related Psychological Distress: Protocol  
5 for a Delphi Study. *JMIR research protocols* 2015;4:107.  
6  
7  
8 37. Preston CC, Colman AM. Optimal number of response categories in rating scales:  
9 reliability, validity, discriminating power, and respondent preferences. *Acta Psychologica*  
10 2000;104:1–15.  
11  
12 38. Zambaldi M, Beasley I, Rushton A. Return to play criteria after hamstring muscle injury in  
13 professional football: a Delphi consensus study. *Br J Sports Med* 2017;51:1221–1226.  
14  
15 39. Taylor RM, Feltbower RG, Aslam N, *et al.* Modified international e-Delphi survey to  
16 define healthcare professional competencies for working with teenagers and young adults  
17 with cancer. *BMJ Open* 2016;6:e01136.  
18  
19 40. Jones J, Hunter D. Qualitative research: consensus methods for medical and health  
20 services research. *British Medical Journal* 1995;31: 376–80.  
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22 41. Patton MQ. Qualitative research methods. Thousand Oaks: Sage Publications. 2002.  
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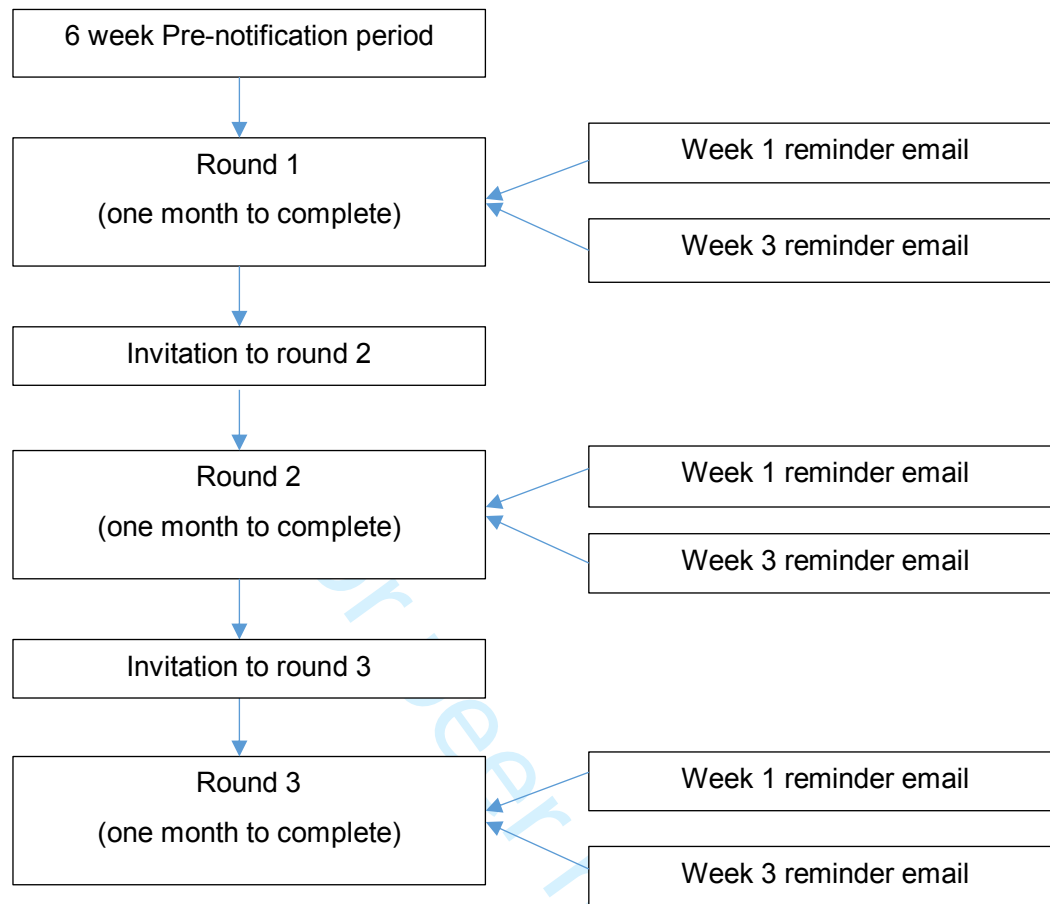
### 31 Figure legends

