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Timing of evidence based non-surgical interventions as part of multi-modal 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 randomized 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, sub-acute and chronic) of CR, using the Delphi method approach.

Methods and analysis

Included participants will be considered experts within the field as measured against predefined eligibility criteria. Through an iterative multistage process, participants 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 5-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 will be obtained from the University of Birmingham ethics committee. The study findings will be submitted to a peer-reviewed journal and to relevant conferences for dissemination of the study results.

Key words

Delphi study; cervical radiculopathy; non-surgical management; timing; treatment modalities

ARTICLE SUMMARY

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 different stages (acute, sub-acute and chronic) of cervical radiculopathy.
- This study will inform clinicians in formulating individually tailored management plans for patients with cervical radiculopathy.
- This study will be reported in line with Conducting and Reporting Delphi Studies (CREDES) recommendations.
- This study is a mixed method design utilizing both qualitative and quantitative data.
- The views of the Delphi panelist 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, paraesthesia 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 cervical radiculopathy 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 labor productivity ⁵.

Conservative management is a preferred first treatment option, since the risk-benefit ratio for surgery is less favourable ⁶⁻¹⁰. Several systematic reviews ⁶⁻⁸ and contemporary (inter)national treatment guidelines ¹¹⁻¹⁵ 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 mobilization and use of a cervical collar .

Systematic reviews, traditionally include outcomes from randomized 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 ^{16 17}; RCTs usually report central tendencies of a cohort, which is not representative of an individual patients ¹⁸. 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, sub-acute or chronic ¹⁹. Rehabilitation programs 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 ^{20 21}. Current evidence on the effectiveness of non-surgical management of patients with CR report a lack of consensus on the optimal timing and dosage of treatment modalities ^{7 8 22}.

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” ^{23 24}. 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. ^{24 25}.

Objective

To establish consensus on effective non-surgical treatment modalities for patients in different stages (acute, sub-acute 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 study²⁴⁻²⁷ and recent studies²⁸⁻³¹. 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^{26 32}. 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 pressure²⁵. The study will be reported in line with the Conducting and Reporting Delphi Studies (CREDES) recommendations to ensure rigour²⁴.

Participants

In line with the CREDES recommendations, experts will be sought globally from a variety of different professional backgrounds (physiotherapy, medicine, allied health care, academia)²⁴. Experts will be defined and agreed upon by the steering committee according to pre-defined eligibility criteria informed by previous similar studies^{28 30 31}.

Proposed eligibility criteria for experts to serve as panellists will be (≥ 1 criterion required for inclusion):

- ≥ 1 peer-reviewed publications on CR or cervical spinal entrapment neuropathies within the past 10 years OR
- ≥ 10 years' experience working in a pain/musculoskeletal outpatient 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.^{25 33 34}. 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 e-mail 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 5 authors of this study: the lead investigator (ET) and four senior academics (MTdG, 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 two, the questionnaire will be returned to each participant, indicating their response from round one 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 consensus³⁵. At the end of round 3, panellists will be asked to rank the treatment modalities in terms of importance. 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 three weeks to complete each round and three weeks will be allocated per round for data analysis^{25 28 30 31}. 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.

Prior to the start of the study, a pre-notification 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 throughout³⁶. Consensus will be assessed through analysing descriptive statistics against pre-defined 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 e.g.: 'acute', 'sub-acute' and 'chronic' as proposed by the International Association for the Study of Pain (IASP) ^{37 38}. 'Acute' pain is pain that has been present for up to 6 weeks ³⁸. '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 ³⁹. 'Chronic' pain is defined as pain that persists or recurs for more than 3 months ^{37 38}.

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 ten years after completion of the study. Content analysis will be used to analyse data from the free text boxes; themes will be identified 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 ^{36 40 41}. Qualitative data will be extracted deductively (to identify themes) and inductively (to identify additional themes). Descriptive statistics including median, IQR, quartile and percentage of agreement ³⁶ will be used to assess consensus in each round according to the following criteria ^{28 29 42}:

Round 1: criteria of consensus

- Median value of participants' Likert scale data ≥ 3
- Percentage of agreement $\geq 50\%$

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 $\geq 60\%$

Round 3: criteria of consensus

- Median value of participants' Likert scale data ≥ 4
- IQR value of participants' Likert scale data ≤ 1
- Percentage of agreement $\geq 70\%$

All quantitative data will be analysed using IBM SPSS V.23.

Ethical considerations

Ethical approval will be obtained from the University of Birmingham ethics committee. 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 participant 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

Information from patients and the public has informed the conception and requirement for this Delphi study as part of an existing programme of research that is centred on radiculopathy.

Discussion

The results from this study will assist clinicians and researchers in formulating an individualized 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 standardized “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.

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 individualized 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 individualized management plans through the natural course of recovery for patients with CR.

Figure Legend:

Figure 1. Procedure and timelines for participants in Delphi study

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Authors' contributions: state how each author was involved in writing the protocol. All authors devised the focus of this Delphi study. ET is a PGR student, DF is the lead supervisor, AG is the co-supervisor, JC and MTdG are co-researchers. ET 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. 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.

Data statement: all study data will be made available upon request from the lead investigator

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Competing interests statement.
None declared

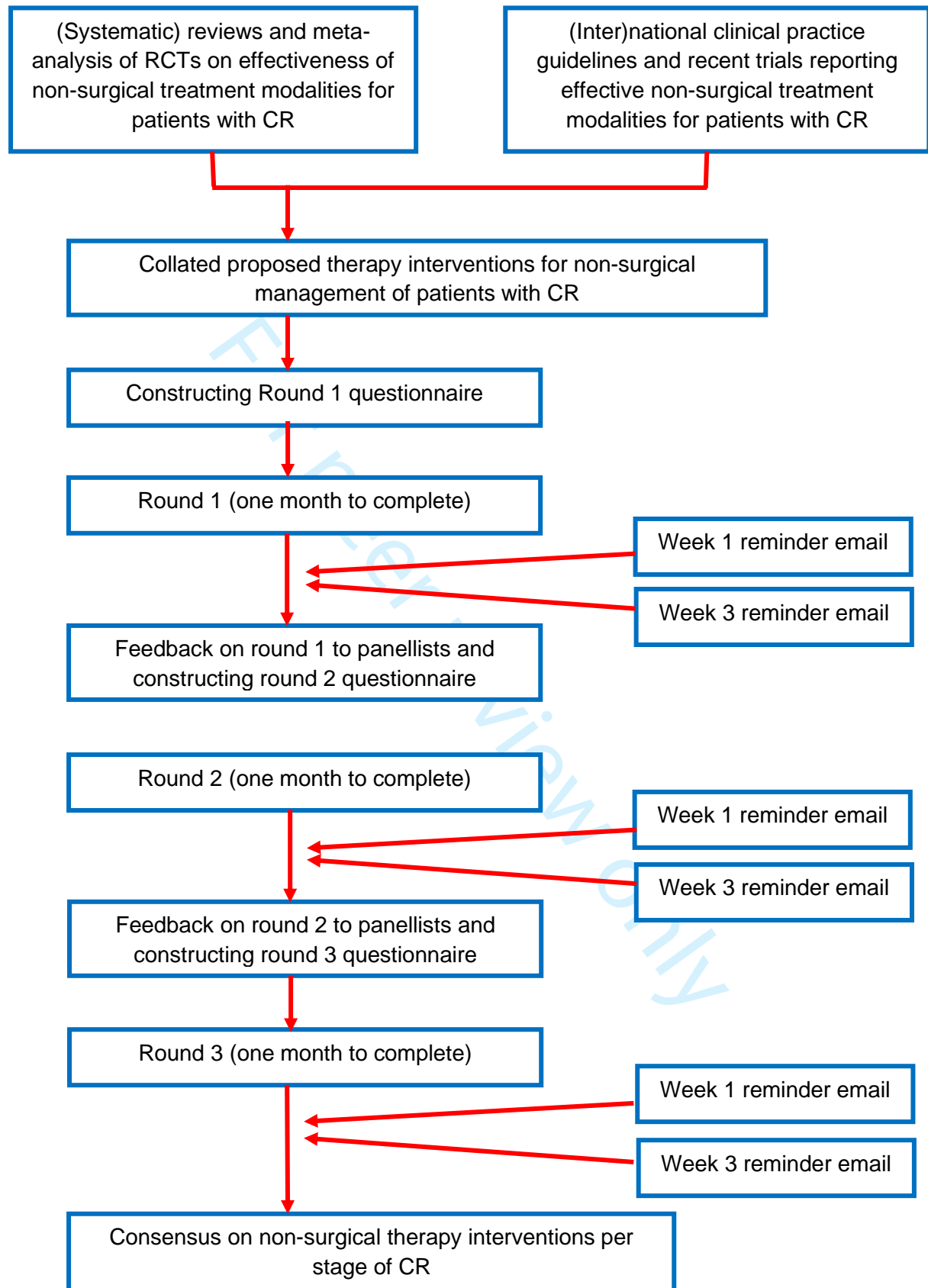


Figure 1. Procedure and timelines for participants in Delphi study

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

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Timing of evidence based non-surgical interventions as part of multi-modal 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 randomized 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, sub-acute 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 5-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.

Key words

Delphi study; cervical radiculopathy; non-surgical management; timing; treatment modalities

ARTICLE SUMMARY

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, sub-acute and chronic) of cervical radiculopathy.
- This study will be reported in line with Conducting and Reporting Delphi Studies (CREDES) recommendations.
- This study will utilize both qualitative and quantitative data.
- The views of the Delphi panelist 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, paraesthesia 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 cervical radiculopathy 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 labor productivity ⁵.

The natural history of CR is favourable as most (83%) patients with symptomatic radiculopathy recover within 24 to 36 months and substantial improvements usually occurs 4 to 6 months post-onset ⁶. It has been suggested 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 mobilization and use of a cervical collar.

Systematic reviews, traditionally include outcomes from randomized 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, sub-acute or chronic ²⁰. Rehabilitation programs 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 report 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, sub-acute 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 study²⁵⁻²⁸ and recent studies²⁹⁻³². 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 pressure²⁶. The study will be reported in line with the Conducting and Reporting Delphi Studies (CREDES) recommendations (**SUPPLEMENTAL FILE 1**) to ensure rigour²⁵.

