

doi: 10.63360/ipmm.v2.e29

Protocols

International Consensus Initiative in Invasive Physiotherapy (ICI-IP): Protocol for an Evidence-Informed Delphi Study on Percutaneous Neuromodulation and Percutaneous Electrolysis

Giorgos Tziggounakis^{1,2}   0009-0005-3823-1861

Zaid Alboloushi³  0000-0002-0842-1104

Katerina Simati^{1,4}  0009-0000-0745-5241

¹Department of Research, Health and Resilience Institute, Athens, Greece.

²Department of Physiotherapy, University of Nicosia, Nicosia, Cyprus.

³Ministry of Health, State of Kuwait, Jaber Hospital Physical therapy department.

⁴Department of Physiotherapy, Mediterranean College, Athens, Greece.

ABSTRACT

Background: Percutaneous neuromodulation and percutaneous electrolysis are increasingly used in physiotherapy for the management of musculoskeletal conditions. However, substantial variability exists in their clinical application, including differences in indications, technical parameters, safety procedures, and integration within multimodal care. Currently, no unified, evidence-informed framework defines best practice for these interventions.

Methods: This protocol describes an evidence-informed modified Delphi study, registered on the Open Science Framework (OSF; registration number: osf.io/tkrn4), aiming to establish international consensus on the clinical application of percutaneous neuromodulation and percutaneous electrolysis. The study will be conducted in accordance with CREDES recommendations. Two parallel Delphi processes will be undertaken, with international experts in each field participating in 3–4 online rounds. An initial item set will be developed through a targeted literature review and internal expert input, and rated using a Likert-type scale with controlled feedback between rounds. Consensus for inclusion will be predefined using percentage agreement and median thresholds.

Ethics and dissemination: Ethical approval has been granted by the CEIC Aragón (CEICA), Zaragoza, Spain (reference: PI26/238, 20 May 2026). The study will be conducted in accordance with the Declaration of Helsinki, and findings will be disseminated through peer-reviewed publication and relevant professional channels.

Discussion: This study is expected to provide structured, consensus-based recommendations to support consistency, safety, and evidence-informed clinical practice in invasive physiotherapy, and to guide future research and educational initiatives.

Keywords: percutaneous neuromodulation; percutaneous electrolysis; Delphi study; invasive physiotherapy; consensus; clinical application; physiotherapy.

1. Introduction

Invasive physiotherapy interventions, including percutaneous neuromodulation (PNM) and percutaneous electrolysis (PE), have gained increasing clinical adoption for the management of musculoskeletal conditions^(1–5). PNM involves the application of electrical stimulation through percutaneously inserted needles to modulate peripheral and central neural structures. PE is a minimally invasive technique in which a galvanic current is delivered through an acupuncture needle to induce a localised controlled inflammatory response in affected soft tissue. The target clinical populations for these interventions include adults presenting with conditions such as tendinopathies, myofascial pain, nerve-related pain, and other neuromusculoskeletal disorders, across both primary care and specialist settings. Despite their growing use, substantial variability exists in how these techniques are applied in clinical practice, including differences in indications, technical parameters, safety procedures, and integration within multimodal treatment strategies⁽⁶⁾. This heterogeneity reflects the absence of standardized, evidence-informed frameworks to guide clinical application and training.

In the current context, clinicians often rely on empirical experience, local practice norms, and heterogeneous educational backgrounds. As a result, inconsistencies in treatment delivery may arise, potentially affecting reproducibility, interpretation of research findings, clinical outcomes, and patient safety.

Although some studies have attempted to describe practice patterns or educational variability in dry needling (DN) and related interventions, these have primarily focused on descriptive analyses rather than establishing consensus-based standards. For example, surveys of physiotherapists have demonstrated wide variation in training exposure, technique selection, and reported adverse events, highlighting the lack of uniformity in clinical practice⁽⁶⁾. Similarly, investigations into educational curricula have identified substantial inconsistencies in instructional hours, competencies, and teaching approaches across training programs, further reinforcing the absence of standardized frameworks⁽⁷⁾.

