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Evidence-informed and consensus-based indications about SAFETY of Physical Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE PAMP): a national Delphi of healthcare scientific societies

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-075348
Article Type:	Original research
Date Submitted by the Author:	05-May-2023
Complete List of Authors:	Gianola, Silvia; IRCCS Galeazzi Orthopaedic Institute, Unit of Clinical Epidemiology Bargeri, Silvia; IRCCS Galeazzi Orthopaedic Institute, Unit of Clinical Epidemiology Pellicciari, Leonardo; IRCCS Istituto Delle Scienze Neurologiche di Bologna Gambazza, Simone; Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico Rossetini, Giacomo; Università degli Studi di Verona, School of Physiotherapy Fulvio, Anna; Associazione Italiana di Fisioterapia Genovese, Vincenzo; Associazione Italiana di Fisioterapia Benedini, Matteo; Associazione Italiana di Fisioterapia Proverbio, Emanuele; Associazione Italiana di Fisioterapia Cecchetto, Simone; Associazione Italiana di Fisioterapia; Provincia autonoma di Trento Azienda Provinciale per i Servizi Sanitari Castellini, Greta; IRCCS Istituto Ortopedico Galeazzi, Clinical Epidemiology Unit Turolla, Andrea; Alma Mater Studiorum University of Bologna; IRCCS Policlinico Sant'Orsola-Malpighi
Keywords:	Physical Therapy Modalities, REHABILITATION MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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3 1 **Evidence-informed and consensus-based indications about SAFETY of Physical**
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6 2 **Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE**
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8 3 **PAMP): a national Delphi of healthcare scientific societies**
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3 **ABSTRACT: 264 words**
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5 **Objective:** A shared consensus on safety about Physical Agent Modalities (PAMs) in physiotherapy
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7 and rehabilitation is lacking. We aimed to develop evidence-informed and consensus-based
8
9 indications about safety of PAMs.
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12 **Study design and setting:** A RAND-modified Delphi rounds' survey was used to reach a consensus.
13
14 We established a steering committee of the Italian Association of Physiotherapy (Associazione
15
16 Italiana di Fisioterapia - AIFI) to identify areas and questions for developing indications about the
17
18 safety of most common used PAMs in physiotherapy and rehabilitation. We invited 28 National
19
20 Scientific and Technical Societies (STS) as a multidisciplinary and multi-professional panel of
21
22 experts to evaluate the proposed indications and formulate additional inputs. The level of agreement
23
24 was measured with a 9-points Likert scale. Consensus in the Delphi rounds was assessed using the
25
26 rating proportion with a threshold of 75%.
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29

30 **Results:** Seventeen (61%) out of 28 STS participated involving their most representative expert
31
32 member. Experts composing the panel were mainly clinicians (88%) reporting multiple expertise in
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34 musculoskeletal (47%), pelvic floor (24%), neurological (18%) and lymphatic (6%) disorders with a
35
36 median experience of 30 years (IQR=17-36). Two Delphi rounds were necessary to reach a
37
38 consensus. The final approved criteria list comprised nine indications about the safety of PAMs in
39
40 adults (electrical stimulation neuromodulation, extracorporeal shock wave therapy, laser therapy,
41
42 electromagnetic therapy, diathermy, hot thermal agents, cryotherapy and therapeutic ultrasound) with
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44 a general note about populations subgroups.
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48
49 **Conclusions:** The resulting evidence-based indications inform patients, healthcare providers and
50
51 policy-makers regarding the safe application of PAMs in physiotherapy and rehabilitation. Future
52
53 research is needed to extend this consensus on pediatric, adolescent and frail patients.
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55

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57 **Key Words:** Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation
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59 Medicine, Delphi Technique
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3 65 **STRENGTH AND LIMITATIONS**
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- 6
7 66 • Indications developed about safety of Physical Agents Modalities in rehabilitation have a solid
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9 67 scientific background coming from 117 systematic reviews
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11 68 • Indications were discussed and approved by a multidisciplinary and multiprofessional panel
12
13 69 of experts including clinicians, researchers, healthcare managers, forensic, patients and lay
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15 70 members
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18 71 • The main limitation is that indications were not extended to specific subgroups of patients
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20 72 (e.g., children, adolescents, frail, etc.) since insufficient literature is available.
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73 INTRODUCTION