Participants

In line with the CREDES recommendations, experts will be sought globally from a variety of different professional backgrounds (physiotherapy, medicine, allied health care, academia)²⁵. Experts will be defined and agreed upon by the steering committee according to pre-defined 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 e-mail 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 5 authors of this study: the lead investigator (ET) and four senior academics (MTdG, 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 two, the questionnaire will be returned to each participant, indicating their response from round one 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 consensus³⁸. 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 three weeks to complete each round and three 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 (**SUPPLEMENTAL FILE 2**) will be sent out mid-December of 2020; collection of the

final data is likely to take six months i.e. in July 2021, at which point analysis of data can begin.

Prior to the start of the study, a pre-notification 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 throughout³⁹. Consensus will be assessed through analysing descriptive statistics against pre-defined 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 e.g.: 'acute', 'sub-acute' and 'chronic' as proposed by the International Association for the Study of Pain (IASP)^{40 41}. 'Acute' pain is pain that has been present for up to 6 weeks⁴¹. 'Subacute' pain is a subset of acute pain: it is pain that has been present for at least 6 weeks but less than 3 months⁴². 'Chronic' pain is defined as pain that persists or recurs for more than 3 months^{40 41}.

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 ten 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, MTdG) 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 agreement³⁹ 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 $\geq 50\%$

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 $\geq 60\%$

Round 3: criteria of consensus

- Median value of participants’ Likert scale data ≥ 4
- IQR value of participants’ Likert scale data ≤ 1
- Percentage of agreement $\geq 70\%$

All quantitative data will be analysed using IBM SPSS V.23.

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 cervical radiculopathy. 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 individualized 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 standardized “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 individualized 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

1
2
3 especially effective during certain stages of recovery, a modified Delphi study has
4 been designed. The clinical implications of this study are the results facilitate the
5 decision-making of clinicians in formulating individualized management plans through
6 the natural course of recovery for patients with CR.
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11 **Figure Legend:**
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14 **Figure 1.** Procedure and timelines for participants in Delphi study
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Authors' contributions: All authors devised the focus of this Delphi study. ET is a PGR student, DF is the lead supervisor, AG is the co-supervisor, JC and MTdG are co-researchers. ET 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. 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.

Data statement: all study data will be made available upon request from the lead investigator

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Competing interests statement.

None declared

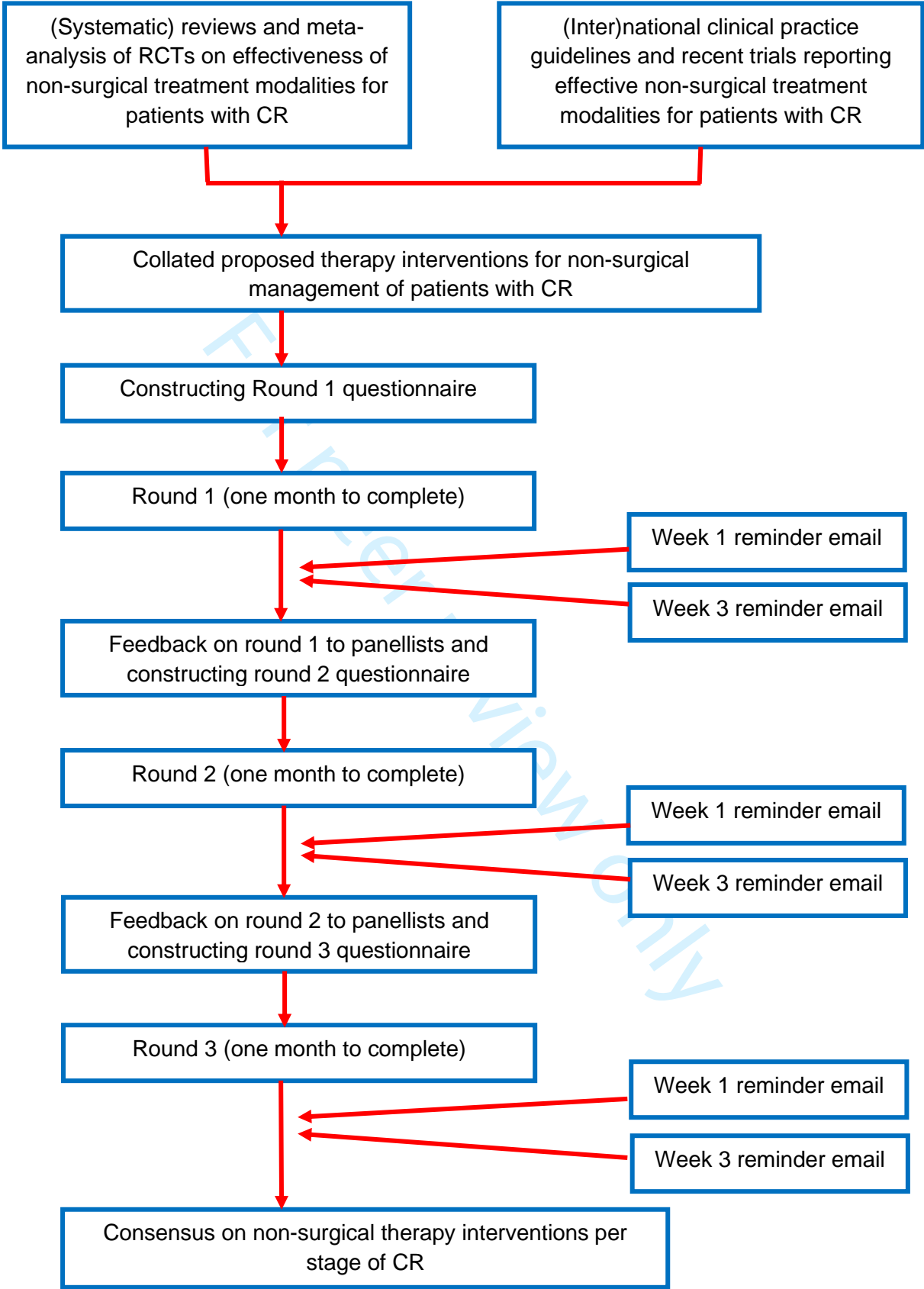


Figure 1. Procedure and timelines for participants in Delphi study

Guidance on Conducting and REporting DELphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review

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Abstract

Background: The Delphi technique is widely used for the development of guidance in palliative care, having impact on decisions with relevance for patient care.

Aim: To systematically examine the application of the Delphi technique for the development of best practice guidelines in palliative care.

Design: A methodological systematic review was undertaken using the databases PubMed, CINAHL, Web of Science, Academic Search Complete and EMBASE.

Data sources: Original articles (English language) were included when reporting on empirical studies that had used the Delphi technique to develop guidance for good clinical practice in palliative care. Data extraction included a quality appraisal on the rigour in conduct of the studies and the quality of reporting.

Results: A total of 30 empirical studies (1997–2015) were considered for full-text analysis. Considerable differences were identified regarding the rigour of the design and the reporting of essential process and outcome parameters. Furthermore, discrepancies regarding the use of terms for describing the method were observed, for example, concerning the understanding of a 'round' or a 'modified Delphi study'.

Conclusion: Substantial variation was found concerning the quality of the study conduct and the transparency of reporting of Delphi studies used for the development of best practice guidance in palliative care. Since credibility of the resulting recommendations depends on the rigorous use of the Delphi technique, there is a need for consistency and quality both in the conduct and reporting of studies. To allow a critical appraisal of the methodology and the resulting guidance, a reporting standard for Conducting and REporting of DELphi Studies (CREDES) is proposed.

Keywords

Delphi technique, palliative care, methodological systematic review, reporting standard

What is already known about the topic?

- The Delphi technique is a relevant source of evidence in health care research.
- It has been employed in palliative care research for diverse purposes, but its application as a method for the development of best practice guidance has not been systematically examined.
- Guidance has been proposed for enhancing rigour and transparent reporting of Delphi studies; however, clear recommendations on the conduct of Delphi studies and a reporting standard for their publication in peer-reviewed journals to date are not available.

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What this paper adds?

- Demonstration of the use of the Delphi technique, including evidence on variation in study design, study conduct and reporting, for the production of consensus, knowledge and guidance on good clinical practice in palliative care.
- Recommendations on the rigorous conduct of studies using the Delphi technique for the development of best practice guidance in health care and a standard for the transparent reporting of Delphi studies (Conducting and REporting of DElphi Studies (CREDES)).

Implications for practice, theory or policy

- The recommendations resulting from this review constitute an internationally applicable guidance for the conduct and reporting of studies using the Delphi technique in health care research.
- We suggest that these can serve as a guide for researchers undertaking Delphi studies, for authors publishing them, as well as for reviewers and journal editors when evaluating the quality of the study design and the transparency of reporting.

Background

The Delphi technique in developing professional guidance

Since the 1950s, the Delphi technique has become an increasingly important tool used to address issues in health and medicine and an attractive method for developing consensual guidance on best practice.^{1–3}

The primary purpose of the Delphi technique is the formation of consensus or the exploration of a field beyond existing knowledge and the current conceptual world.^{4,5} It is characterised by four methodological features which enable the involvement of experts with diverse backgrounds irrespective of their geographical location:^{4,6–8} (1) a group of experts, called ‘panellists’, is questioned about the issue of interest; (2) the process is anonymous in order to avoid social pressure and conformity to a dominant view (bandwagon effect); (3) the procedure is iterative in nature, comprising several rounds of enquiry; and (4) the design of subsequent rounds is informed by a summary of the group response of the previous round. It can be tailored to the particular requirements of the research objective, ranging from open and exploratory to standardised confirmatory approaches.^{8,9}

In this review, the term *Delphi technique* is used to refer to the method as such; *Delphi study* describes a research endeavour employing the Delphi technique as a method, *Delphi survey* relates to the actual survey (rounds) conducted as part of the Delphi technique and *Delphi process* covers the overall process of consensus building during a Delphi study.