Given the absence of definitive high-quality evidence or universally accepted clinical guidelines, structured expert consensus methods such as the Delphi technique provide a robust and transparent approach to synthesizing expert opinion and developing practice-oriented recommendations. Modified Delphi approaches integrate evidence-informed item generation with iterative consensus processes and are widely used in healthcare research to establish clinical standards and competency frameworks⁽⁸⁾. Consequently, Delphi studies have been successfully employed to establish performance standards and competency-based frameworks in physiotherapy and critical care settings^(9–12).

Against this background, there is a clear need for a structured approach to synthesizing expert knowledge and aligning clinical practice in PNM and PE. Accordingly, this study will employ a modified Delphi methodology to develop international expert consensus on their clinical application, integrating current scientific evidence, expert clinical experience, and international perspectives.

The objectives of this study are to:

- Identify and define key domains relevant to the clinical application of percutaneous neuromodulation and percutaneous electrolysis, including indications, technical parameters, safety considerations, and clinical integration.
- Achieve expert consensus on evidence-informed statements describing best practice in the application of these techniques.
- Refine statements and achieve consensus through iterative Delphi rounds with international experts.
- Develop a structured consensus-based framework to support clinical practice, education, and future research.

The resulting consensus is expected to improve consistency in practice and training, support clinical decision-making, inform guideline development, enhance patient safety, and guide future research.

2. Materials and Methods

2.1 Study Design

A modified e-Delphi (electronic Delphi) methodology will be employed to develop an international expert consensus on the clinical application of PNM and PE. The study design will be informed by established methodological guidance for Delphi studies, including the CREDES recommendations⁽¹³⁾, to ensure methodological rigor and transparency. The study protocol was prospectively registered on the Open Science Framework (OSF; osf.io/tkrn4) prior to initiation of the Delphi process.

All rounds will be conducted electronically using an online survey platform to ensure anonymity, reduce group pressure bias, and allow international participation. The Delphi process is expected to include three to four rounds, depending on the level of consensus achieved. Participant responses will be analysed anonymously, and controlled feedback will be provided between rounds to support reflection while minimizing group influence.

2.2 Study Setting, Participants and selection criteria

A purposive sampling strategy will be used to recruit an international panel of experts with clinical and/or academic expertise in PNM and PE. In line with recommendations for Delphi studies, a heterogeneous panel will be sought to capture a broad range of perspectives while maintaining relevant expertise.

Potential participants will be identified through targeted searches of the scientific literature (authors of relevant publications), professional networks of the research team, and direct invitations to recognised experts in the field. Snowball sampling will also be employed, whereby invited participants may recommend additional eligible experts.

Participants will be eligible if they are healthcare professionals or academics with demonstrable expertise in the clinical practice, education, or research of DN, PNM, or PE. As the study

comprises two parallel consensus processes, one addressing percutaneous neuromodulation and one addressing percutaneous electrolysis, eligibility will be assessed separately for each technique. Accordingly, participants may be eligible to contribute to the percutaneous neuromodulation panel, the percutaneous electrolysis panel, or both, depending on their area of expertise. Professionals with expertise in dry needling (DN) may be considered eligible where their practice encompasses or directly informs PNM or PE techniques, given the technical and conceptual overlap between these interventions.

Clinicians must be registered healthcare professionals with documented formal training and at least five years of active clinical practice in PNM and/or PE. Academics must hold a postgraduate qualification and demonstrate a sustained contribution to the field of at least five years through peer-reviewed research, formal teaching, curriculum development, or equivalent professional activity in PNM and/or PE. While direct clinical experience with these techniques is preferred, candidates without it may be considered on a case-by-case basis where their academic or research contributions are deemed relevant. However, to ensure that the resulting consensus remains clinically grounded, participants without direct clinical experience will comprise only a minority of each panel. All participants must demonstrate a minimum level of English language competency sufficient to read, understand, and respond to the study questionnaires. Efforts will be made to ensure geographical diversity across participating countries.