74 Physical agent modalities (PAMs) such as electrical stimulation, extracorporeal shock wave therapy,
75 laser therapy, hot/cold thermal agents are widely used in adjunction to other physiotherapy and
76 rehabilitation treatments to produce therapeutic responses in tissues (e.g., reducing pain and swelling)
77 ¹⁻⁴. Among different interventions, they are prescribed and applied by healthcare professionals in
78 various medical specialties (e.g., neurology, orthopedics, geriatrics, pediatrics, oncology,
79 urogynecology) to carry on patient-centered healthcare pathways. However, both clinicians and
80 patients should be informed about their safety with regard to patient-centered care pathways⁵. A
81 Canadian guideline on contraindications and precautions in the use of the six most common physical
82 agents (i.e., ultrasound, cryotherapy, superficial thermal agents, electrical stimulation, low-level laser
83 therapy, and short-wave diathermy) was published in 2010; for example, deep vein thrombosis or
84 thrombophlebitis and haemorrhagic conditions, pacemaker or other implanted electronic device, were
85 reported as contraindications for all the six physical agents.⁶

86 Moreover, the safety of PAMs in patients undergoing physical therapy and rehabilitation was recently
87 assessed by a recent scoping review investigating the occurrence of adverse events after the
88 application of these therapies^{7, 8}: nine PAMs (i.e., cryotherapy, electrical stimulation, transcutaneous
89 electrical nerve stimulation, functional electrical stimulation, extracorporeal shockwave therapy, laser
90 therapy, magnetotherapy, pulsed electromagnetic field and diathermy) and no important harms about
91 these interventions were found, except for extracorporeal shockwave therapy reporting mild adverse
92 events.

93 However, an up-to-date multidisciplinary and multiprofessional expert consensus on PAMs safety is
94 still lacking. Therefore, the purpose of SAFE PAMP (SAFEty of Physical Agent Modalities Practice)
95 consensus in physiotherapy and rehabilitation is to develop evidence-informed and consensus-based
96 indications⁹ on safety of PAMs, by consensus via a RAND Delphi procedure among content experts.

99 METHODS

100 Design

101 A RAND-modified Delphi rounds' survey process was used as the facilitation technique for reaching
102 consensus¹⁰. We followed the guidance on "Conducting and REporting of DELphi Studies" (CREDES)
103 that can be generalized for our field¹¹, according with the EQUATOR initiative⁹.

104 This project is exempted from ethical approval according to the "ethics and data protection"
105 regulations of the European Commission¹². More details are reported in **Supplementary File 1**. The
106 protocol was a-priori registered on OSF online repository (<https://osf.io/53j27>).

107
108 The process consisted of three phases: (i) establishment of the steering committee and invitation of
109 experts from scientific and technical societies (STS) to constitute the panel; (ii) generation of
110 indications by the steering committee using a comprehensive approach based on a published scoping
111 review of existing systematic reviews on PAMs safety in physiotherapy and rehabilitation medicine⁷,
112 ⁸ and on expertise from content expert consultations; (iii) voting of indications through a national
113 Delphi survey from the panel of experts aiming to identify, assess and modify indications importance
114 for each field (e.g., musculoskeletal); (iv) as last round, an online workshop meeting was attended by
115 participants to finalize the list of indications reaching the final consensus (**Figure 1**). Finally, we
116 planned a dissemination of the final indications list as good clinical practices.

[Figure 1]

120 **Phase I. Establishment of the steering committee and panel of experts**

121 *Steering committee*

122 In June 2022, the project team nominated a steering committee that was responsible for: the definition
123 of the list of indications, the selection of STS for expert participants, the development of the Delphi
124 questionnaires, the analysis of responses and handling of feedback from participants, after each round.

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3 125 The steering committee involved 11 content experts and members of the Italian Association of
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5 126 Physiotherapy (Associazione Italiana di Fisioterapia – AIFI). In order to assure the external validity
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8 127 of the consensus process, the group included two content experts on PAMs (MB, EP), three on
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10 128 rehabilitation of musculoskeletal disorders (GR, VG, SB), one on neurological physiotherapy and
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12 129 neuroscience (AT), one on pelvic floor rehabilitation (AF), and four methodologists (SGa, SGi, GC,
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14 130 LP).