The role of the Delphi technique in palliative care research

With the increasing professionalisation of palliative care, there are expanding demands concerning the quality and quantity of palliative care service provision. In an

environment of rapidly increasing knowledge, there are continuously changing assumptions about best practice and health care professionals need guidance for their clinical decisions. Defining professional standards and developing guidance on best practices have become important concerns in order to guide the commissioning of services, the organisation of care and the allocation of resources.¹⁰

Evidence from meta-analysis, randomised controlled trials (RCTs) or high-quality observational studies is considered of highest quality to inform professional guidance.¹¹ In comparison, expert consensus is regarded as the lowest grade of evidence.¹² However, in palliative care research, for ethical, economic or practical reasons, it is not always appropriate to undertake clinical trials or large-scale observational research.^{13–15} As a consequence, sparse evidence from RCTs and observational studies has been identified for relevant areas of symptom treatment.^{16–21}

Many clinical guidelines are therefore grounded in expert opinions and experiences,¹ captured using consensus building processes such as the Delphi technique. The method has been adopted by researchers and key opinion leaders in palliative care for the development of clinical guidelines, treatment recommendations and assessment tools; to define diagnostic criteria, disease classification and quality indicators; and to establish frameworks for policy and advocacy.⁶ The resulting recommendations are endorsed by leading authorities and professional organisations in the field; they are cited and used as a resource for scientific justification and health policy decision making. Hence, the results of Delphi studies constitute an important foundation for decisions with relevance for clinical practice.

Rationale and aim of this study

In order for the Delphi technique to be a reliable and credible source of evidence in palliative care research, an

examination of the rigour in its application is warranted.^{8,22} To assess the soundness of the resulting guidance and its contribution to the scientific and clinical knowledge base, it is important to systematically examine the rationale for choosing the Delphi technique, its conduct and the quality and transparency of reporting.²² Biondo et al.⁶ have examined the use of the Delphi technique in palliative care research and focused on its application for palliative care tool development. However, to date, no attention has been given to its use for the development of good clinical practice in palliative care. The aim of this review is to systematically examine the application of the Delphi technique for the development of guidance for best practice in palliative care.

Methods

A qualitative and quantitative methodological systematic review^{23–26} was undertaken to answer the review question ‘How is the Delphi technique being used for the development of guidance for best practice in palliative care?’ A particularity of a methodological systematic review is its focus on the studies’ methodological features, instead of

appraising the evidence on the therapeutic effects of medical interventions.²⁵ Its purpose is to examine the quality of the study design and the rigour of the conduct and reporting of the respective studies. We adopted this methodology to determine whether key components of the Delphi technique were adequately applied and featured in studies using the method for the development of best practice guidance in palliative care. The procedures for searching, identifying relevant publications, screening, appraising quality criteria and handling of data extraction were informed by the Centre for Reviews and Dissemination²⁷ guidance for systematic reviews and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).²⁸

Search strategy

The literature search was conducted using the databases PubMed, CINAHL, Web of Science, Academic Search Complete and EMBASE between 15 and 22 March 2015. For each database, a specific search strategy was constructed to ensure high precision and sensitivity (as an example, see Box 1 for the search strategy in PubMed).

Box 1. Search terms and search strategy in PubMed.

Search (((('Delphi Technique'[Mesh]) OR 'Consensus'[Mesh]) OR (delphi OR consensus))) AND (((('Hospice and Palliative Care Nursing'[Mesh] OR 'Palliative Medicine'[Mesh] OR 'Palliative Care' [Mesh] OR 'Hospice Care'[Mesh] OR 'Terminal Care'[Mesh] OR 'Hospices'[Mesh])) OR (hospice OR palliative OR 'end of life'))

The main search was supplemented by publications identified through other sources during online retrieval of full-text articles.

the publication date of the study. Any uncertainty was resolved through review by S.G.B. and S.A.P.

Study selection

All records were screened by title and abstract by S.J. and were considered for full-text analysis if they fulfilled the eligibility criteria (Box 2). No limits were set in terms of

Data extraction

Qualitative and quantitative data extraction was conducted by S.J. using a structured form based on the principles of the Centre for Reviews and Dissemination²⁷ guidance for systematic reviews. Since no reporting

Box 2. Criteria for eligibility.

Topic	The focus of the study addresses a research question or issue in the field of palliative and/or hospice care
Purpose	The study aimed at improving patient care through identifying consensus-based components of best practice in palliative care and seeking to develop some sort of guidance about these, such as a list of best practices, a protocol, a standard or a guideline
Language	English
Type of publication	Full-text article reporting on an empirical study (excluded: conference abstracts; papers referring to a Delphi study but not reporting the methodology)
Methodology	Delphi technique/modified Delphi technique (excluded: surveys or qualitative enquiries not fulfilling the criterion of an iterative process with at least two rounds; consensus procedures other than Delphi (conferences, nominal group technique, workshops))

criteria for Delphi studies exist to date, criteria were developed from key publications on the Delphi

technique and based on our own experience of conducting Delphi studies.^{8,22,29} We collected all data pertaining

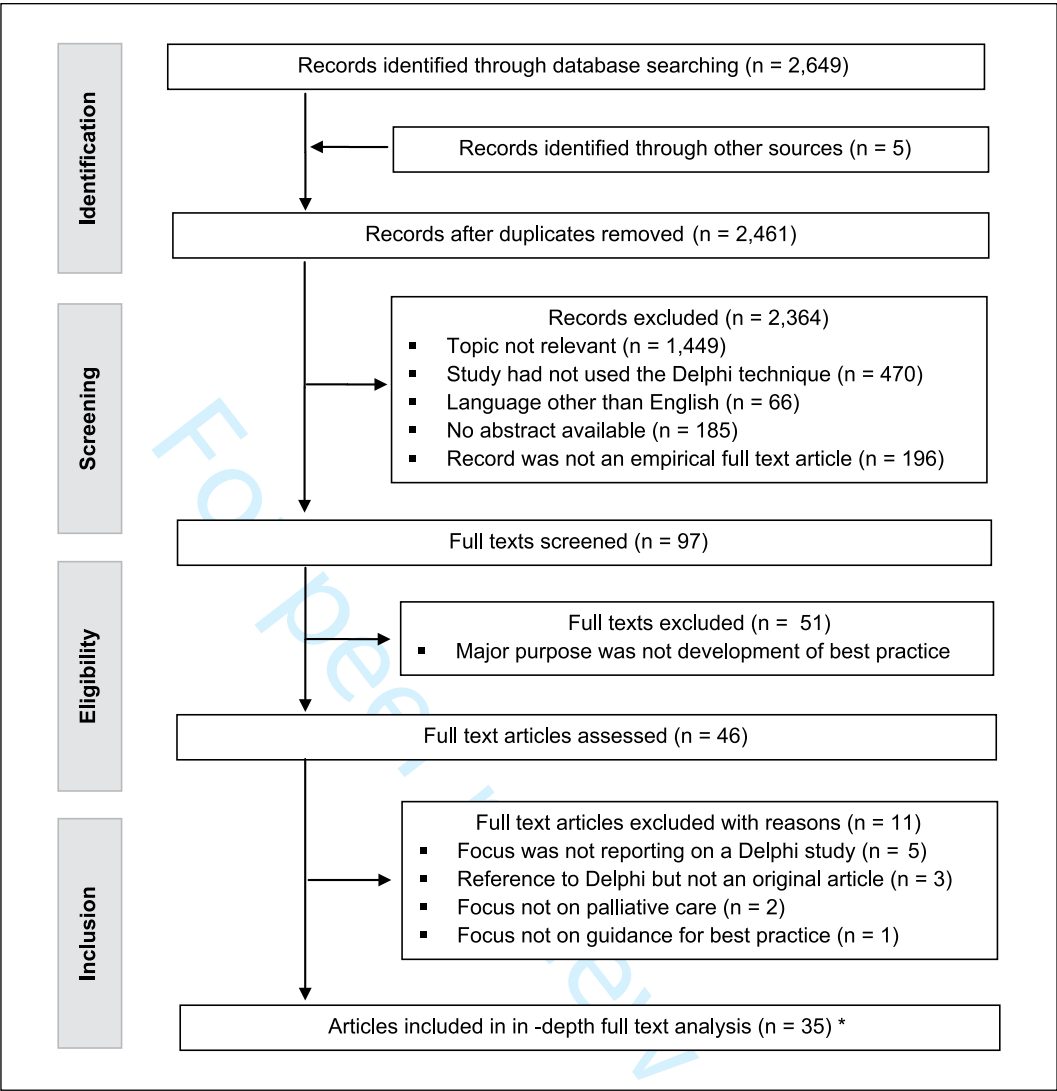


Figure 1. Flow diagram of the systematic literature search.

*These $n=35$ articles pertain to $n=30$ Delphi studies since for four studies, more than one article was identified.

to the key methodological components of the Delphi process. Data extraction included details on (1) inclusion and exclusion criteria of the article, (2) the focus of the study, (3) the rationale for the use of the Delphi technique, (4) the overall study design, (5) the applied methods and the procedure, (6) data analysis and (7) key outcomes of the consensus process. Finally, a quality assessment was undertaken to rate the rigour of the methodology and the transparency of reporting. The evaluation assessed whether the following elements were considered and transparently described: purpose of the study and rationale for using the Delphi technique, justification for the selection of experts, sound description of methodology including flow chart, clear definition of consensus, piloting of instruments, appropriate use of statistics, transparent reporting of results, adequate feedback and information of next survey round,

discussion of limitations and whether the conclusions drawn by the authors adequately reflected the process and the results of the Delphi study.

Results

The search yielded 2649 records. In addition, five records were identified through other sources (Figure 1). Of these, 35 papers published between 1997 and 2015 were identified as meeting the inclusion criteria and were eligible for in-depth analysis (Tables 1–4). These 35 papers pertained to 30 Delphi studies since for four of the studies,^{30–34,40,41,46,47} more than one publication was identified. The $n=30$ Delphi studies will constitute our sample and will be referred to for further analysis. In all, 11 of these studies had an international scope, 14 had a national scope with a (potential) international applicability and 5

Table 1. Projects focusing on best practice in the field of specific interventions.