2.3 Sample size

There is no universally accepted standard for sample size in Delphi studies. Recent Delphi studies in physiotherapy, clinical intervention development, and reporting guidelines have reported panels ranging from 14 to 41 participants^(9,11,12,14). In the present study, a target of 20 to 30 experts per panel will be sought. No formal subgroup analysis by professional role is planned, however, the panel composition will be monitored to ensure an adequate balance between clinicians and academics. This range is considered sufficient to capture a breadth of informed perspectives while remaining feasible for participant retention across iterative Delphi rounds^(15,16). Given that attrition rates of up to 50% have been reported in Delphi studies across two rounds⁽¹⁷⁾, and that the present study anticipates three to four rounds, recruitment will aim for the upper end of this range to ensure an adequate number of completing participants.

Because two parallel consensus processes will be undertaken, one for percutaneous neuromodulation and one for percutaneous electrolysis, sample size will be considered separately for each panel.

Participant retention across rounds will be monitored and attrition rates will be calculated and reported for each round. Analyses will be based on the number of participants completing each round, and no imputation will be performed for missing responses.

2.4 Item generation and questionnaire development

Prior to initiating the first round of the Delphi procedure, an initial set of items will be developed through an evidence-informed and conceptually structured process. First, a targeted, non-systematic literature review will be conducted to identify key domains, constructs, and variables relevant to the clinical application of percutaneous neuromodulation and percutaneous elec-

trolysis. Sources will include peer-reviewed publications, existing clinical recommendations, educational frameworks, and safety reports related to invasive physiotherapy interventions. Based on this evidence base, an initial pool of candidate statements will be generated by the research team. These statements will be structured to reflect core domains, including clinical indications, technical parameters, safety considerations, contraindications, practitioner competencies, and integration within multimodal care. Prior to Delphi Round 1, the draft item set, developed by the research team, will undergo internal review (Round 0) by a small international core group of subject-matter experts selected for their recognised standing in the field and a minimum of 15 years of clinical and/or academic experience in invasive physiotherapy. This core group is distinct from the main Delphi panel; their role at this stage is limited to refining item clarity and content relevance. Members of the core group who meet the eligibility criteria for the main panel are welcome to participate in the subsequent scored Delphi rounds.

2.5 Delphi procedure

The Delphi process will consist of sequential online questionnaire rounds administered via SurveyMonkey (Momentive Global Inc., San Mateo, CA, USA), conducted anonymously to facilitate international participation and reduce group pressure bias. Participant data will be pseudoanonymised prior to analysis; responses will be linked to participant codes rather than identifiable information, and only the research team will have access to the linkage key.

In Round 1, participants will rate predefined statements on the clinical application of PNM and PE across key thematic domains. Free-text comments will be invited to justify ratings, suggest modifications, and identify missing concepts. Only participants completing Round 1 will be invited to subsequent Delphi rounds, whereas those missing a subsequent round will remain eligible for later rounds.

In Round 2, participants will re-rate the revised statements after receiving anonymised group-level feedback from Round 1, compiled and summarised by the research team. Statements meeting predefined consensus criteria will be provisionally accepted, while those not meeting consensus will be reviewed by the research team and either revised, retained, or removed before the next round.

In Round 3, participants will re-evaluate unresolved statements with additional feedback from the previous round. If consensus is still not reached for a limited number of key statements, a fourth round may be conducted. At the end of the process, statements meeting the predefined consensus criteria will form the final set of expert-informed recommendations.

Items reaching consensus ($\geq 70\%$ of participants rating 4 or 5, median ≥ 4) are accepted and removed from subsequent rounds. Items not reaching consensus are reviewed by the research team and either revised, retained, or removed before the next round. The number of rounds is guided by response stability, assessed using the coefficient of variation, with a maximum of four rounds. Separate but parallel processes are conducted for the percutaneous neuromodulation (PNM) and percutaneous electrolysis (PE) panels.