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19 132 *Panel of experts*

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21 133 It is known that the impact of the quality of the final recommendations is given by the diversity of a
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24 134 Delphi panel whereas no agreement on the panel size for Delphi studies exist. Panels of 20–30
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26 135 participants are common.^{13, 14} Thus, the steering committee invited 28 multidisciplinary and
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28 136 multiprofessional STS dealing with physiotherapy and rehabilitation care. These STS are entitled to
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31 137 generate good clinical practice guidelines by the published list of the Italian Ministry of Health ^{15, 16}.
32
33 138 The panel of expert members was multidisciplinary and multiprofessional including clinicians,
34
35 139 researchers, and healthcare managers coming from different fields¹⁴ (e.g, orthopedics, neurology).
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37 140 The panel included also forensic, patients and lay members (e.g., people working with relevant
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40 141 voluntary organizations). Each STS delegated the most representative member involved in
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42 142 physiotherapy and rehabilitation care to join the panel of experts.
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47 144 ***Phase II. Generation of indications***

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49 145 The steering committee formulated indications ensuring that all the potentially relevant topics in the
50
51 146 field would be included in the initial list of questions, for the first Delphi round.
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54 147 Indications to be included in the questionnaires were selected based on the literature^{7, 8} and clinical
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56 148 expertise. We moved from a recent scoping review including 117 systematic reviews on the safety of
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58 149 PAMs in physiotherapy and rehabilitation medicine^{7, 8}. This type of review is a method for knowledge
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60 150 synthesis used to map the concepts underpinning a research area and the main sources and type of

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3 151 evidence available. Clinical expertise was assured by content experts of AIFI in musculoskeletal
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5 152 disorders, neurological physiotherapy and pelvic floor rehabilitation. They discussed indications
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8 153 through brainstorming on the following research area:

- 10 154 1. Electrical stimulation
- 11
12 155 2. Neuromodulation, antalgic and interferential electrical currents
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15 156 3. Extracorporeal shock wave therapy
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17 157 4. Laser therapy
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19 158 5. Electromagnetic therapy
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22 159 6. Diathermy
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24 160 7. Hot thermal agents
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26 161 8. Cryotherapy
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28 162 9. Therapeutic ultrasound
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33 164 **Supplementary File 2** reported details about each included intervention.

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37 166 ***Phase III. Voting of indications through Delphi Rounds***

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40 167 We used an electronic Delphi process allowing participants to submit responses anonymously and
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42 168 independently without being biased by other participants' identities and responses. The steering
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44 169 committee sent a blinded electronic voting platform (by a web-based survey) to the panel of experts
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46
47 170 using the SurveyMonkey online platform (Palo Alto, CA, USA; www.surveymonkey.com).

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49 171 The web-based survey consisted of two sections: the first regarded the participants' demographics
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51 172 (e.g., type of profession, the field of expertise, years of experience), and the second covered how to
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54 173 vote for indications. Particularly, the panel of experts evaluated the proposed indications and
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56 174 formulated additional comments using a free text box to ensure complete coverage of the topic.
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58 175 According to the RAND method, for each indication, the panel of experts used a 9-points Likert scale
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3 176 (i.e., 1-3 = highly inappropriate, 4-6 = undecided, 7-9 = highly appropriate) for rating the level of
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5 177 concordance.

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8 178 In addition, the experts can abstain from voting, selecting the answer "Not my expertise" for
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10 179 indications when they felt not have the appropriate level of expertise to rate.

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12 180 A summary of results was provided according to the total number of experts voting as feedback to
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14 181 inform panel members on consensus development with feedback and descriptive statistics
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16 182 incorporated for the next round. Panel of experts were asked to re-rate their evaluation in more rounds
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18 183 only for those indications needing clarification, or for indications for which consensus (i.e., $\geq 75\%$ in
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20 184 7-9 points scale or in 1-3 points scale) was not reached.

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22 185 Anonymous report of each round was provided to each expert showing the distribution of responses
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24 186 for each indication with all additional comments provided in the free text box. Based on previous
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26 187 voting, indications were modified and presented for the next round. Up to three remind emails for
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28 188 completion were sent to each component individually. Data collection occurred over a 5-month period
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31 189 (June-November 2022).

