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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, paraesthaesia 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.

Strengths and limitations of this study

- This will be the first study to establish consensus from international experts on effective non-surgical treatment modalities for patients in three different stages (acute, subacute and chronic) of cervical radiculopathy.
- This study will be reported in line with Conducting and Reporting Delphi Studies recommendations.
- This study will use both qualitative and quantitative data.
- The views of the Delphi panellist may differ from those experts that declined to participate and so may not fully represent an opinion of all experts in the field.

INTRODUCTION

Cervical radiculopathy (CR) is a clinical condition whereby motor, reflex and/or sensory changes such as radicular pain, paraesthaesia or numbness may be present and may be provoked by neck posture(s) and/or movement(s).[1 2] An incidence of approximately 83 per 100 000 persons is reported[3] with a prevalence of 3.5 per 1000 persons.[4] 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.[5]

The natural history of CR is favourable as most (83%) patients with symptomatic radiculopathy recover within 24–36 months and substantial improvements usually occurs 4–6 months post onset.[6] 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.[5]

Conservative management is a preferred first treatment option, since the risk–benefit ratio for surgery is less favourable.[7–11] Several systematic reviews[7–9] and contemporary (inter)national treatment guidelines[12–16] 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[17 18]; RCTs usually report central tendencies of a cohort, which is not representative of an individual patients.[19] 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.[20] 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.[21 22] 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.[8 9 23]

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'.[24 25] 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.[25 26]

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[25–28] and recent studies.[29–32] 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.[27 33] 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.[26] The study will be reported in line with the Conducting and Reporting Delphi Studies (CREDES) recommendations (online supplemental file 1) to ensure rigour.[25]

Participants

In line with the CREDES recommendations, experts will be sought globally from a variety of different professional backgrounds (physiotherapy, medicine, allied healthcare, academia).[25] Experts will be defined and agreed on by the steering committee according to predefined eligibility criteria informed by previous similar studies.[29 31 32]

Proposed eligibility criteria for experts to serve as panellists 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.[26 34 35] 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-dG, 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.[9 12 13 23 36 37] 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.[38] 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.[26 29 31 32] Non-responders will be sent two reminders per round at equally distributed intervals and/or contacted in person by the lead investigator. Figure 1 details the procedure and timeline for the study. Round 1 of the questionnaire (online supplemental file 2) will be sent out mid-December of 2020; collection of the final data is likely to take 6 months, that is, in July 2021, at which point analysis of data can begin.

Prior to the start of the study, a prenotification period of 6 weeks will be allocated to recruit participants. Questions will be sent to the panellists en bloc and comments will be returned in a non-blinded fashion to the lead investigator (ET), who will incorporate the comments. A five-point Likert scale (1=strongly disagree, 2=disagree, 3=do not agree or disagree, 4=agree, 5=strongly agree) will evaluate level of agreement throughout.[39] Consensus will be assessed through analysing descriptive statistics against predefined criteria for consensus.

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.[40 41] 'Acute' pain is pain that has been present for up to 6 weeks.[41] '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.[42] 'Chronic' pain is defined as pain that persists or recurs for more than 3 months.[40 41]

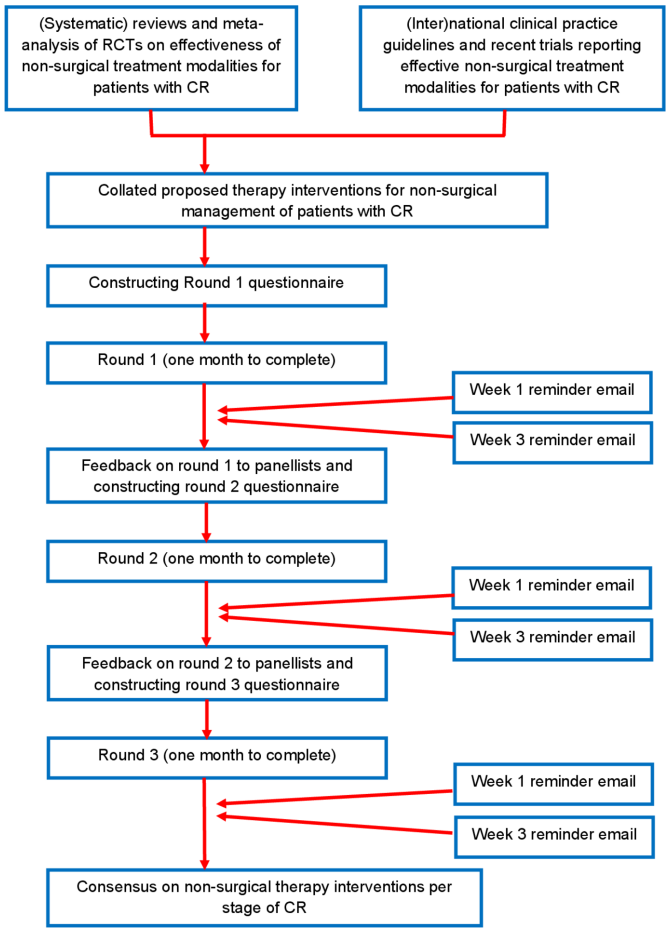

Figure 1 Procedure and timelines for participants in Delphi study. CR, cervical radiculopathy; RCT, randomised controlled trial.

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.[39 43 44] 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[39] will be used to assess consensus in each round according to the following criteria[29 30 45]:

Round 1: criteria of consensus
- Median value of participants' Likert scale data≥3.
- Percentage of agreement ≥50%.

Round 2: criteria of consensus
- Median value of participants' Likert scale data≥3.5.
- 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.[9 12 13 23 36 37]

CONCLUSION

Current literature provides the clinician with only a list of potential effective individual treatment modalities derived from RCTs and CCTs. It does not allow for individualised management plans tailored to the stage of recovery patients might be in. In order to ascertain a consensus derived set treatment modalities, thought to be especially effective during certain stages of recovery, a modified Delphi study has been designed. The clinical implications of this study are the results facilitate the decision-making of clinicians in formulating individualised management plans through the natural course of recovery for patients with CR.

Twitter Erik Thoomes @Fysio_Experts and Deborah Falla @Deb_Falla

Contributors All authors devised the focus of this Delphi study. ET is a PGR student, DF is the lead supervisor, AG is the cosupervisor, JC and MT-dG are coresearchers. ET drafted the initial protocol manuscript with lead and cosupervisors providing guidance on methodological decisions and proposed analyses. All authors have contributed subject-specific expertise. ET will recruit participants into the study. All authors will contribute to data interpretation, conclusions and dissemination. All authors have read, contributed to and agreed to the final manuscript. DF is the guarantor of the study.

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