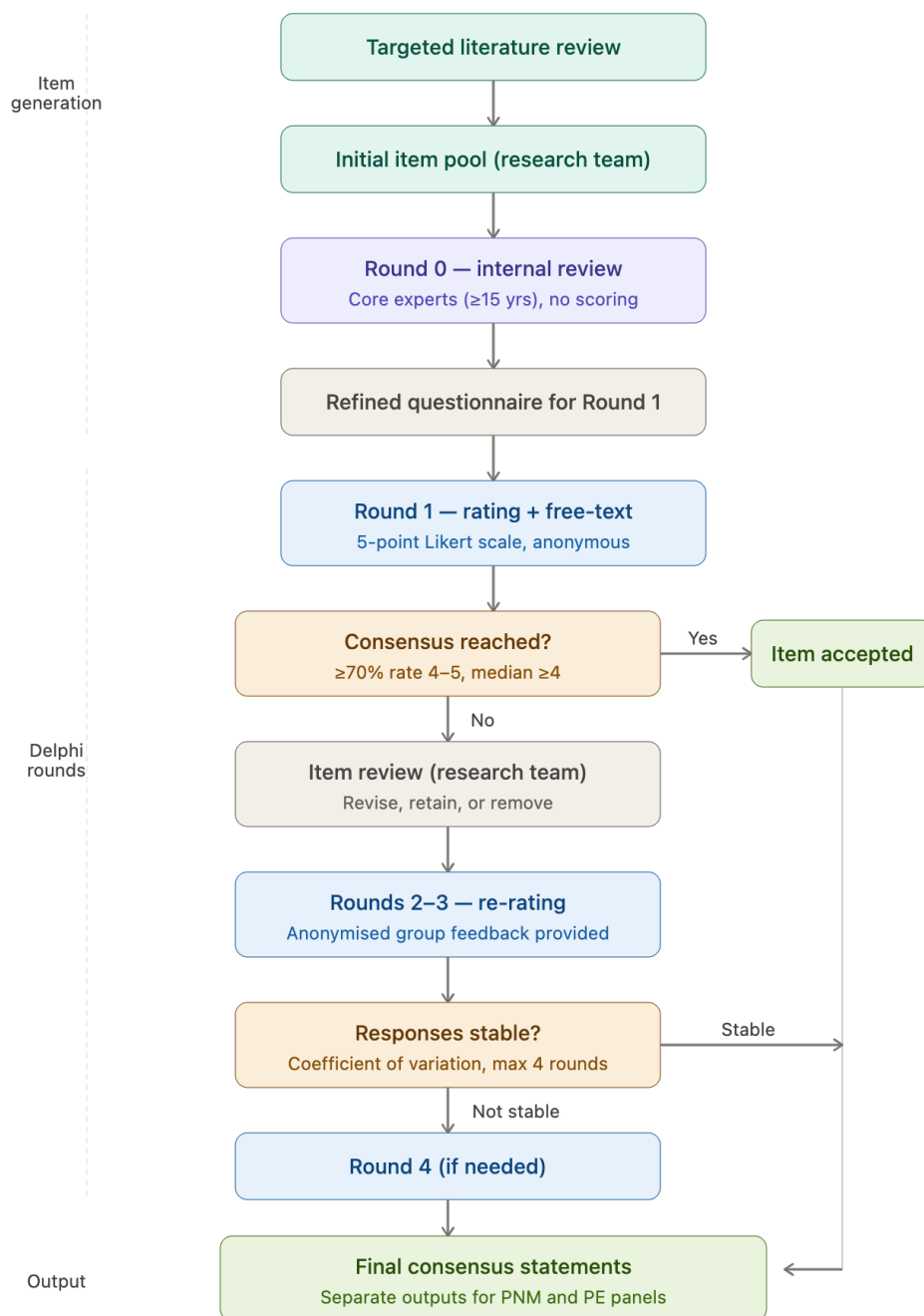


Figure 1. Flowchart of the modified e-Delphi process.