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34 35 191 ***Phase IV. Workshop Meeting as last round***

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37 192 After reaching a consensus, the steering committee joined an online meeting as the last round to refine
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39 193 indications according to each expert contribution and to confirm indications to be included in the final
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41 194 criteria list. Finally, the panel of experts was asked to vote on the final indications list for the closing
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43 195 audit procedure.

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46 47 197 **Definition and calculation of consensus**

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49 198 In agreement with the RAND appropriateness method, to inform the development of consensus we
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51 199 adopted predefined criteria¹⁷ assessing the consensus in the Delphi method using the proportion of
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53 200 ratings with a threshold of 75% according to previous review¹⁸. Particularly:
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3 202 1. Consensus in: $\geq 75\%$ of participants scored the item as “critical” (score 7 to 9) and $< 15\%$
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5 203 scored the item as of “limited importance” (score 1 to 3)
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8 204 2. Consensus out: $\geq 75\%$ of participants scored the item as of “limited importance” (score 1
9
10 205 to 3) and $< 15\%$ scored the item as “critical” (score 7 to 9)
11
12 206 3. No consensus: All other results.
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17 208 **Statistical Analysis**

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19 209 We used descriptive statistics such as mean and standard deviation (SD), median and interquartile
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21 210 range (IQR) or absolute value and frequency as appropriate to summarize general characteristics of
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23
24 211 participants and percentage of agreement during the Delphi rounds.
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26 212

28 213 **Role of the Funding Source**

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30 214 The work was supported by AIFI. The funder played no role in the design, conduct, or reporting of
31
32
33 215 this study.
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35 216

37 217 **Patient and public involvement**

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39 218 One patient representative was involved as expert panellist in this study to rate the indications.
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44 220 **RESULTS**

46 221 **Participants**

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49 222 Overall, 17 out of 28 (61%) invited STS responded to the questionnaire. The Delphi process flow
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51 223 chart with the STS participants list is reported in **Figure 2**. One expert represented each STS. Most
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53 224 experts were clinicians (88%), with half having expertise in the musculoskeletal field (47%). Experts
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55
56 225 had a median experience of 30 years (IQR:17-36) in their area of expertise. The general characteristics
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58 226 of the experts included in this study are reported in **Table 1**. No conflict of interest was present
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60 227 (**Appendix 1**).

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[Figure 2]

[Table 1]

Delphi rounds

Two rounds Delphi were necessary to reach consensus.

Round 1

Overall, 17 experts representing each of the invited STS completed the survey. All indications passed the first round with a consensus out of 75% (**Table 2**). Five experts provided justifications for their choices (e.g., examples of clinical practice) and gave important inputs for some indications. In particular, additional comments regarded concerns about the definition of children and adolescent age, the safety of patients or providers and acceptability. Thus, round 2, was prepared adding specific notes based on suggestions posed: the age to define children and adolescents and the focus on the safety of patients.

[Table 2]

Round 2

Overall, 14 STS (82%) completed the whole survey. All the indications passed the first round with a consensus out of 75%. (**Table 2**). One expert of the panel provided additional comments reporting examples from clinical practice.

Workshop Meeting as last round

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3 252 On September 27, 2022 nine STS (53%) joined the online meeting to discuss comments, justifications
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5 253 and highlights. A comprehensive digital presentation of Round 1 and Round 2 findings were reported
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8 254 during the workshop. Indications were finally reworded, as suggested by the participants. In addition,
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10 255 the panel of experts suggested introducing a general note considering different subgroups of the
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12 256 population (e.g., children, adolescents, frail). A final list of indications with a general note was
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14
15 257 shared in order to reach the final approval through a last round. All STS (100%) approved and released
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17 258 the final indications list of indications. One expert voted the option “Not my expertise” in the
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19 259 indication on the cryotherapy (**Table 2**). In **Appendix 2**, the whole document released for good
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21 260 clinical practice with details of sources (evidence and expertise) and application in different
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24 261 population settings was reported.
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DISCUSSION

This study aimed to develop indications about the safety of PAMs in physical therapy and rehabilitation medicine. These indications were developed by a steering committee (including clinical and methodological experts) of AIFI and informed by 17 national STS with high expertise in different fields related to physiotherapy and rehabilitation (e.g., orthopedics, neurology), including forensic scientists, patients and lay members (e.g., people working with relevant voluntary organizations).

