Timing of evidence-based non-surgical interventions as part of multimodal treatment guidelines for the management of cervical radiculopathy: a Delphi study protocol

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ABSTRACT

Introduction Cervical radiculopathy (CR) is a clinical condition whereby motor, reflex and/or sensory changes such as radicular pain, paraesthesia or numbness can exist. Conservative management is a preferred first treatment option as the risk–benefit ratio for surgery is less favourable. Systematic reviews and treatment guidelines gather evidence on the effectiveness of non-surgical management of patients with CR from randomised controlled trials, which do not consider the natural course of recovery to modify the management strategy accordingly. The aim of this study is to establish consensus on effective non-surgical treatment modalities for patients in different stages (acute, subacute and chronic) of CR, using the Delphi method approach.

Methods and analysis Through an iterative multistage process, experts within the field will rate their agreement with a list of proposed treatment modalities and suggest any missing treatment modalities during each round. Agreement will be measured using a five-point Likert scale. Descriptive statistics will be used to measure agreement (median, IQR and percentage of agreement). Consensus criteria will be defined a priori for each round. Data analysis at the end of round three will produce a consensus list of effective treatment modalities for the management of patients with CR in different stages of recovery.

Ethics and dissemination Ethical approval has been granted from the University of Birmingham ethics committee under ERN_20-1121. The study findings will be submitted to a peer-reviewed journal and to relevant conferences for dissemination of the study results.

INTRODUCTION

Cervical radiculopathy (CR) is a clinical condition whereby motor, reflex and/or sensory changes such as radicular pain, paraesthesia or numbness may be present and may be provoked by neck posture(s) and/or movement(s). An incidence of approximately 83 per 100 000 persons is reported with a prevalence of 3.5 per 1000 persons. The societal burden of CR is substantial. In the Netherlands, with a population of 17 million, on average 2000 patients yearly receive surgery for a cervical herniated disc, resulting in direct costs of about €30 million per year. Although direct costs for conservative care are lower, this group might have higher indirect costs due to a longer period of reduced labour productivity.

The natural history of CR is favourable as most (83%) patients with symptomatic radiculopathy recover within 24–36 months and substantial improvements usually occur 4–6 months post onset. It has been suggested that that those who receive conservative care might have higher indirect costs due to a longer period of reduced work productivity.

Conservative management is a preferred first treatment option, since the risk–benefit ratio for surgery is less favourable. Several systematic reviews and contemporary (inter)national treatment guidelines suggest effective non-surgical management strategies could include: information and...
patient education, advice to stay physically active, manual therapy alone or in combination with different types of supervised exercise, traction, neurodynamic mobilisation and use of a cervical collar.

Systematic reviews, traditionally include outcomes from randomised controlled trials (RCTs) and sometimes controlled clinical trial (CCTs). RCTs have a limitation in that the management strategies are often not tailored to the individual. RCTs usually report central tendencies of a cohort, which is not representative of an individual patient. The limited external validity is partly related to the inclusion of patients and practitioners in RCTs which are different from those in routine practice. Additionally, RCTs in general do not relate the management strategy under scrutiny to the different stages of the studied condition. Instead they manage all participants identically, regardless of the stage of the studied condition being acute, subacute or chronic. Rehabilitation programmes, however, are based on the logical assumption that some treatment modalities might potentially be better suited in the early acute stage of the disorder, while others might be better for the management during the subacute or chronic phases. Current evidence on the effectiveness of non-surgical management of patients with CR reports a lack of consensus on the optimal timing and dosage of treatment modalities.

The Delphi technique is described as ‘a method used to obtain the most reliable consensus of opinion of a group of experts by a series of intensive questionnaires interspersed with controlled feedback’. Delphi studies are often used to combine clinical expertise and achieve consensus on what preferred management options should or could be included in the management of patients with CR at varying stages.

Objective
To establish consensus on effective non-surgical treatment modalities for patients in different stages (acute, subacute and chronic) of CR, using the Delphi method approach.

METHODS AND ANALYSIS
Design
An electronic version of the Delphi method will be used, modified for the purpose of this study and recent studies. The e-Delphi technique used will involve the iterative process of administering rounds of surveys to an international expert panel, using an electronic platform to construct and distribute the rounds of surveys to panellists. This design will allow the recruitment of a homogenous group of international experts (participants) and allow participation without geographical constraints, avoid dominance of opinion from minority members, and offer anonymity therefore encouraging freedom of expression and removing peer or authoritative pressure. The study will be reported in line with the Conducting and Reporting Delphi Studies (CREDES) recommendations (online supplemental file 1) to ensure rigour.