2.6 Statistical Analysis and Consensus Definition

Consensus criteria will be defined a priori based on methodological literature on Delphi studies. Participants will rate each statement using a 5-point Likert scale, where 1 indicates strongly disagree, 2 disagree, 3 neutral, 4 agree, and 5 strongly agree. A statement will be considered to have reached consensus for inclusion if at least 70% of participants rate it as 4 or 5, and the median score is 4 or higher. This threshold was selected because it is consistent with ranges commonly used in physiotherapy Delphi studies and clinical practice standard devel-

opment^(11,12,14,18). Responses will be summarised at each round using percentage agreement, median, interquartile range (IQR), and coefficient of variation (CV); lower IQR values indicate greater agreement among participants.

Items not meeting the consensus criteria will be reviewed by the research team and, where appropriate, revised or refined based on free-text feedback from participants before being reintroduced in the subsequent round. Items that are considered unclear, poorly worded, or conceptually redundant may be modified or merged. Decisions to revise, retain, or remove items will be based on participants' ratings and qualitative feedback, and will be documented and reported.

The level of agreement will be expressed as the percentage of participants rating statements as 4 or 5. The number of rounds will be guided primarily by the stability of responses between consecutive rounds, assessed using the coefficient of variation. Response stability will be considered achieved when the relative change in the coefficient of variation between consecutive rounds is $\leq 10\%$. When ratings show stability across rounds — indicating that controlled feedback is no longer producing meaningful changes in participant responses — the process will be concluded regardless of the number of rounds completed. A maximum of four rounds will be set as an upper limit to ensure feasibility and minimise participant fatigue.

The final consensus statements will be interpreted in relation to the existing evidence base, their clinical applicability, and remaining knowledge gaps. The final outputs will include agreed statements, unresolved areas where consensus was not achieved, and implications for future research. Reporting of the study and its outputs will follow relevant methodological guidance for Delphi research. Depending on the findings, the project may be reported as separate consensus papers for PNM and PE.

3. Ethical Aspects and Dissemination

The study will be conducted in accordance with the principles of the Declaration of Helsinki and relevant data protection regulations. Prior to participation, all participants will receive an information sheet outlining the aims of the study, the Delphi process, expected time commitment, and data handling procedures.

Informed consent will be obtained electronically before participation in the first Delphi round. Participation will be voluntary, and participants will be informed that they may withdraw at any stage without providing a reason. Only the research team will have access to identifiable data, which will be stored securely and retained only for the duration necessary to complete the study. All data handling procedures will comply with applicable data protection regulations, including the General Data Protection Regulation (GDPR, EU 2016/679). Ethical approval has been granted by the CEIC Aragón (CEICA), Zaragoza, Spain (reference: PI26/238, 20 May 2026). The study will be conducted in full accordance with the approved protocol.

The study involves expert participants only and does not include patients, clinical interventions, or patient data. Limited personal information, including participants' names and email addresses, will be collected for invitation and follow-up purposes. Participants will not be identifiable to other panel members at any stage of the Delphi process. Responses will be anonymised

prior to analysis, and all data will be reported in aggregated form. No individual responses will be identifiable in any output, thereby preventing attribution of findings to specific experts and ensuring that no individual-level interpretation is possible.

Participants will receive a summary of the study findings. No financial compensation will be offered. Contributions to the Delphi process will be acknowledged, and opportunities for group authorship will be considered in accordance with the International Committee of Medical Journal Editors (ICMJE) authorship criteria and journal policies.