The response rate was moderate with 61% of participation, as suggested by literature¹⁹. All nine indications were approved in the first round, reaching an important consensus of over 75%, with minor edits on age and fields of applications refined with a second round. After a workshop meeting, a general note was added limiting the use of PAMs to the adult population (>18 years) and all panel experts approved and released the final indications list with overall consensus. In summary, all PAMs proposed are safe to the adult population (>18 years) and can be prescribed and applied by a healthcare provider (e.g., physiotherapist, physician) formed and informed as a requirement from education and licensure²⁰. Before proposing PAMs to patients, clinicians have to keep in mind the individual medical history (e.g., comorbidities) during the comprehensive initial examination to better

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3 278 determine the diagnosis, prognosis, anticipated goals and expected outcomes for identified
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5 279 impairments, activity limitations and participation restrictions²¹. Thus, following an evidence-based
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8 280 approach, healthcare providers should propose the various efficacious treatment options available
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10 281 according to patients' needs and preferences. In this context, patient should be informed of the
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12 282 potential undesirable effects, especially for the application of PAMs. In particular, in case of ESWT
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15 283 as some expected mild adverse events (e.g., pain, erythema) at the application site can occur ⁷.

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17 284 For safety purposes, developed indications were not generally extended to other subgroups such as
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19 285 children, adolescents and frail people, since limited and insufficient literature on harms is available.²²
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22 286 For example, in children and adolescents some PAMs could influence the biological tissues still in
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24 287 the growth phase ^{23 6, 24}. This population have open growth plates and their ligaments (tissues holding
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26 288 bone to bone) are stronger than the bony attachment sites, where they serve as connectors.

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28 289 Thus, adopting safety principle, decision-makers adopt precautionary measures when scientific
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31 290 evidence on harms is uncertain, and the population is vulnerable^{25 26, 27} (e.g., populations historically
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33 291 considered at risk for being misused in clinical research or for whom a truly voluntary decision may
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35 292 be compromised from a regulatory perspective such as children or frail people).

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38 293 Considering an evidence-based approach, clinicians should balance efficacy and safety, according to
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40 294 patients' preferences. Among all the rehabilitation interventions with demonstrated efficacy^{28, 29},
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42 295 those with trivial adverse events should be encouraged (after informing the patient of the possible
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45 296 occurrence of mild adverse events), whereas those with unknown related harms should not. "*Primum*
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47 297 *non nocere*" is one of the essential ethical principles of medicine; first of all a treatment should not
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49 298 cause harms to the patient³⁰.

50 51 299 52 53 300 **Implications for clinical practice**

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56 301 Good practices for safety of patients should be managed by national agencies with a living monitoring
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58 302 system and shared in international initiatives such as the WHO Global Patient Safety Challenge
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3 303 Medication Safety³¹ to facilitate the strengthening of systems and practices adopting corrective action
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5 304 within countries.
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8 305 In this context, our consensus could take place into the Good Clinical Practices (GCP) of the Italian
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10 306 Ministry of Health system by Istituto Superiore di Sanità (ISS)³² for the production of national
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12 307 guidelines and the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi
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14 308 Sanitari Regionali – AGENAS)³³ for reporting any experience of improvement in patient safety made
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17 309 by healthcare organizations.
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19 310 Together with public or private healthcare institutions and organizations and in accordance with
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21 311 recent national legislation on clinical responsibility and safety of treatment¹⁶, STS must sustain any
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24 312 initiative on safety of interventions, with the largest involvement of stakeholders included patients at
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26 313 first instance. The STS should act as facilitator of dissemination of GCP in different strategies. On
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28 314 one hand STS can promote local experiences of improvement in patient safety stored in shared
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30 315 repository (i.e., AGENAS)³³ on the light of evidence-based consensus (e.g., SAFE PAMP) to
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32 316 facilitate national collaboration between different institutions. On the other hand, STS can
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34
35 317 disseminate a plain patient-oriented version of good clinical practices indications. We planned to
36
37 318 develop patient and stakeholder versions of our evidence-informed and consensus-based indications.
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39
40 319 We aim to use a conceptual framework based on public health digitalization to put people and patients
41
42 320 at the center of care delivery, supporting patient empowerment and making healthcare system more
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44 321 efficient and safer.^{34, 35} For example, we can plan stakeholders meetings and webinars, as well as
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47 322 educations and counselling via pamphlets/video/and social messages.
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51 324 **Implications for research**