No.	Author(s), year	Geographical scope	Major topic	Aim/purpose/expected outcome	Guidance for best practice – content	Guidance – format and product
3a	Bridgman and Carr, 1997 ³⁰	UK	Family support for patients in need of palliative care in a hospital	To identify (a) supportive nursing behaviours/the most helpful care in assisting families of palliative care patients to deal with the demands of the illness and (b) difficulties nurses encounter in trying to meet the needs of these families and factors against effective provision of family care in a hospital	Categories for providing family-focused palliative care in hospital	Two tables listing the 10 most important topics for providing family-focused care and the 10 most important difficulties in providing that care; discussion with focus on the four most important aspects for each category, illustrating them with free text answers from the first Delphi round
3b	Bridgman and Carr, 1998 ³¹	UK	Family end-of-life support in hospital	To identify what nurses regarded as the most helpful way to provide care and assistance to the families of patients receiving palliative care, to help them deal with the illness and the difficulties nurses encounter		
6a	De Lima et al., 2007 ³²	Worldwide	Symptom treatment/essential medicines in palliative care	To develop a list of essential medicines for palliative care, based on the recommendation from palliative care experts, taking into consideration the criteria of efficacy and safety	International Association for Hospice and Palliative Care (IAHPC) List of Essential Medicines for Palliative Care	Table listing 33 medications including details on formulation, indication and reference to the World Health Organization (WHO) Essential Medicines Model List
6b	De Lima, 2012 ³³	Worldwide	Symptom treatment/essential medicines in palliative care	To develop a list of essential medicines for palliative care by expert consensus, facilitating provision of the best possible care for all those with advanced life-threatening illness		
6c	De Lima et al., 2007 ³⁴	Worldwide	Symptom treatment; essential medicines in palliative care	To develop a list of essential medicines for palliative care, based on the consensus of international palliative care clinicians, following the criteria of efficacy and safety		
8	Downar and Hawryluck, 2010 ³⁵	CAN	Discussion of do-not-resuscitate (DNR) order and goals of care	To develop content guidelines for physicians for the discussion of cardiopulmonary resuscitation (CPR) or 'code status' and goals of care. To facilitate effective, informed and ethically sound decision making	Guidelines for the discussion of CPR and goals of care	A full list of consensus statements provided in the appendix of the paper (9 statements on timing, framing, offering a prognosis, etc.)
9	Dreesen et al., 2012 ³⁶	Europe; study based in BE; 5 countries involved (BE, FR, DE, IT, ES)	Home parenteral nutrition for cancer patients	To identify key interventions to ensure high-quality home parenteral nutrition care for cancer patients and to rank/to agree on main outcome indicators	Key interventions and outcome indicators for home parenteral nutrition for cancer patients	Table listing a set of 42 key interventions for good clinical practice in home parenteral nutrition; table with top 10 quality of care outcome indicators
12	Holmes et al., 2008 ³⁷	USA	Medication use in palliative care for patients with advanced dementia	To evaluate the feasibility of developing consensus recommendations for appropriate prescribing for patients with advanced dementia in whom palliation of symptoms is the primary goal, using a conceptual framework; and to determine the frequency of inappropriate medication use	Recommendations for appropriate medication use for persons with advanced dementia in need of palliative care	Table providing a full final list of medications according to their level of appropriateness (always/sometimes/rarely/never appropriate; no consensus)

Table 1. (Continued)

No.	Author(s), year	Geographical scope	Major topic	Aim/purpose/expected outcome	Guidance for best practice – content	Guidance – format and product
13	Hudson et al., 2012 ³⁸	AUS/ international	Family caregivers	To develop clinical practice guidelines for multidisciplinary health care professionals and clinical services commonly involved in caring for adult patients receiving palliative care to guide the provision of psychosocial and bereavement support for family caregivers of palliative care patients	Guidelines for the psychosocial and bereavement support for family caregivers of palliative care patients	Two tables, one listing 14 principles for family caregiver support and one with a summary of 20 guideline statements comprising four parts; complete guidelines available online
15	Lindqvist et al., 2013 ³⁹	International; 9 participating countries: AR, DE, IT, NZ, SI, SE, CH, NL, UK	Essential medicines/ medical symptom treatment in palliative care	To explore the degree of consensus about appropriate pharmacological treatment for common symptoms in the last days of life for patients with cancer, among physicians working in specialist palliative care	Essential drugs for quality care of the dying	Four classes of essential drugs that should be available for all patients in the last days of life
16	Mahler et al., 2010 ⁴⁰	USA; worldwide	Symptom management; dyspnoea; advanced lung or heart disease	To provide consensus statements on effective relief of dyspnoea to address the problem that patients with advanced lung or heart disease are not being treated consistently and effectively for the relief of dyspnoea	American College of Chest Physicians (ACCP) consensus statement on the management of dyspnoea in patients with advanced lung or heart disease	List of 20 ACCP consensus statements, covering five domains, with additional explanation in the text body of the article
16b	Mahler et al., 2010 ⁴¹	USA/ international	Symptom management; dyspnoea; advanced lung or heart disease	To develop a consensus statement on the management of dyspnoea in patients with advanced lung or heart disease; to influence clinical practice and to provide suggestions for consistent and effective treatment of dyspnoea in patients with advanced lung or heart disease		
18	Morita et al., 2005 ⁴²	JP	Palliative sedation	To construct a clinical guideline for palliative sedation therapy to help clinicians adequately perform sedation and ensure better quality care for terminally ill patients	Clinical guideline for palliative sedation therapy	Extensive and detailed guideline comprising four sections with narrative guidance, four diagrams for clinical application (algorithms) and two tables listing standard treatments for symptoms and sedatives used in palliative sedation therapy
19	Morita et al., 2007 ⁴³	JP	Artificial hydration therapy for adult patients with incurable cancer	Establishing a clinical guideline with recommendations on best practice for artificial hydration therapy that can contribute to patient well-being and to improve quality of life, dying and death by clarifying best practice for Japan	Clinical guideline for artificial hydration therapy for terminally ill patients with cancer	Extensive and detailed guideline including a conceptual framework (flow chart), a list of 14 general recommendations, and nine sections of specific recommendations for practice of artificial hydration therapy in diverse conditions

(Continued)

Table 1. (Continued)

No.	Author(s), year	Geographical scope	Major topic	Aim/purpose/expected outcome	Guidance for best practice – content	Guidance – format and product
20	Onwuteaka-Philipsen and van der Wal, 2001 ⁴⁴	NL/ international	Euthanasia and physician-assisted suicide	To develop a protocol for consultation of another physician for euthanasia. To make it easier for general practitioners to find an independent and knowledgeable consultant, but also to professionalise consultation and to ensure uniformity	Protocol for consultation of another physician in case of euthanasia and assisted suicide	Four boxes listing necessary and recommended guidelines for consultation addressing independence, expertise, tasks and judgement of the consultant
21	Pigni et al., 2010 ⁴⁵	International, Europe	Symptom management; opioid treatment for cancer pain	To critically revise and update the EAPC recommendations on cancer pain management	European guidelines on the use of opioids for cancer pain	Table listing 22 key topics to be further analysed for good clinical practice by means of systematic reviews to assess current evidence
22a	Rayner et al., 2011 ⁴⁶	International, Europe	Symptom management/ depression in palliative cancer care	To produce a European evidence-based clinical guideline on the management of depression in patients receiving palliative care to inform practice, establish policy, promote European consensus and ultimately improve patient outcomes	Evidence-based European guidelines on the management of depression in palliative cancer care (European Palliative Care Research Collaborative depression guideline)	Guideline with three main sections: (1) prevention; (2) detection, diagnosis and assessment; and (3) treatment. Summary of the final key recommendations including an explanation, references and the quality of evidence/strength of recommendation based on GRADE (Grading of Recommendations, Assessment, Development and Evaluation)
22b	Rayner et al., 2011 ⁴⁷	International, Europe	Symptom management; depression in palliative care	To inform the development of best practice recommendations for the European Palliative Care Research Collaborative clinical practice guideline on managing depression in palliative care		
27	Van der Maaden et al., 2014 ⁴⁸	NL, USA, CAN, UK, IT, DE, CH, CZ ^a	Symptom relief for patients with pneumonia and dementia	To develop a practice guideline for a structured and consensus-based approach for optimal symptom relief and comfort specifically for patients with pneumonia and in nursing homes	Practice guideline for optimal symptom relief for patients with pneumonia and dementia in nursing homes	Practice guideline consisting of an introduction, a checklist of symptoms and the core guidelines
29	Vermandere et al., 2013 ⁴⁹	BE, NL	Spiritual care in palliative home care	To develop a consensus-based framework of the main elements of spiritual care within the context of palliative home care	Framework for spirituality in palliative home care	Table listing nine domains with 14 core elements of spiritual care within the context of palliative home care
30	Vignaroli et al., 2012 ⁵⁰	International	Pain management with opioids in adults	To develop an opioid essential prescription package (OEPP) to be used when initiating a prescription for the control of moderate to severe chronic pain, that would ensure that opioids are better tolerated by patients and therefore lead to more sustained improvements in pain control	International Association for Hospice and Palliative Care (IAHPC) OEPP (IAHPC) OEPP	Table listing the OEPP including details on drug class, recommended medicine, routes of administration and dosage

EAPC: European Association for Palliative Care.

^aDutch focus, therefore some of the decisions were adjusted to the Dutch experts/context. The authors note that certain recommendations should be re-evaluated in other countries because when literature and consensus were lacking, they prioritised the situation in the Netherlands (p. 495).

Table 2. Projects focusing on specific conditions.

No.	Author(s), year	Geographical scope	Major topic	Aim/purpose/expected outcome	Guidance for best practice – content	Guidance – format and product
25	Strupp et al., 2014 ⁵¹	DE	Specialised palliative care integration for patients with multiple sclerosis	Analysis of when and why specialised palliative care integration for patients with multiple sclerosis would be beneficial by examining health care professionals' attitudes	Guidance on integration of palliative care for severely affected patients with multiple sclerosis	Table listing possible criteria for integrating specialist palliative care in multiple sclerosis, completed by explanations in the text
28	Van der Steen et al., 2014 ⁵²	Europe-wide; international	Palliative care for people with dementia	To define optimal palliative care in dementia as distinct from palliative care for other patient groups Definition of domains and provision of guidance on palliative care for people with dementia	White Paper defining optimal palliative care in older people with dementia	Box listing 11 core domains of optimal palliative care for people with dementia, with a set of 57 recommendations and a figure on goals of care in the course of disease progression; final version including explanatory text available as online supplementary Annexe

had an explicitly stated national or local scope, mostly conducted by within-country or local research teams.