4. Discussion

This Delphi study seeks to address the current lack of standardised, evidence-informed guidance for the clinical application of percutaneous neuromodulation and percutaneous electrolysis. Substantial variability exists in relation to indications, technical parameters, safety procedures, and integration within multimodal care, which may impact clinical consistency and patient outcomes. By developing international expert consensus statements, this study may contribute to improved standardisation of practice, enhanced safety, and greater alignment between clinical application, education, and research. The use of a modified Delphi methodology allows integration of expert perspectives while minimising bias through anonymity and controlled feedback. However, as with all Delphi studies, the findings will reflect expert consensus rather than direct empirical validation. In addition, the composition of the expert panel and potential attrition across rounds may influence the final outcomes. Despite these limitations, this study represents an important step toward establishing a coherent and clinically relevant framework for the application of invasive physiotherapy interventions.

References

1. Plaza-Manzano G, Gómez-Chiguano GF, Cleland JA, Arias-Burúa JL, Fernández-de-las-Peñas C, Navarro-Santana MJ. Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis. *European Journal of Pain*. 2020;24(6):1023–44. doi: [10.1002/ejp.1559](https://doi.org/10.1002/ejp.1559)
2. Rodríguez-Sanz J, Rodríguez-Rodríguez S, López-de-Celis C, Malo-Urriés M, Pérez-Amodio S, Pérez-An-toñanzas R, et al. Biological and Cellular Effects of Percutaneous Electrolysis: A Systematic Review. *Biomedicines*. 2024;12(12):2818. doi: [10.3390/biomedicines12122818](https://doi.org/10.3390/biomedicines12122818)
3. Asensio-Olea L, Leirós-Rodríguez R, Marqués-Sánchez MP, de Carvalho FO, Maciel LYS. Efficacy of percutaneous electrolysis for the treatment of tendinopathies: A systematic review and meta-analysis. *Clin Rehabil*. 2023;37(6):747–59. doi: [10.1177/02692155221144272](https://doi.org/10.1177/02692155221144272)
4. Badia M, Figueroa J, Penagos P, Carcasona-Otal A. Effect of Percutaneous Electrical Stimulation on Active Muscle Functionality. A Systematic Review. *Invasive Physiotherapy and Musculoskeletal Medicine*. 2025;1. doi: [10.63360/ipmm.v1.e11](https://doi.org/10.63360/ipmm.v1.e11)
5. Guerrero Troyano J. Aplicación de la Estimulación Eléctrica Nerviosa Percutánea (PENS) en trastornos musculoesqueléticos: una revisión narrativa. *Invasive Physiotherapy and Musculoskeletal Medicine*. 2025;1. doi: [10.63360/ipmm.v1.e8](https://doi.org/10.63360/ipmm.v1.e8)