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53 325 We believe that indications developed by the multidisciplinary and multi-professionally panel of
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55 326 experts can be generalized worldwide. These results could provide essential information for Good
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58 327 Clinical Practices for the production of national and international guidelines to improve patient safety
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60 328 and decrease avoidable harms related to interventions. However, in some rehabilitation fields,

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3 329 indications about safety were offered only on clinical expertise in the absence of evidence. The
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5 330 absence of evidence is not evidence of absence³⁶. Studies should convey their efforts to plan and
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8 331 adequately report adverse events before objectively estimating these harms. The assessment,
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10 332 monitoring and reporting of adverse events should be mandatory in protocols of primary studies, in
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12 333 prospective registration and in public access. This can allow to study data, fulfilling ethical
13
14 334 obligations towards patients, and ensuring a basis for fully-informed decision making in the
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17 335 healthcare system. We call for multicentric randomized controlled trials based on the core outcome
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19 336 set also for harms and not only for benefit³⁷.

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21 337 As well, specific subgroups of populations should be studied. It is a serious matter to exclude a group
22
23
24 338 from research eligibility, and this must be done only when no less restrictive option is sufficient to
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26 339 ensure protection from undue risk. Deciding to exclude certain groups from studies to protect them
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28 340 from the risks inherent in clinical research, investigators take away patients' right to decide the
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31 341 desirable participation in research.³⁸

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33 342 In addition, future studies can better explore our indications to ensure the optimal modality
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35 343 application of the proposed PAMs (e.g., optimal voltage, amperage, frequency, current density, dose)
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38 344 especially for the subgroups mentioned above where therapies should be proposed according to
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40 345 population-specific characteristics (e.g., age of children).³⁹

41 42 346 43 44 347 **Limitations**

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47 348 This is the first effort to develop indications on the safety of PAMs in physiotherapy and
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49 349 rehabilitation. We strictly followed published guidelines for reporting and conduction. In addition,
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51 350 we a-priori publicly registered (<https://osf.io/w8kgs>) the consensus criterion used to determine
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54 351 agreement within the Delphi process^{17, 40}.

55
56 352 Indications from this study have a solid scientific background and external validity since they were
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58 353 developed according to a previous evidence based scoping review^{7, 8} (protocol stored at
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60 354 <https://osf.io/6vx5a/>) and discussed by large groups of experts with various backgrounds, including

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3 355 lay member and patients. The panel of experts, as occurs in clinical practice guidelines, declared their
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5 356 interests to inspect any possible related conflict of interest.
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8 357 Some limitations should be acknowledged. We used a consensus threshold of 75% even if the
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10 358 definition varies widely in the literature and it is poorly reported.¹⁸ However, our threshold was one
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12 359 of the most conservative and in all rounds the consensus was reached with high percentage of
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14 360 agreements.

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17 361 In addition, even if PAMs were found to be safe in this consensus, we did not exclude that some
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19 362 patients could experience mild adverse events (e.g., bruising, muscle soreness) that can be
20
21 363 underestimated considering the real-world data (RWD) relating to patient health status. Patients
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23 364 experiences of adverse events should be collected in public dataset of RWD from electronic health
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25 365 records and insurance claims⁴¹. However, the analysis of RWD requires special vigilance to prevent
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27 366 data users from drawing unjustified conclusions not supported by data, based on spurious correlations
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29 367 ⁴¹. Some initiatives across countries exists such as the Food and Drug Administration (FDA)
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31 368 repository for the reporting of adverse events related to FDA-approved devices⁴² and the European
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33 369 database on medical devices (EUDAMED) to access information for the public and healthcare
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35 370 professionals⁴³.

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38 371 Accelerating and standardize national and international medical device regulation can promote an
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40 372 efficient and effective regulatory model for medical devices responsive to emerging challenges while
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42 373 protecting and maximizing public health and safety⁴⁴
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47 374 48 49 375 **CONCLUSION**

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51 376 These evidence-based indications inform patients, healthcare providers and policy-makers regarding
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53 377 the safety of a wide range PAMs used in physiotherapy and rehabilitation after a comprehensive
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55 378 clinical evaluation of patients' needs. This consensus can provide a basis for decision-making and
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57 379 future research on this field.
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381 **DECLARATIONS**