Focus and purpose of the studies

The majority of the 30 studies focused on interventions in palliative care (n=16); two studies focused on specific conditions, five studies dealt with paediatric or neonatal palliative care and seven studies concerned standards for palliative care delivery in specific settings or work fields (Tables 1–4). Half of the 16 intervention-focused studies (n=8) dealt with the pharmacological or non-pharmacological management of symptoms such as pain, dyspnoea or depression.^{32–34,37,39–41,45–48,50} The remainder considered artificial nutrition or hydration (n=2),^{36,43} psychosocial or spiritual support (n=3),^{30,31,38,49} end-of-life decision making (n=1),³⁵ palliative sedation (n=1)⁴² or euthanasia and physician-assisted suicide (n=1).⁴⁴ Studies addressing specific conditions focused on dementia⁵² and multiple sclerosis.⁵¹ Five studies aimed at developing guidance in the field of paediatric or neonatal palliative care.^{53–57} Of the studies concerning standards for palliative care delivery in specific settings or work fields, five were in institutional settings (hospital or nursing home),^{58,60,62–64} one in primary care⁵⁹ and one focusing on general conditions for palliative care service delivery.⁶¹

Rationale for the use of the Delphi technique

All but three studies (n=27) explicitly provided a rationale for using the Delphi technique. This included a lack of published guidance, the appropriateness of the method when evidence is needed to be drawn outside the gold

standard RCTs and the aim to build systematic consensus in order to resolve uncertainty about a clinical question or a concept of care. Two studies emphasised the qualitative nature of the Delphi technique and therefore considered it particularly appropriate for clinical questions where quantitative methods are unlikely to yield results that can be successfully implemented in practice.^{30,58}

Study design and type of Delphi

Most studies (n=28) explicitly referred to undertaking a consensus Delphi study. In 10 publications, the term ‘modified Delphi technique’ was used; only two of these specified what exactly the modification entailed. In nine articles, modifications were identified but not labelled as such; for example, the use of intermediate face-to-face meetings between Delphi survey rounds⁴³ or the involvement of different expert panels in the consensus process.⁶⁰

Of the 30 studies, 10 comprised the Delphi technique alone and 11 comprised a Delphi survey plus additional elements such as a preparatory literature review or an evaluative assessment of the guidelines during an expert workshop. In 9 of the 30 studies, the Delphi technique formed part of a larger piece of work with a more complex research design including multiple other stages such as subsequent field testing of a protocol or a 1-year follow-up to evaluate implementation of a clinical guideline.

Selection of experts

The most prominent criteria for the identification and selection of experts were (1) representation of a particular profession or stakeholder group (n=24), (2) affiliation to a

Table 3. Projects focusing on paediatric palliative care.

No.	Author(s), year	Geographical scope	Major topic	Aim/purpose/expected outcome	Guidance for best practice – content	Guidance – format and product
1	Bradford et al., 2014 ⁵³	AUS	Paediatric palliative care	To define the components and principles of an early paediatric palliative care consultation (i.e. not end of life); to develop a published framework from expert consensus	Framework of components and principles of a paediatric palliative care consultation	Algorithm/flow chart
4	Carter and Bhatia, 2001 ⁵⁴	Medical College of Georgia, Augusta, USA	Neonatal intensive care	To develop a clinical practice guideline for providing comfort care to newborns with life-limiting conditions for the neonatal intensive care unit, with the following purposes: to be (1) practical, (2) family-centred, (3) respectful of the infant patient and (4) educational	Comfort/palliative care guidelines for neonatal practice	Guidelines comprising three sections (purpose, newborns for whom the guidelines are appropriate and 17 guideline statements)
5	Catlin and Carter, 2002 ⁵⁵	USA	Neonatal palliative care	To create a palliative care protocol for newborns, delineating the needs of patients, families and staff necessary to provide a pain-free, dignified, family- and staff-supported death for newborns who cannot benefit from intensive, life-extending, technological support	Neonatal end-of-life protocol	Detailed narrative guideline comprising 14 sections/domains with an introduction and bullet points providing guidance for practice
10	Finlay et al., 2008 ⁵⁶	UK	Paediatric palliative care/psychosocial end-of-life care	To develop a 'best practice framework' to improve child and family engagement in the planning process at the end of life and to aid communication and decision making with parents and children	Best practice 'lifetime' framework for planning for the end of life for children with a non-malignant life-limiting condition	A '3 × 3 framework' addressing plans and actions for the child, the family, and extra-familial others during three different stages in the disease trajectory before death, acute event/at death and after death
17	Mendes and da Silva, 2013 ⁵⁷	PT	Neonatal palliative care	To develop a new programme for better end-of-life care for infants and their families in Portugal Specific objectives: (1) to identify the main areas for the protocol, (2) to build consensus and (3) to elaborate a protocol for neonatal palliative care that could be used in the Portuguese NICUs	Protocol for neonatal palliative care	Detailed narrative guidance for neonatal palliative and end of life care comprising seven areas of practice

NICUs: neonatal intensive care units.

Table 4. Projects focusing on standards for palliative care delivery in specific settings or work fields.

No.	Author(s), year	Geographical scope	Major topic	Aim/purpose/expected outcome	Guidance for best practice – content	Guidance – format and product
2	Bradley and Brasel, 2009 ⁵⁸	USA	Palliative care in a surgical intensive care unit (SICU)	To formulate patient-specific guidelines for identifying patients most in need of palliative care consultation in the SICU; clinically relevant 'triggers' that can be used in the SICU to identify those patients who can benefit from palliative care involvement	Guidelines to identify patients who would benefit from palliative care services in the SICU	Table with 10 criteria to identify patients in a SICU setting in need of a palliative care consult
7	De Lima et al., 2012 ⁵⁹	Worldwide	Primary palliative care; essential components for optimal pc provision	To identify the essential practices in primary palliative care that could be provided by physicians, nurses and nurse aides working at the primary care level and providing guidance on practices aimed at meeting the most prevalent needs of palliative care patients and their families	International Association for Hospice and Palliative Care (IAHPC) List of Essential Practices in Palliative Care	Table listing 62 consented and approved essential practices in palliative care, subdivided into four categories addressing physical and psychological care needs, care planning and communication
11	Hawryluck et al., 2002 ⁶⁰	CAN	Palliative care and palliative sedation in the intensive care unit (ICU)	To develop consensus guidelines on the administration of analgesia and sedation in dying ICU patients that help distinguish palliative care from euthanasia, decrease confusion and anxiety regarding the use of opioids and sedatives, and that consider the unique challenges encountered when palliating dying ICU patients	Guidelines on analgesia and sedation in dying ICU patients	Four tables with guidance for practice listing 16 consensus statements addressing general aspects of palliative care in an ICU setting, management of pain and suffering, ways of improving palliative care in the ICU and areas of controversy
14	Jünger et al., 2012 ⁶¹	International scope/Europe	General concepts and principles of palliative care delivery	To provide an empirical basis for a common understanding of palliative care delivery in Europe; to provide guidance and recommendations for service providers, stakeholders and policy makers	White Paper on standards and norms for hospice and palliative care in Europe	Figure with key dimensions for the development of norms for palliative care in Europe; reference to full text of White Paper
23	Sasahara et al., 2009 ⁶²	JP	Hospital palliative care consultation teams for cancer patients	To develop a hospital-based palliative care consultation team standard/to standardise the role of palliative care consultation teams, providing guidance on minimum standards for new palliative care consultation teams	Standard for hospital-based palliative care consultation teams	Detailed guideline comprising four sections with specific recommendations for practice
24	Sprung et al., 2014 ⁶³	Worldwide	End-of-life care for the critically ill in intensive care (adults)	To develop worldwide professional consensus for key end-of-life practices and to determine the extent of worldwide consensus/lack of consensus on end-of-life practices	Principles of end-of-life care for the critically ill	Extensive and detailed table listing 22 specific recommendations for worldwide end-of-life practice in ICUs
26	Temkin-Greener et al., 2015 ⁶⁴	USA	Palliative care in nursing homes	To achieve consensus on guidance for palliative care teams in nursing homes, based on the guidelines developed by the National Consensus Project	Palliative care practice guidelines and standards for nursing home-based palliative care teams	Table listing 17 practice guidelines in 7 domains of care

particular setting or work field ($n=23$) and (3) relevant clinical and/or academic expertise ($n=20$; Table 5). Other criteria included membership of an organisation or professional board ($n=11$), being a recognised authority in the field ($n=11$) and geographical origin ($n=13$), with several studies paying particular attention to a balanced composition of the expert panel with representation from different regions and socio-economic backgrounds, or a relevant participation of experts from developing countries.^{32–34,50}

Definition of consensus

Most studies ($n=25$) reported a definition of consensus; five did not. Nearly all of them ($n=22$) had set an a priori criterion or cut-off (Table 5); one used a post hoc criterion for exclusion of items if more than 10% of panellists rated a specific guideline as not important.⁶⁴

For the majority of studies ($n=25$), consensus was conceptualised using statistical measures such as the percentage of ratings or the median value on a rating scale. The attainment of consensus based on statistical measures was operationalised depending on the rating scales employed in the study; the most prominent response formats were either a traditional 9-point scale ($n=6$) referring to the original RAND UCLA* method^{32–35,42,43,49,62} or a 5-point Likert scale,^{38,40,41,48,52,53,61,63,64} but 6-/7-/10- or 11-point scales were also used.^{43,45–47,52,53,57,60,64} Some studies used a ranking ($n=4$)^{30,31,39,50,58} or selection of items ($n=3$)^{37,51,59} rather than a scale.

The cut-off for (non)consensus was mostly based on percentage of agreement (mainly 75% or 80%), median score or a combination of both ($n=23$) (Table 5). Three studies distinguished between different degrees of (dis) agreement and consensus, reporting combined parameters to define low, moderate and high levels.^{48,52,61} Two studies used a more procedural definition such as ‘stability of group response over successive rounds’³⁰ or the cut-off for inclusion of items being based on a ‘natural break’ in the overall score.⁵⁸

Number and purpose of rounds

The number of rounds ranged from one to five, with the majority of the 30 studies reporting either two ($n=14$) or three ($n=8$) survey rounds. Only one survey round was reported in two studies.^{32–34,38} In terms of duration, for most studies ($n=19$), no details were provided on the length of survey rounds or the overall process. Seven studies specified the duration of rounds ranging from 10 days to 10 weeks; four studies provided details on the duration of the overall study process, ranging from 2 to 18 months.

The majority of studies ($n=27$) stated the purpose of the survey rounds (Table 6) which comprised rating or evaluating statements ($n=24$), identifying issues or generating items ($n=8$), collecting qualitative responses or comments ($n=7$), ranking or prioritising items ($n=6$), reviewing or approving a (final) framework or document ($n=5$) and developing guiding principles or a draft document ($n=4$).