6. Gattie E, Cleland JA, Snodgrass S. A survey of American physical therapists' current practice of dry needling: Practice patterns and adverse events. *Musculoskelet Sci Pract.* 2020;50:102255. doi: [10.1016/j.msksp.2020.102255](https://doi.org/10.1016/j.msksp.2020.102255)
7. Barrett TL, Kearns GA, Puente dura EJ, Brismée JM. Curricular Variability in Dry Needling Education Across Entry-Level DPT Programs in the US. *Med Sci Educ.* 2025;35(6):3013–24. doi: [10.1007/s40670-025-02511-8](https://doi.org/10.1007/s40670-025-02511-8)
8. McPherson S, Reese C, Wendler MC. Methodology Update. *Nurs Res.* 2018;67(5):404–10. doi: [10.1097/nnr.0000000000000297](https://doi.org/10.1097/nnr.0000000000000297)
9. Gianola S, Barger i S, Pellicciari L, Gambazza S, Rossetini G, Fulvio A, et al. Evidence-informed and consensus-based statements about SAFETY of Physical Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE PAMP): a national Delphi of healthcare scientific societies. *BMJ Open.* 2024;14(3):e075348. doi: [10.1136/bmjopen-2023-075348](https://doi.org/10.1136/bmjopen-2023-075348)
10. Naqvi WM, Mishra G V, Shaikh SZ, Pashine AA, Sánchez Romero EA, Swaminathan N, et al. PhyCARE reporting guidelines for physiotherapy case reports: a consensus-based development. *BMJ Open.* 2026;16(1):e110765. doi: [10.1136/bmjopen-2025-110765](https://doi.org/10.1136/bmjopen-2025-110765)
11. Tzigkounakis G, Simati K, Georgiadis K, Kostaridou V, Battersby P, Calvo S, et al. CARE-DN: An Extension of the CARE Guidelines for Dry Needling Case Reports. *Cureus.* 2026; doi: [10.7759/cureus.101789](https://doi.org/10.7759/cureus.101789)
12. Rhim HC, Singh M, Maffulli N, Saxena A, Leal C, Gerdesmeyer L, et al. Recommendations for use of extracorporeal shockwave therapy in sports medicine: an international modified Delphi study. *Br J Sports Med.* 2025;59(18):1287–301. doi: [10.1136/bjsports-2024-109082](https://doi.org/10.1136/bjsports-2024-109082)
13. Jünger S, Payne SA, Brine J, Radbruch L, Brearley SG. Guidance on Conducting and REporting DELphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review. *Palliat Med.* 2017;31(8):684–706. doi: [10.1177/0269216317690685](https://doi.org/10.1177/0269216317690685)
14. Lang JK, Haines KJ, Hodgson CL. Development of a performance standard for physiotherapists delivering exercise and mobilisation to the critically ill: A modified Delphi consensus study. *Australian Critical Care.* 2023;36(4):470–6. doi: [10.1016/j.aucc.2022.07.003](https://doi.org/10.1016/j.aucc.2022.07.003)
15. Boulkedid R, Abdoul H, Loustau M, Sibony O, Alberti C. Using and Reporting the Delphi Method for Selecting Healthcare Quality Indicators: A Systematic Review. *PLoS One.* 2011;6(6):e20476. doi: [10.1371/journal.pone.0020476](https://doi.org/10.1371/journal.pone.0020476)
16. Hohmann E, Beaufils P, Beiderbeck D, Chahla J, Geeslin A, Hasan S, et al. Guidelines for Designing and Conducting Delphi Consensus Studies: An Expert Consensus Delphi Study. *Arthroscopy.* 2025;41(10):4208. doi: [10.1016/j.arthro.2025.03.038](https://doi.org/10.1016/j.arthro.2025.03.038)
17. Deng C, Sidebotham D. Using the Delphi process to determine the minimum clinically important effect size for the Balanced-2 randomised controlled trial. *Clinical Trials.* 2023;20(5):473–8. doi: [10.1177/17407745231173058](https://doi.org/10.1177/17407745231173058)
18. Twose P, Jones U, Cornell G. Minimum standards of clinical practice for physiotherapists working in critical care settings in the United Kingdom: A modified Delphi technique. *J Intensive Care Soc.* 2019;20(2):118–31. doi: [10.1177/1751143718807019](https://doi.org/10.1177/1751143718807019)

Editorial information

✉ Correspondence

info@healthandresilience.org

Dates

Received: 14.04.2026

Accepted: 26.06.2026

Published: xx.07.2026

Author Contributions

Conceptualization: G.T., Z.A., and K.S.; Methodology: G.T., Z.A., and K.S.; Writing – Original Draft: G.T., Z.A., and K.S.; Writing – Review & Editing: G.T., Z.A., and K.S.; Project Administration: G.T. All authors have read and agreed to the published version of the manuscript and agree to be accountable for all aspects of the work in accordance with the International Committee of Medical Journal Editors (ICMJE) criteria.

Acknowledgement

The authors thank Alberto Carcasona Otal and Diego Lapuente Hernández for procedural guidance in relation to the ethics submission. Their contribution did not extend to the conception or design of the study, the Delphi content, the analysis plan, or the drafting of this manuscript, and therefore did not meet ICMJE authorship criteria.