382 **Author Contributions**

383 Concept/idea/research design: S. Gianola, S. Bargerì, G. Castellini

384 Writing: S. Gianola, S. Bargerì, G. Castellini

385 Data collection: S. Gianola, S. Bargerì

386 Data analysis: S. Gianola, S. Bargerì

387 Project management: S. Gianola, S. Bargerì

388 Consultation (including review of manuscript before submitting): S. Gianola, S. Bargerì, L.

389 Pellicciari, S. Gambazza, G. Rossetini, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S.

390 Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators

392 **Ethics Approval**

393 This study was declared exempt from institutional review board review

395 **Disclosures**

396 The authors declared they had no conflicts of interest.

398 **Funding**

399 The work was supported by AIFI. The funder played no role in the design, conduct, or reporting of
400 this study.

402 **Data sharing statement**

403 Research data are stored in OSF repository <https://osf.io/w8kgs/>

405 **Manuscript word count:** 3259/4000

406 **Figure 1.** Phases of the RAND Delphi process

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407 **Figure 2.** Flow chart of Delphi process

408 **Table 1.** General characteristics of experts

409 **Table 2.** Agreement results for each round

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525 **Tables**

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Table 1. General characteristics of experts

Professional profile*	Responses (N=17)
Clinicians	88.0%
Researchers	41.0%
Management	23.5%
Field of expertise*	
Musculoskeletal	47.0%
Pelvic floor disorders	23.5%
Neurological	18.0%
Lymphatic disorders	6.0%
Other**	35.3%

*more than one answer was possible

** e.g, lay or forensic members

530 **Table 2. Agreement results for each round**

Indications about safety of...	ROUND 1		ROUND 2		FINAL LIST	
	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Approved	NME
Electrical stimulation	85.7	7.1	85.7	0.0	100.0	0.0
Neuromodulation, antalgic and interferential electrical currents	100.0	0.0	100.0	0.0	100.0	0.0
Extracorporeal shock wave therapy	83.3	0.0	76.9	0.0	100.0	0.0
Laser therapy	84.6	7.7	90.9	0.0	100.0	0.0
Electromagnetic therapy	81.8	9.1	76.9	0.0	100.0	0.0
Diathermy	90.0	10.0	84.6	0.0	100.0	0.0
Hot thermal agents	81.8	9.1	91.7	0.0	100.0	0.0
Cryotherapy	75.0	0.0	90.9	0.0	94.2	5.8
Therapeutic ultrasound	90.9	0.0	91.7	0.0	100.0	0.0
General note^	-	-	-	-	100.0	0.0

531 ^added for the Final Criteria List

532 Abbreviations: NME: not my expertise

533 **Appendix 1. SAFE PAMP Collaborators**

Name and Surname	Affiliation	STS	COI
Armando Perrotta	IRCCS Neuromed, Pozzilli (IS)	Società Italiana per lo Studio delle Cefalee (SISC)	none
Viviana Rosati	A.U.O. Policlinico Umberto I	Società Italiana di Riabilitazione Neurologica (SIRN)	none
Enrico Marinelli	Department of Anatomical, Histological, Forensic, and Orthopedic Sciences, "Sapienza" University of Rome	Società Italiana di Medicina Legale e delle Assicurazioni (SIMLA) - Dipartimento di Scienze Biotecnologiche e Medico-chirurgiche Università di Roma Sapienza	none
Bianca Masturzo	Obstetrics and Gynecology department. Ospedale degli infermi. Ponderano (Biella)	Associazione degli Ostetrici e Ginecologi Ospedalieri Italiani (AOGOI)	none

Mauro Roselli	ASL CittadiTorino- Ospedale Martini- S.C. Ortopedia e Traumatologia	Ortopedici Traumatologi Ospedalieri d'Italia (OTODI)	none
Stefano Vercelli	Laboratorio di Ricerca in Riabilitazione 2rLab, Dipartimento Economia Aziendale, Sanità e Sociale. SUPSI. Manno (CH)	Federazione Italiana delle Associazione Scientifiche di Fisioterapia (FIASF)	none
Gianmarco Rea	Asl Latina, 04100 Latina, Italy	Società Italiana di Medicina Generale e delle Cure Primarie (SIMG)	none
Gianfranco Lamberti	Dipartimento Medicina Riabilitativa AUSL Piacenza	Società Italiana di Urodinamica (SIUD)	none
Roberto Bortolotti	UO Reumatologia Ospedale S.Chiera, Trento	Società Italiana di Reumatologia (SIR)	none