Design of Delphi rounds

Different ways of informing the first and subsequent Delphi rounds were used within the studies. Methods used to inform the first Delphi round included systematic or scoping literature reviews,^{33,37,38,41–46,48,51,53,59–61,64} a synthesis of already existing guidelines,^{36,45,48,55,56,62} the identification of relevant elements and priorities for best practice,^{32,39,43,47,57,61,63} the development of a conceptual framework,^{34,37,43,47,53,56,61,62} the drafting of statements or guidelines,^{34,36,41–45,48,51–53,57,59,62–64} and information packages provided before the start of the first round in order to standardise the knowledge base of panellists.^{37,60,62}

The studies in this review reported diverse strategies of processing results between survey rounds and feedback provided to inform the experts’ judgements during the next survey round (Table 6). These included a statistical group response of quantitative parameters ($n=11$), a summary of qualitative comments ($n=8$), the inclusion of newly generated items ($n=10$), the modification of items ($n=6$), the selection or reduction of items ($n=9$) and the presentation of a document for review or approval ($n=8$). The reduction of items can both refer to items with (very) high agreement that were instantaneously accepted and therefore did not need further consideration in a subsequent survey round or to items with (very) low agreement or relevance that were therefore entirely discarded from the list. The process of achieving consensus was not always visible; for example, eight studies did not detail how the synthesis of responses in one survey round was used to design the following round; for six studies, the design of the next survey round was either not reported or was unclear.

The role of the research team was identified in 25 of the analysed studies and included planning and managing of the overall study process and processing results to inform the next Delphi round. Sometimes this involved complex and difficult decisions such as managing persistent non-consensus⁵² or a conflict between the majority opinion on the best medical treatment and ethical concerns about this treatment.⁴⁸

Key outcomes resulting from the studies

The format of the guidance resulting from the Delphi studies varied and included elementary tables with the top 10 criteria identified as relevant for the field in question;^{30,31,57}

*Research and Development Corporation/University of California Los Angeles

Table 5. Selection of experts, definition of consensus and quality of reporting.

Author(s), year	Transparency and quality of reporting													Selection criteria expert panel						Definition of consensus
	Purpose well defined	Rationale for Delphi	Selection of experts clearly justified	Clear description of methods	Flow chart	Clear definition of consensus	Pilot test of instruments	Transparent reporting of results	Data analysis clearly justified and reported	Information of rounds	Discussion of limitations	Adequacy of conclusions	Member of organisation	Recognised authority	Relevant clinical expertise	Geographical scope	Setting/work field	Professional/ stakeholder		
Bradford et al., 2014 ⁵³	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥80% of panellists (strongly) agree	
Bradley and Brasel, 2009 ⁵⁸	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Cut-off for inclusion of items based on a 'natural break' in overall score	
Bridgman and Carr, 1997 ³⁰	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Stability of group response on an item over successive rounds	
Bridgman and Carr, 1998 ³¹	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	/	
Carter and Bhatia, 2001 ⁵⁴	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	/	
Catlin and Carter, 2002 ⁵⁵	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	/	
De Lima et al., 2007 ³⁴	✓	✓	✓	✓	✓	✓	✓	✓	n/a	n/a	✓	✓	✓	✓	✓	✓	✓	✓	1–3 (9-point scale) not safe/effective; 7–9 very safe and effective	
De Lima et al., 2007 ³²	✓	✓	✓	✓	✓	✓	✓	✓	n/a	n/a	✓	✓	✓	✓	✓	✓	✓	✓	≥50% rating score ≥ 7 on a 9-point scale for both safety and efficacy	
De Lima, 2012 ³³	✓	✓	✓	✓	✓	✓	✓	✓	n/a	n/a	✓	✓	✓	✓	✓	✓	✓	✓	1–3 (9-point scale) not safe/effective; 7–9 very safe and effective	
De Lima et al., 2012 ⁵⁹	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥80% of panellists rating a practice as 'essential'	
Downar and Hawryluck, 2010 ³⁵	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	70% of panellists rating of ≥ 7 on a 9-point scale	
Dreesen et al., 2012 ³⁶	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Median > 5 (6-point scale); 75% rated intervention as '(strongly) contributes'	
Finlay et al., 2008 ⁵⁶	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	/	

(Continued)

Table 5. (Continued)

Author(s), year	Transparency and quality of reporting													Selection criteria expert panel					Definition of consensus
	Purpose well defined	Rationale for Delphi	Selection of experts clearly justified	Clear description of methods	Flow chart	Clear definition of consensus	Pilot test of instruments	Transparent reporting of results	Data analysis clearly justified and reported	Information of rounds	Discussion of limitations	Adequacy of conclusions	Member of organisation	Recognised authority	Relevant clinical academic expertise	Geographical scope	Setting/work field	Professional/stakeholder	
Hawryluck et al., 2002 ⁶⁰	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	80% agreement (Median ≥ 5.6 on a 7-point scale)	
Holmes et al., 2008 ³⁷	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Agreement on categorisation ^a of a medication by 7/12 experts ≥ 75% of panellists (strongly) agree with statement (4/5 on a 5-point scale)	
Hudson et al., 2012 ³⁸	✓	✓	✓	✓	✓	✓	✓	✓	✓	n/a	✓	✓	✓	✓	✓	✓	✓	Detailed parameters for very high/high/moderate/low consensus ^b	
Jünger et al., 2012 ⁶¹	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥ 75% agreement on priority ranking/choice of a certain medicine	
Lindqvist et al., 2013 ³⁹	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥ 70% of panellists (somewhat) agree (rating 4 or 5 on a 5-point scale)	
Mahler et al., 2010 ⁴¹	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥ 70% of panellists (somewhat) agree (rating 4 or 5 on a 5-point scale)	
Mahler et al., 2010 ⁴⁰	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥ 80% ratings ≥ 8 on a 10-point scale + average of ratings > 7.5 ^c	
Mendes and da Silva, 2013 ⁵⁷	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Median ≥ 8 (9-point scale) + difference between min and max rating ≤ 5	
Morita et al., 2005 ⁴²	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Median ≥ 8 (9-point scale) + difference between min and max rating ≤ 5	
Morita et al., 2007 ⁴³	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Median ≥ 8 (9-point scale) + difference between min and max rating ≤ 5	

Table 5. (Continued)

Author(s), year	Transparency and quality of reporting										Selection criteria expert panel							Definition of consensus	
	Purpose well defined	Rationale for Delphi	Selection of experts clearly justified	Clear description of methods	Flow chart	Clear definition of consensus	Pilot test of instruments	Transparent reporting of results	Data analysis clearly justified and reported	Information of rounds	Discussion of limitations	Adequacy of conclusions	Member of organisation	Recognised authority	Relevant clinical academic expertise	Geographical scope	Setting/work field	Profession/stakeholder	
Onwuteaka-Philipsen and van der Wal, 2001 ⁴⁴	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	/
Pigni et al., 2010 ⁴⁵	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Average relevance rating of a statement ≥ 8 (11-point scale 0–10)
Rayner et al., 2011 ⁴⁷	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	/
Rayner et al., 2011 ⁴⁶	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	/
Sasahara et al., 2009 ⁶²	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Median ≥ 8 (9-point scale) + difference between min and max rating ≤ 4 ^d
Sprung et al., 2014 ⁶³	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥ 80% of panellists (strongly) agree with statement (4/5 on a 5-point scale)
Strupp et al., 2014 ⁵¹	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥ 75% of panellists agree on a statement (yes/no responses)
Temkin-Greener et al., 2015 ⁶⁴	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	No a priori criteria for agreement; disagreement: ≥ 10% ratings of a guideline as not (at all) important
van der Maaden et al., 2014 ⁴⁸	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Detailed parameters for strong/moderate consensus ^e and a compromise option 'I can live with it'

(Continued)

Table 5. (Continued)

Author(s), year	Transparency and quality of reporting													Selection criteria expert panel					Definition of consensus
	Purpose well defined	Rationale for Delphi	Selection of experts clearly justified	Clear description of methods	Flow chart	Clear definition of consensus	Pilot test of instruments	Transparent reporting of results	Data analysis clearly justified and reported	Information of rounds	Discussion of limitations	Adequacy of conclusions	Member of organisation	Recognised authority	Relevant clinical academic expertise	Geographical scope	Setting/work field	Stakeholder/Professional	
Van der Steen et al., 2014 ⁵²	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Detailed parameters for importance rating and for high/moderate/low agreement on recommendations ^f
Vermandere et al., 2013 ⁴⁹	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Median ≥ 8 (9-point scale); ≥ 30% ratings 1–3 and 8–9 = disagreements ^g
Vignaroli et al., 2012 ⁵⁰	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	≥ 75% of panellists ranking a medication as safe and effective ^h

n/a: not applicable; IQR: interquartile range.

^aCategorisation of a medication as 'never'/'rarely'/'sometimes'/'always' appropriate for patients with advanced dementia.

^bVery high consensus: median = 5 and percentage agreement ≥ 80%, IQR = 0; high agreement – median = 4/5, percentage agreement ≥ 80%, IQR = 0; moderate agreement – median ≤ 4; 60%–79% agreement, IQR = 1; low agreement – median rating < 4, < 60% agreement, IQR > 1.

^cStatements with less than 30% agreement were excluded from the study.

^dIf panellists rated a statement as less than 6, they were asked to give the reason.

^eMedian 4 or 5, IQR ≤ 2 → moderate consensus on agreement with statement; median 1 or 2, IQR ≤ 2 → moderate consensus on disagreement with statement; median 4 or 5, IQR ≤ 1 → strong consensus on agreement with statement; median 1 or 2, IQR ≤ 1 → strong consensus on disagreement with statement; median 1/2/4/5; IQR > 2; median 3; no IQR → no consensus.

^fImportance rating of domains: mean score ≥ 8; elimination of items scoring ≤ 6; recommendations: high, or very high agreement based on measures of central tendencies and dispersion = full consensus; very high agreement → median = 5, IQR = 0 and ≥ 80% scoring a 4 or 5; high agreement → median = 5, IQR ≤ 1, ≥ 80% scoring of 4 or 5; moderate agreement → median 4–5, IQR ≤ 2, ≥ 60% scoring of 4 or 5; low agreement (no consensus) → median 4–5, IQR ≤ 2 or ≥ 60% scoring of 4 or 5. Items with medians between 2 and 4 were rejected; full consensus on very high disagreement → median = 1, IQR = 0, ≥ 80% scoring 1 or 2.

^gTo ensure that views of stakeholder groups were equally represented, the scores were weighed since physicians were overrepresented.

^hMedications rated lower than 15% after the first round were dropped from the list.

Table 6. Characteristics of the Delphi procedure.