Funding

This research did not receive external funding.

Data Availability Statement

Anonymised consensus data will be available on reasonable request to the corresponding author.

Conflicts of Interest

The authors declare no conflict of interest.

Suggested citation

Tzigkounakis G, Alboloushi Z, Simati K. International Consensus Initiative in Invasive Physiotherapy (ICI-IP): protocol for an evidence-informed Delphi study on percutaneous neuromodulation and percutaneous electrolysis. Invasive Physiother Musculoskelet Med. 2026;2:e29. doi: 10.63360/ipmm.v2.e29

Disclaimer/Publisher's Note

The statements, opinions, and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of IPMM and/or the editor(s). IPMM and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions, or products referred to in the content.

Copyright

© 2026 by the authors.

Publication under the terms and conditions of the Creative Commons Attribution (CC BY-NC-SA) license

(<https://creativecommons.org/licenses/by-nc-sa/4.0>)

Appendix 1. CREDES Checklist

Guidance on Conducting and REporting DElphi Studies (Jünger et al., Palliative Medicine, 2017)
International Consensus Initiative in Invasive Physiotherapy (ICI-IP): Protocol for an Evidence-Informed Delphi Study on Percutaneous Neuromodulation and Percutaneous Electrolysis.

CREDES Item	Description	Location in Manuscript (page)
1. Rationale for Use of the Delphi Technique		
Justification	The choice of the Delphi technique needs to be well justified as the most appropriate method to achieve the research aim.	2-3
2. Planning and Design		
Planning and process	Any modifications to the standard Delphi technique should be justified and applied systematically and rigorously.	3-4
Definition of consensus	An a priori criterion for consensus should be defined, including: (a) how to proceed with items in the next round; (b) the threshold to terminate the process; (c) procedures when consensus is or is not reached.	5-8
3. Study Conduct		
Informational input	All material provided to the expert panel should be carefully reviewed and piloted in advance to examine the effect on experts' judgements and to prevent bias.	5
Prevention of bias	Researchers need to take measures to avoid directly or indirectly influencing the experts' judgements. Conflicts of interest should be declared.	5-6
Interpretation and processing of results	Consensus does not necessarily imply the 'correct' answer; non-consensus and stable disagreement provide informative insights.	8
External validation	It is recommended that the final draft of the resulting guidance be reviewed and approved by an external board or authority before publication.	Not applicable at protocol stage. External validation of the resulting consensus statements will be considered for the reporting paper following completion of the Delphi rounds.
4. Reporting		
Purpose and rationale	The purpose of the study should be clearly defined and demonstrate the appropriateness of the Delphi technique to achieve the research aim.	2-3
Expert panel	Criteria for the selection of experts and transparent information on recruitment of the expert panel must be reported.	3-4
Description of the methods	Methods must be comprehensible, including: preparatory steps, piloting of materials, design of survey instrument(s), number and design of survey rounds, methods of data analysis, processing and synthesis of expert responses to inform subsequent rounds, and methodological decisions made throughout.	3-6
Procedure / flowchart	A flowchart illustrating the stages of the Delphi process should be provided, including preparatory phase, Delphi rounds, interim steps of data processing and analysis, and concluding steps.	Figure 1, p. 6
Definition and attainment of consensus	It must be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	5-8
Results	Results for each round should be reported separately to make the evolution of consensus transparent. This includes average group responses, changes between rounds, and any modifications to the survey instrument.	To be completed following Delphi rounds (reporting paper)
Discussion of limitations	Reporting should include a critical reflection of potential limitations and their impact on the resulting guidance.	8
Adequacy of conclusions	Conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance.	8
Publication and dissemination	The resulting guidance should be clearly identifiable from the publication, including recommendations for transfer into practice. A dissemination plan should include endorsement by professional associations and healthcare authorities.	8