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34 Figure 1: Modified Delphi processes to construct list of clinical indicators  
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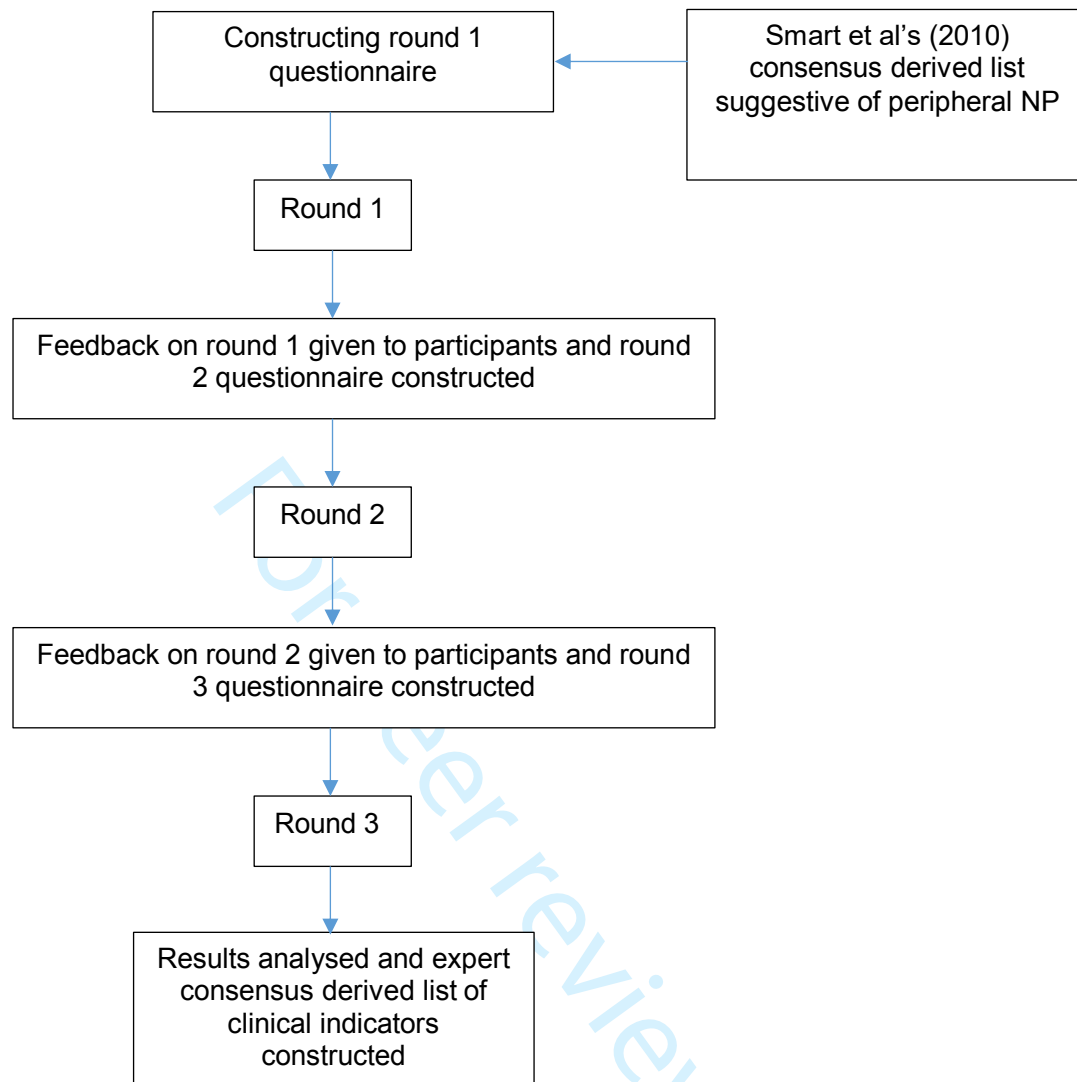
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38 Figure 2: Procedure and timelines for participants in Delphi study  
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**Figure 1.** Modified Delphi processes to construct list of clinical indicators