Author(s), year	Purpose and number of Delphi rounds ^a							Feedback and design of next round(s) ^b							
	Identification of issues; generation of items	Development of a draft document	Rating/evaluation of statements/document	Ranking/selection/prioritisation	Qualitative responses/comments/feedback	Review/approval of (final) framework	Not reported/not entirely clear	Number of rounds	Statistical group response	Summary of qualitative comments	Inclusion of items newly generated/added by experts	Modification of items	Selection/reduction of items ^c	Presentation of final document for approval	Not reported/not entirely clear
Bradford et al., 2014 ⁵³		✓	✓			✓		5			✓			✓	
Bradley and Brasel, 2009 ⁵⁸				✓		✓		3		✓	✓		✓	✓	
Bridgman and Carr, 1997 ³⁰	✓			✓		✓		3		✓	✓				✓
Bridgman and Carr, 1998 ³¹	✓			✓		✓		3		✓	✓			✓	
Carter and Bhatia, 2001 ⁵⁴	✓	✓	✓				✓	/							✓
Catlin and Carter, 2002 ⁵⁵							✓	4						✓	✓
De Lima et al. (#485), 2007 ³⁴			✓					1			✓ ^d		✓ ^d		
De Lima et al., 2007 ³²			✓					1			✓ ^d		✓ ^d		
De Lima, 2012 ³³			✓					1			✓ ^d		✓ ^d		
De Lima et al., 2012 ⁵⁹			✓					3	✓					✓	
Downar and Hawryluck, 2010 ³⁵	✓		✓					2		✓					
Dreesen et al., 2012 ³⁶	✓		✓	✓	✓			2	✓		✓				
Finlay et al., 2008 ⁵⁶							✓	/							✓
Hawryluck et al., 2002 ⁶⁰	✓		✓		✓			3	✓	✓	✓			✓	
Holmes et al., 2008 ³⁷			✓					3	✓						
Hudson et al., 2012 ³⁸			✓		✓			1							
Jünger et al., 2012 ⁶¹			✓		✓			2					✓		✓
Lindqvist et al., 2013 ³⁹	✓			✓				2			✓				
Mahler et al., 2010 ⁴¹			✓					2							
Mahler et al., 2010 ⁴⁰			✓					2				✓			
Mendes and da Silva, 2013 ⁵⁷	✓		✓					3	✓			✓	✓		
Morita et al., 2005 ⁴²			✓					3	✓						
Morita et al., 2007 ⁴³			✓					3							
Onwuteaka-Philipsen and van der Wal, 2001 ⁴⁴			✓		✓	✓		2			✓				
Pigni et al., 2010 ⁴⁵			✓					2	✓				✓		
Rayner et al., 2011 ⁴⁶			✓					2	✓	✓					
Rayner et al., 2011 ⁴⁷			✓					2	✓	✓	✓				
Sasahara et al., 2009 ⁶²			✓					2				✓	✓	✓	
Sprung et al., 2014 ⁶³			✓					2		✓		✓			
Strupp et al., 2014 ⁵¹							✓	2							
Temkin-Greener et al., 2015 ⁶⁴			✓					2							
Van der Maaden et al., 2014 ⁴⁸		✓	✓		✓			5	✓			✓	✓		
Van der Steen et al., 2014 ⁵²		✓	✓	✓		✓		5	✓	✓		✓	✓	✓	
Vermandere et al., 2013 ⁴⁹			✓					2		✓	✓		✓		
Vignaroli et al., 2012 ⁵⁰	✓		✓	✓	✓			2	✓				✓		

^aThis refers to aspects that were explicitly reported as elements of one or more survey rounds. The development of a draft document in some studies was seen as preparatory step before the start of the actual 'Delphi process'.

^bThis refers to aspects that were explicitly reported in the respective publication as elements of the feedback provided – while more general descriptions (or missing mention) in other publications may imply these features as well.

^cThis can either refer to items with (very) high agreement so that these could be instantaneously accepted and no further consideration was warranted in a subsequent survey round or to items with (very) low agreement or relevance that were therefore entirely discarded from the list.

^dIn this study, only one round was referred to as 'Delphi process' while there were still details provided on the nature of feedback and the design of the subsequent stages.

detailed listings of key recommendations, and lists of recommended medicines;^{32–34,50,59} and complex guidelines comprising several sections including an introduction, definitions, charts and clinical algorithms.^{38,42,43,52} Variation was also found with respect to the scope of the resulting guidance claimed by the authors, and the official or even binding character of the guideline, ranging from rather moderate narrative descriptions of the key aspects resulting from the Delphi study^{30,31,57} to intensely advocated guidelines with a high level of dissemination, often endorsed by one or more authorities in the field.^{32–34,38–41,61}

Quality assessment

A quality assessment was undertaken with respect to the rigour of the conducted studies and the transparency of reporting (Table 5). While the majority of studies ($n=24$) fulfilled at least 9 of the 12 predefined quality criteria, for a number of studies, one or more of these criteria were not reported. A clear definition of consensus was not provided for 5 studies; for 9 studies, an appropriate discussion of potential limitations was not included; and only for 5 out of 30 studies some sort of piloting of the survey instruments was reported. The methods were clearly described for 25 studies, but only 6 provided a flow chart illustrating the process. In cases where two articles were included about one study ($n=4$), the publications differed in terms of the transparency of reporting; variation was observed not only concerning the total number of quality criteria met but also with respect to which of the criteria were met in either of the two articles (Table 5).

Discussion

This methodological systematic review identified considerable variation in the design and the reporting of process and outcome parameters of studies using the Delphi technique to develop guidance for best practice in palliative care. In the following, the main findings will be summarised and related to previous treatises on the Delphi technique, with a focus on (1) the rigour of the design and conduct of the analysed studies, (2) the quality of reporting and (3) the dissemination politics for the resulting guidance. Subsequently, implications and recommendations for research will be discussed, and a standard for Conducting and REporting DELphi Studies (CREDES) will be proposed.

Summary of main findings

The rigour of the design and conduct of Delphi studies

Across the studies assessed in this review, variation was found regarding the rigour of the design and the conduct of the Delphi process; this included the absence of a clear consensus criterion or a piloting of the survey instrument.

Also, diverse interpretations were identified of what constitutes a ‘Delphi round’ and which steps are conceived of as additional preparatory or concluding stages. Notably, for two studies, only one survey round was reported while an iterative process with at least two rounds is characteristic of the Delphi technique and constitutes its distinguishing feature compared to a regular survey.

These findings reveal a lack of clarity and unanimity regarding the core elements of the Delphi process. This makes the studies vulnerable to bias and arbitrariness during data collection, analysis and interpretation of findings. Furthermore, it renders the Delphi technique susceptible to criticism as an undependable research method.

The quality of reporting

The identified variations in the level of detail in reporting make it difficult for the reader to appraise to quality of the study design, its conduct and the resulting outcomes. For example, across the assessed studies, it was not always clear how the synthesis of responses in one survey round was used to design the following round. A number of exemplary articles analysed in this review illustrate how a sound and substantial reporting of essential parameters of the applied Delphi technique is even possible with limited space;^{35–37,40–42,48,49,51–53,59–62,64} these can serve as good examples of what is needed to allow the reader to make a judgement about the rigour of the applied methods, the nature of the consensus building process and the quality of the resulting recommendations.

This review also revealed inconsistencies in the nomenclature and discrepancies regarding the terms used to describe the methods applied in the Delphi studies. For example, a heterogeneous use of the term ‘modified Delphi’ was observed. Although some authors have treated the concept ‘modified Delphi’ as a methodological variant on its own,^{8,65} there is no standard definition as to what a ‘modified Delphi’ exactly entails. Since a range of methodological variations do exist in the application of the Delphi technique, the use of the term ‘modified’ should be critically reconsidered – even more when used without further specification or explanation. In addition, the reference against which the definition as ‘modified’ is made needs to be reassessed. Many studies in this review referred to early literature on the Delphi technique; although some early works can still be considered as standard references, it needs to be taken into account that the methodology has been further developed since its first usage.

Dissemination politics for guidelines resulting from Delphi studies

Across the analysed studies, the scope of the resulting guidance claimed by the authors varied. Depending on the researchers’ scientific provenance and professional affiliation within the palliative care research community, studies

with only isolated reception were identified, while others were intensely advocated with a high degree of dissemination activities and international coverage. Some of these were used to inform political decision making or textbook knowledge and were lent credibility through endorsement by one or more authorities in the field, including the World Health Organization. These findings emphasise the impact of Delphi studies on knowledge production in palliative care and underline the importance of methodological rigour and robustness of the results.

Recommendations for CREDES

Since clinical guidance in palliative care relies to a considerable extent on the Delphi technique, there is a need for consistency and quality both in the conduct and in the reporting of studies using this method.^{8,22,29} This will constitute a prerequisite for acknowledgement of the method as a contribution to robust evidence and for a higher appraisal of the value of expert judgement in evidence-based medicine. Guidance has been proposed for enhancing rigour and transparent reporting of Delphi studies by authors from diverse disciplines;^{1,8,9,22,29} however, clear recommendations on the conduct of Delphi studies and a generally accepted reporting standard for their publication in peer-reviewed journals to date are not available. We therefore propose recommendations concerning the rationale for the choice of the Delphi technique, its conduct and the reporting of Delphi studies. Building on previous treatises,^{6,8,22,29} and drawing on the findings from this review, a guide on minimal requirements was created for CREDES (Box 3). Like existing reporting standards for other types of research, such as CONSORT⁶⁶, COREQ⁶⁷ or PRISMA,²⁸ these can be used by researchers undertaking Delphi studies, by authors publishing

them and by reviewers and journal editors when evaluating the quality of the study design and the transparency of reporting. Since such a standard to date does not exist, CREDES may also be used for studies using the Delphi technique outside palliative care research.

Recommendations concerning the rationale for the use of the Delphi technique

In line with Greenhalgh et al.,¹¹ we argue that there is a need for an alternative view of evidence-based medicine which emphasises the value of expert judgement, including implicit or tacit knowledge, for example pertaining to clinical routines, that is not directly accessible through clinical trials. However, this implies that the choice of the Delphi technique as a method of systematically collating expert consultation and building consensus needs to be well justified. When choosing it for the development of good clinical practice in palliative care, two aspects need to be taken into account: (1) it is a heuristic device that relies on expert knowledge to negotiate a shared reality and to co-construct knowledge, rules and recommendations and (2) its outcomes can only be as reliable as the available evidence and the participating experts.^{1,68,69} In consequence, it is important to keep in mind its constructivist nature when selecting the Delphi technique to answer a particular research question.^{68,70–72}

Recommendations for a sound and rigorous conduct of Delphi studies

When properly employed, the Delphi technique has the potential to create an environment that will allow experts to arrive at justifiable, valid and credible solutions based on the best available evidence and their experiential expertise (Box 3).^{2,22}

Box 3. Recommendations for the Conducting and REporting of DELphi Studies (CREDES).