Participants
In line with the CREDES recommendations, experts will be sought globally from a variety of different professional backgrounds (physiotherapy, medicine, allied healthcare, academia). Experts will be defined and agreed on by the steering committee according to predefined eligibility criteria informed by previous similar studies.

Proposed eligibility criteria for experts to serve as panelists will be (≥1 criterion required for inclusion):
- ≥1 peer-reviewed publications on clinically relevant CR or cervical spinal entrapment neuropathies within the past 10 years or
- ≥10 years’ experience working in a pain/musculoskeletal outpatient of either primary and/or secondary care service with patients with CR or spinal entrapment neuropathies.

Additionally, potential panellists need to have sufficient English and computer literacy skills, which will be judged by the language of authored publications as well as being the corresponding author of that publication.

Past work has suggested that 20–30 panellists are appropriate in a Delphi study to enable consensus. An upper limit for panellist numbers will not be defined.

Recruitment
Electronic libraries (PubMed, Embase, CINAHL, Google Scholar) will be searched for individuals meeting the eligibility criteria. Potential panellists will then be contacted via email that they have been identified by the steering committee as an expert within the field, together with a provision of the study objective and an outline of the Delphi procedure. The recruitment period duration will be set at 6 weeks. A snowballing strategy will be adopted by the recruiting author (ET), requesting contacted panellists to recommend peers who satisfy the eligibility criteria. Additionally, members of the steering committee will also be eligible to recommend potential panellists from their professional network. Additionally, the steering committee will post invitations on social media. Participation will be confirmed following receipt of a signed consent form, conflict of interest form and participant information form.

Steering committee
The steering committee consists of the five authors of this study: the lead investigator (ET) and four senior academics (MT-AG, JC, AG and DF), all with experience in the Delphi technique, qualitative and quantitative research methods and more than 10 years of clinical experience within musculoskeletal medicine. The responsibility of the committee will be to recruit experts and to design, circulate and analyse the questionnaires. The steering committee will make collective decisions regarding methodology, data analysis and quality assurance.
Delphi procedure
Panellists will receive an email containing a link to the platform hosted on LimeSurvey (www.limesurvey.com). All the participants’ information such as age, country of origin, country of current habitation/ work, highest qualification, current occupation, professional background and working period in patients with CR or nerve-related arm pain will be collected.

The steering committee will compose a list of proposed treatment modalities collated from systematic reviews and (inter)national guidelines. Panellists will be invited to provide their level of agreement for each proposed treatment modality for each stage of CR. Additionally, an open question will be provided in each section in order to explore any missing treatment modalities which may have been overlooked. All additional treatment modalities, which are suggested by at least one panellist, will be added into the next round. In round 2, the questionnaire will be returned to each participant, indicating their response from round 1 and how this compares with the overall panel’s response. As a result, participants will be given the opportunity to reconsider the issues they identified in round one. A third repeat round of this process will be carried out to reach consensus. At the end of round 3, panellists will be asked to rank the treatment modalities in terms of importance based on consensus agreement of effectiveness. The treatment modalities generated following round 3 will be collated to create the final list of treatment modalities for each stage of CR. In line with similar studies, panellist will be allowed 3 weeks to complete each round and 3 weeks will be allocated per round for data analysis.

A pilot will be conducted with eight students at the University of Birmingham with musculoskeletal expertise (PhD/MRes/MSc) who will be invited to complete the round 1 survey over a 1-week period and asked to feedback any points to help improve the usability of the survey.

Definition of stages of CR terminology
For this study we will choose to align the different clinical stages of CR with established pain terminology for example, ‘acute’, ‘subacute’ and ‘chronic’ as proposed by the International Association for the Study of Pain. ‘Acute’ pain is pain that has been present for up to 6 weeks. ‘Subacute’ pain is a subset of acute pain: it is pain that has been present for at least 6 weeks but less than 3 months. ‘Chronic’ pain is defined as pain that persists or recurs for more than 3 months.

Data collection and analysis
All data will be stored offline on a password encrypted computer in a locked office with access only available to the researchers. In accordance with university guidelines, data will be destroyed 10 years after completion of the study. Content analysis will be used to analyse data from the free text boxes; treatment modalities will be identified by two authors (ET, MT-dG) which will help to inform the construction of the round 2 survey. Results of the descriptive statistics and content analysis will be fed back to the steering committee and discussed before constructing the round 2 survey. The five-point Likert scale is an ordinal scale. Qualitative data will be extracted deductively (to identify treatment modalities) and inductively (to identify additional treatment modalities). Descriptive statistics including median, IQR, quartile and percentage
of agreement will be used to assess consensus in each round according to the following criteria:

Round 1: criteria of consensus
- Median value of participants’ Likert scale data ≥ 23.
- Percentage of agreement ≥ 50%.