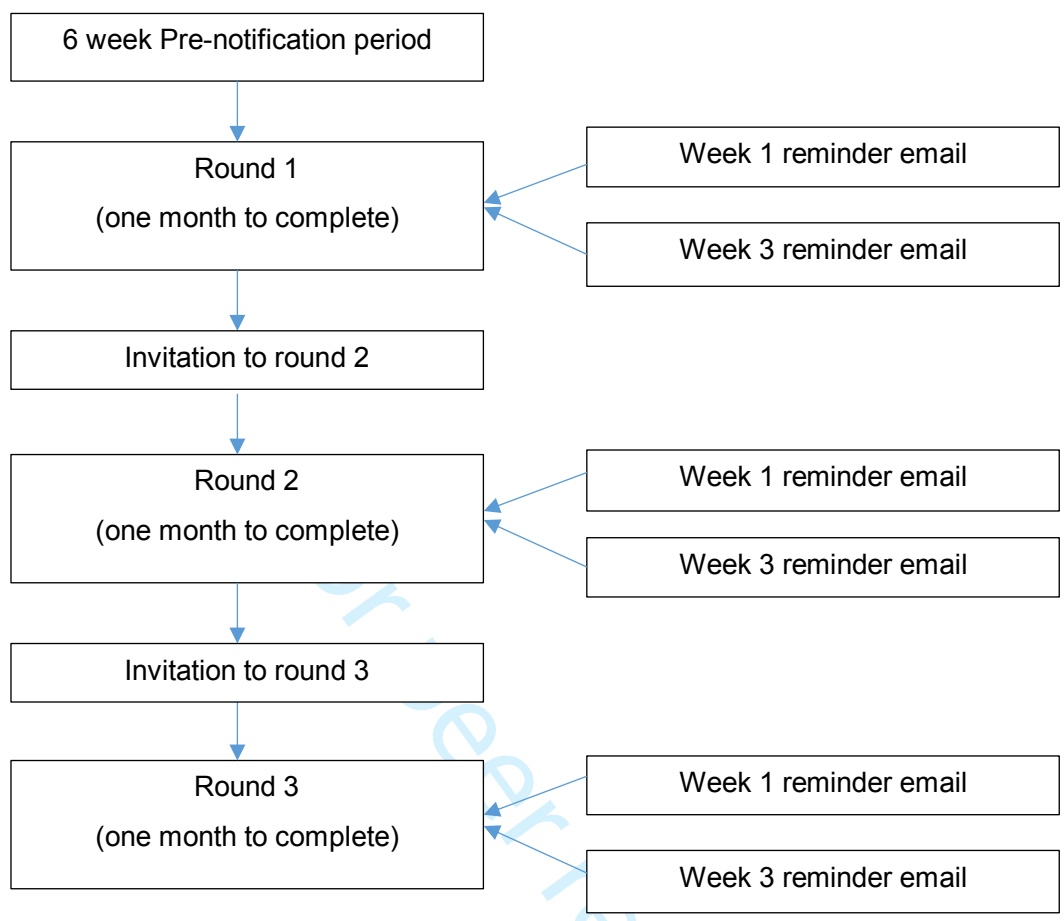


**Figure 2.** Procedure and timelines for participants in Delphi study.



**Figure 1.** Modified Delphi processes to construct list of clinical indicators

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**Figure 2.** Procedure and timelines for participants in Delphi study.