Rationale for the choice of the Delphi technique

- 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

- 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
- 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

- 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
- 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

*Consolidated criteria for reporting qualitative research

**Consolidated Standards of Reporting Trials

Box 3. (Continued)

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

Design, planning and process. Flexibility of the Delphi technique allows adaptation of the method to the requirements of the study.²² However, this should be done systematically and rigorously, justified by a rationale and (whenever possible) a reference, to avoid arbitrariness. This includes systematic methodological decisions such as careful planning of the process and justification of potential modifications as well as thorough development, review and piloting of all relevant materials used throughout the consensus process such as cues and questions, survey instruments, information and feedback provided to experts.

Definition of consensus. Ideally, an a priori criterion for consensus should be defined that is suitable for the purpose of the study and applicable for the research question. As Diamond et al.²⁹ concluded from their systematic review on operationalisation of consensus, the mere fact of conducting a Delphi study does not automatically imply consensus as its outcome. In the field of palliative care, perfect agreement may often not be realistic due to different values, world views and ethical dilemmas concerning

medical decision making. Therefore, the definition of consensus needs to include procedures to be followed when consensus is not reached after several iterations. This should be done in line with the envisaged scope of the resulting guidance, for example, in terms of its geographical span (local, national or international); the range of settings for which it is intended; or the applicability for one specific disease versus diverse conditions. The criteria for consensus should provide a clear and transparent guide for action how to proceed with certain items or topics in the next survey round – for example, delete them from the list, or refine them in order to attain higher consensus.²⁹ If an a priori definition of consensus is not realistic due to the explorative nature of the study, it should be identified and established by the research team in the course of the process.

Interpretation of results. When interpreting the results of a Delphi study, it needs to be considered that consensus does not necessarily imply that the 'correct' answer or judgement has been found.⁷¹ The meaning of (non)consensus

needs critical reflection; the value of stable disagreement must not be underestimated since it provides informative insights and highlights differences in perspectives regarding complex issues.⁷⁰

Ensuring credibility and preventing bias. It is the responsibility of the research team to allow the experts to arrive at valid and credible judgements. Research is often driven by an original interest of the principal investigator who is likely to have a determined position on a given topic; the technique may force consensus while several individuals still maintain their different positions.^{8,68} It is therefore important to make sure to refrain from directly or indirectly influencing the experts' judgements.

Informational input. Attention should be paid to how information will influence – and possibly bias – panellists' judgements. This includes information provided at the outset of the study, such as a synthesis of the available evidence, as well as the synthesis of experts' responses provided as feedback to inform the next survey round. Piloting informational input is indispensable to examine its effect on experts' judgements, preferably with selected candidates who are representative of the expert panel. Likewise, the survey instrument needs to be pilot-tested for the impact of cues and questions on the panellists' responses. In addition, prevention of bias can entail a balanced composition of the core research group, entrusting an independent researcher with the main coordination of the consensus process, ensuring critical reflection of outcomes within the team and having a final draft of the outcomes reviewed by an external board or authority before publication and dissemination.

Recommendations for a transparent reporting of Delphi studies

All methodological decisions throughout the Delphi process should be reported transparently to allow readers to understand the steps taken, the involvement of consensus building and to judge the results obtained (Box 3).^{22,29} This comprises a transparent description of the expert panel, the procedure, the attainment of consensus, as well as the impact of methodological limitations on the interpretation of results and the ensuing guidance for good practice in palliative care. The format of reporting should be thoroughly reflected; in addition to the resulting guidance on good clinical practice in palliative care (e.g. a clinical guideline or a white paper), the publication of an additional methodological paper or at least a study protocol should be considered to inform transparently on details of the study process.^{52,61} A careful dissemination plan includes advocating the outcomes of the Delphi study by seeking professional endorsement and political support.² On an overarching level, clarity regarding the nomenclature and

the terminology when reporting on Delphi studies should be attained. For example, the use of terms such as 'round' or 'modified Delphi study' should be clear and unambiguous. Therefore, agreement needs to be settled on essential elements of the Delphi technique, on the definition of its core features (e.g. what constitutes a 'round'), as well as the necessary features to qualify a study as a 'Delphi process'. This will lay the foundation for unambiguous reporting on the methodological features of a particular Delphi study, including possible modifications.

Strengths and limitations

A particular feature of this review is its focus on research methodology. Since the credibility of scientific knowledge depends on the rigour of the underlying research, a systematic investigation of its methodology contributes to quality of health care and palliative care research. Robustness and credibility of the analysis was supported by a multi-professional team of international researchers.

A limitation of this review is that it was restricted to English language and only considered original articles published in peer-reviewed journals while not including grey literature. Best practice guidance for palliative care with a national or local scope, or published outside the scientific databases, may therefore be underrepresented in the analysis. In addition, the consideration of grey literature – including the full clinical guidelines resulting from the Delphi studies or final project reports – may have allowed for extraction of more complete methodological details in order to inform the quality assessment performed as part of this review; in consequence, the rigour of the applied methods and the transparency of reporting may have been underestimated. However, several of the reviewed articles exemplified that essential information on the applied methods can be provided even with limited space.

The abovementioned limitations notwithstanding, the elaborated recommendations have the potential to improve the future conduct and reporting of Delphi studies and to facilitate the scientific review process of the resulting publications.

Conclusion

The Delphi technique as a means of attaining expert consensus plays an important role for the development of guidance for good medical practice not only in the absence of sufficient published evidence from RCTs. The quality of the resulting recommendations largely depends on the rigour of the application and reporting of consensus processes. This methodological systematic review analysed the application of the Delphi technique for the development of best practice guidance in palliative care with a particular focus on the quality of the study conduct and the transparency of reporting. In line with Hasson and Keeney⁸

and Diamond et al.,^{22,29} we recommend a rigorous use of the technique including justification of details in the study design. Building on previous treatises,^{1,6,8,22,29} a guide for the conducting and reporting of Delphi studies (CREDES) was created to allow an appraisal of the methodological quality and the robustness of the resulting recommendations. Like existing standards for other types of research, this can be used by researchers, reviewers and journal editors. Future research should aim for settling international agreement on the definition of essential elements of the Delphi technique and on the nomenclature of its core features. This will constitute a prerequisite for acknowledgment of the method as a contribution to robust evidence.

Author contribution

S.J. developed the research idea, the review question and the design; conducted the literature search; constructed the data extraction form; performed data extraction and analysis; and drafted the manuscript. S.A.P. and S.G.B. provided support with identifying the final review question, reviewed the data extraction form, critically reviewed selected papers for inclusion or exclusion and provided expertise and advice with writing the manuscript. J.B. provided expertise and support with developing the search strategy for the different databases and with doing the literature search. L.R. critically reviewed the manuscript for important intellectual content and contributed with expertise to the discussion of results. All authors provided critical comments on drafts of the manuscript and approved the final version.

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SUPPLEMENTAL FILE 2
List of Questions for Round 1 of the Delphi Questionnaire

Participant Characteristics

- What is your age (in years)?
- What is your country of origin?
- In which country do you currently live / work?
- What is your highest professional qualification (e.g. PhD, MSc, etc.)?
- What is your professional background? (multiple answers possible)
- What is your current main occupation?

Eligibility criteria

- Do you have ≥ 1 peer-reviewed publications on cervical radiculopathy or cervical spinal entrapment neuropathies within the past 10 years?
- Can you list 1 or 2 of your (most relevant) publication(s)?
- Do you have ≥ 10 years' experience working in a pain/musculoskeletal outpatient service with patients with cervical radiculopathy or cervical spinal entrapment neuropathies?

ROUND 1 QUESTIONNAIRE

In this section you will find a list of treatment modalities that have been proposed to be effective for patients with cervical radiculopathy. Some modalities might be more relevant to a particular stage of the process of recovery i.e. the first 6 weeks = "acute"; from 6-12 weeks = "sub-acute"; > 12 weeks = "chronic". In this section please rate the relevance of each individual treatment modality for each of the different stages (acute, sub-acute, chronic). Later on in the questionnaire you can add treatment modalities you feel have not yet been mentioned.

List of proposed effective treatment modalities

Counseling

- Information / patient education
- Pain education
- Behavioral therapy
- Physiotherapy
-

General Physiotherapy

- General aerobic exercise
- General strength training
- Focused / targeted strength training
- Individualized physical activity
- Supervised exercise
- Motor control exercise
- Directional preference exercise
-

Spinal Manipulative Therapy

- Spinal manipulative therapy as a stand-alone treatment

- Cervical manipulation
- Cervical mobilization
- Thoracic manipulation
- Thoracic mobilization
- Chiropractic treatment
- Neurodynamic mobilization
- Spinal manipulative therapy combined with (specific) exercise
- Spinal manipulative therapy combined with neurodynamic mobilization
- Spinal manipulative therapy combined with neurodynamic mobilization and (specific) exercise

Traction

- Mechanical “over the door” traction
- Continuous mechanical traction
- Intermittent mechanical traction
- Manual traction

Miscellaneous

- Hard collar
- Soft collar
- Massage
- Acupuncture
- Dry Needling
- Medical Tape / Kinesiotape
- Transcutaneous electrical nerve stimulation (TENS)

Medication

- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) e.g. Ibuprofen, Diclofenac, Meloxicam, Naproxen, Celecoxib, Indomethacin, etc.
- Opioids (e.g. Codeine, Hydrocodone, Vicodin, Morphine, Oxycodone, Percocet, Fentanyl, etc.)
- Combination of NSAIDs and Opioids
- Anti-epileptic drugs (e.g. Pregabalin, Gabapentin, Lyrica, etc.)
- Combination of NSAIDs and Anti-epileptic drugs
- Combination of Opioids and Anti-epileptic drugs
- Combination of NSAIDs and Opioids and Anti-epileptic drugs

Additions

In this final section you can add treatment modalities you feel have not been mentioned in the previous section. Please rate them also for each individual stage of CR (acute, sub-acute, chronic)