Round 2: criteria of consensus
- Median value of participants’ Likert scale data ≥ 23.5.
- IQR value of participants’ Likert scale data ≥ 2.
- Percentage of agreement ≥ 60%.

Round 3: criteria of consensus
- Median value of participants’ Likert scale data ≥ 4.
- IQR value of participants’ Likert scale data ≥ 1.
- Percentage of agreement ≥ 70%.

All quantitative data will be analysed using IBM SPSS V.26.

Ethical considerations
Ethical approval has been granted from the University of Birmingham ethics committee under ERN_20-1121. Formal consent and declaration of conflict of interests will be required prior to participation. Quasi-anonymity will be guaranteed which refers to blinding of participation between panel members but not to the researchers. All participants will be assigned a unique identification code to aid the feedback process and to protect confidentiality of responses.

There are no conflicts of interest between the steering committee and this project.

Dissemination plan
To ensure methodological rigour, this study protocol will be submitted to an open access peer-reviewed journal. The study findings will be submitted to a relevant peer-reviewed journal for dissemination and then presented at relevant conferences.

Patient and public involvement
The research question in this study forms part of a larger discussion within our patient and public involvement meetings as part of an existing programme of research that is centred on CR. Patients will not be involved in the analysis and data collection of the study.

DISCUSSION
The results from this study will assist clinicians and researchers in formulating an individualised management plan for patients with CR. By grouping separate effective treatment modalities with respect to the stage of recovery, clinicians will better able to tailor management plans to the individual patient through their course of recovery, instead of using a standardised ‘one size fits all’ approach. The results from this study will also serve a need both clinically and within the contemporary literature to inform further research.

We also aim to contrast this study’s findings with systematic reviews and (inter)national guidelines.

REFERENCES
1. Kuiper B, Tans J, Schimsheimer R, et al. Degenerative cervical radiculopathy: diagnosis and conservative treatment. A review. Eur J Neurol 2009;16:15–20.
2. Thoomees E, Scholten-Peeters GGM, de Boer AJ, et al. Lack of uniform diagnostic criteria for cervical radiculopathy in conservative intervention studies: a systematic review. Eur Spine J 2012;21:1459–70.
3. Radhakrishnan K, Litchy WJ, O’Fallon WM, et al. Epidemiology of cervical radiculopathy. A population-based study from Rochester, Minnesota, 1976 through 1990. Acta Neurol Scand 1996;93:184–8.
5 van Geest S, Kuiper B, Oetroodm M, et al. CASINO: surgical or nonsurgical treatment for cervical radiculopathy, a randomised controlled trial. *BMC Musculoskelet Disord* 2014;15:129.

6 Wong JI, Côté P, Quessele J, et al. The course and prognostic factors of symptom persistence in patients with cervical disc herniation with radiculopathy: a systematic review of the literature. *Spine J* 2014;14:1781–9.

7 Bono CM, Ghiselli G, Gilbert TJ, et al. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. *Spine J* 2011;11:64–72.

8 Salt E, Wright C, Kelty S, et al. A systematic literature review on the effectiveness of non-invasive therapy for cervicobrachial pain. *Man Ther* 2011;16:53–65.

9 Thoomes EJ, Scholten-Peeters W, Koes B, et al. The effectiveness of conservative treatment for patients with cervical radiculopathy: a systematic review. *Cin J Pain* 2013;29:1073–86.

10 Nikolaids I, Foyias IP, Sandercoc PAG, et al. Surgery for cervical radiculopathy or myelopathy. *Cochrane Database Syst Rev* 2010;24:Cd001466.

11 van Middelkoop M, Rubinstein SM, Ostelo R, et al. Surgery versus conservative care for neck pain: a systematic review. *Eur Spine J* 2013;22:87–95.

12 Bier JD, Scholten-Peeters WGM, Staal JB, et al. Clinical practice guideline for physical therapy assessment and treatment in patients with nonspecific neck pain. *Phys Ther* 2018;98:162–71.

13 Blanpied PR, Gross AR, Elliott JM, et al. Neck pain: revision 2017. *J Orthop Sports Phys Ther* 2017;47:A1–83.

14 Kjaer P, Kongsted A, Hartvigsen J, et al. National clinical guidelines for non-surgical treatment of patients with recent onset neck pain or factors of cervical disc herniation. *European Spine J* 2019;28:942–57.

15 Lin I, Wiles L, Waller R, et al. What does best practice care for musculoskeletal pain look like? eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. *Br J Sports Med* 2020;54:79–86.

16 Chou R, Côté P, Randhawa K, et al. The global spine care initiative: applying evidence-based guidelines on the non-invasive management of back and neck pain to low- and middle-income communities. *Eur Spine J* 2018;27:851–60.

17 Hannan EL. Randomized clinical trials and observational studies. *JACC Cardiovasc Interv* 2017–7.

18 Shadish WR, Clark MH, Steiner PM. Can nonrandomized experiments yield accurate answers? A randomized experiment comparing random and nonrandom assignments. *J Am Stat Assoc* 2008;103:1334–44.

19 Williams BA. Perils of evidence-based medicine. *Perspect Biol Med* 2010;53:106–20.

20 Bibbald B, Roland M. Understanding controlled trials. why are randomised controlled trials important? *BMJ* 1998;316:201.

21 Alemadro VJ, Lubelski D, Steinmetz MP, et al. Optimal duration of conservative management prior to surgery for cervical and lumbar radiculopathy: a literature review. *Global Spine J* 2014;4:279–86.

22 Meadows JR, Finnoff JT. Lower extremity nerve entrapments in athletes. *Curr Sports Med Rep* 2014;13:299–306.

23 Thoomes EJ. Effectiveness of manual therapy for cervical radiculopathy, a review. *Chiropr Man Therap* 2016;24:45.

24 Dalkey N, Helmer O. An experimental application of the Delphi method to the use of experts. *Manage Sci* 1969;9:458–67.

25 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. * Palliat Med* 2017;31:684–706.

26 Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. *J Adv Nurs* 2005;53:15–12.

27 Gill FJ, Leslie GD, Grech C, et al. Using a web-based survey tool to undertake a Delphi study: application for nurse education research. *Nurse Educ Today* 2013;33:1322–8.

28 McKenna H. The Delphi technique: a worthwhile research approach for nursing? *J Adv Nurs* 1994;19:1221–31.

29 Mistry J, Falla D, Noblet T, et al. Clinical indicators to identify neuropathic pain in low back-related leg pain: protocol for a modified Delphi study. *BMJ Open* 2020;10:e033547.

30 Rushton AB, Fawkes CA, Barnes D, et al. A modified Delphi consensus study to identify UK osteopathic profession research priorities. *Man Ther* 2014;19:445–52.

31 Wangkham 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.

32 Zambaldi M, Beasley I, Rushton A. Return to play criteria after hamstring muscle injury in professional football: a Delphi consensus study. *Br J Sports Med* 2017;51:1221–6.

33 Helms C, Gardner A, McNees E. The use of advanced web-based survey design in Delphi research. *J Adv Nurs* 2017;73:3168–77.

34 Armstrong D, Marshall JK, Chiba N, et al. Canadian Consensus Conference on the management of gastroesophageal reflux disease in adults - update 2004. *Can J Gastroenterol* 2005;19:29–42.

35 Akins RB, Tolson H, Cole BR. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. *BMJ Med Res Methodol* 2005;5:37.

36 Kjaer P, Kongsted A, Hartvigsen J, et al. National clinical guidelines for non-surgical treatment of patients with recent onset neck pain or cervical radiculopathy. *Eur Spine J* 2017;26:2242–57.

37 Côté P, Wong JI, Sutton D, et al. Management of neck pain and associated disorders: a clinical practice guideline from the Ontario protocol for traffic injury management (optima) collaboration. *Eur Spine J* 2016;25:202–13.

38 Jairath N, Weinstein J. The Delphi methodology (Part one): a useful administrative approach. *Can J Nurs Adm* 1994;7:29–42.

39 De Vet HC, Terwee CB, Mokkink LB. Measurement in medicine: a practical guide: Cambridge university press 2011.

40 Meskhey HE. Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. *Pain* 1986;3:226–26.

41 IASP. Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms: IASP press 1994.

42 van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain. A systematic review of randomized controlled trials of the most common interventions. *Spine* 1997;22:2128–66.

43 Norman G, scales L. Likert scales, levels of measurement and the “laws” of statistics. *Adv Health Sci Educ Theory Pract* 2010;15:625–32.

44 Allen IE, Seaman CA. Likert scales and data analyses. *Quality progress* 2007;40:64–5.

45 Rayens MK, Hahn EJ. Building consensus using the policy Delphi method. *Policy Polit Nurs Pract* 2000;1:306–15.