Chiara Torresetti	Paideia International Hospital	Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico (AIUG)	none
Fabio Bandini	Department of Neurology, ASL 3 Genovese, Genova, Italy	Società Italiana Neurologia (SIN)	none
Giuseppe Botta	Istituto Fisioterapico Michelangelo di Arezzo	Società Italiana di Flebolinfologia (SIFL)	none
Giancarlo Tancredi	Pediatric Department. Sapienza Università di Roma	Società Italiana di Pediatria (SIP)	none
Luigi Nappi	Department of Medical and Surgical Sciences Policlinico Riuniti di Foggia UNIVERSITY OF FOGGIA	Società Italiana Di Ginecologia E Ostetricia (SIGO)	none
Marco Scorcu	Servizio di Medicina dello Sport e	Federazione Medico Sportiva Italiana (FMSI)	none

	dell'Esercizio Fisico, Cagliari, ATS Sardegna, Cagliari, Italy		
Monica Pierattelli	Presidente SICuPP Toscana, Pediatra di libera scelta Campi Bisenzio (FI)	Societa' Italiana Delle Cure Primarie Pediatriche (SICuPP)	none
Carla Berliri	Cittadinanzattiva- APS - Sede Nazionale -Staff area Salute - Tribunale per i Diritti del Malato - Politiche della Salute-	Cittadinanzattiva - APS	none

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535 Legend: COI, Conflict of Interest; STS, Scientific and Technical Societies

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536 **Appendix 2. Final criteria list**

537 **1. Electrical stimulation (e.g., Functional electrical stimulation (FES), Neuromuscular** 538 **electrical stimulation (NMES), Electrical muscle stimulation (EMS)) is safe in the adult** 539 **population**

540 *- in musculoskeletal disorders, especially in the following conditions:*

541 o Evidence: neck pain, knee osteoarthritis, musculoskeletal pain, muscle hypotrophy.

542 o Expertise: spinal osteoarthritis, knee osteoarthritis, musculoskeletal pain, knee
543 osteoarthritis, muscle and joint pain.

544 *- in pelvis-perineal disorders, especially in the following conditions:*

545 o Evidence: urinary incontinence, faecal incontinence, lower urinary tract symptoms in
546 postpartum women, overactive bladder.

547 o Expertise: prolapse, descending perineum syndrome, perineal hypotonia, bladder-sphincter
548 or anorectal dyssynergia, erectile dysfunction, premature ejaculation, abdominal diastasis.

549 *- in neurological disorders, especially in the following conditions:*

550 o Evidence: migraine, spasticity in multiple sclerosis, stroke, spinal cord injury.

551 o Expertise: post-stroke urinary incontinence, neurogenic bowel dysfunction in spinal cord
552 injury, second motor neuron disease (e.g., Amyotrophic Lateral Sclerosis), muscular
553 dystrophies, head trauma, lesions of the peripheral nervous system.

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3 555 **2. Neuromodulation, antalgic and interferential electrical currents (e.g., TransCutaneous**
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5 556 **Electrical Nerve Stimulation (TENS), Transcutaneous Tibialis Posterior Stimulation (TTNS))**
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8 557 **are safe in the adult population**
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11 558 *- in musculoskeletal disorders, especially in the following conditions:*
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15 559 *o Evidence: low back pain, neck pain, rotator cuff disease, whiplash-associated disorders,*
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17 560 *fibromyalgia.*

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20 561 *o Expertise: musculoskeletal pain, spine osteoarthritis, neuropathic pain.*
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24 562 *- in pelvis-perineal disorders, especially in the following conditions:*
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26
27 563 *o Evidence: overactive bladder, urinary incontinence, faecal incontinence, persistent pelvic*
28
29 564 *pain.*

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33 565 *o Expertise: Urinary incontinence, pudendal neuralgia, constipation, urinary retention.*
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37 566 *- in neurological disorders, especially in the following conditions:*
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40 567 *o Evidence: neuropathic pain, stroke, multiple sclerosis, neurogenic bowel dysfunction after*
41
42 568 *spinal cord injury.*

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46 569 *o Expertise: neurogenic bladder dysfunction after central and peripheral nervous system*
47
48 570 *injuries.*
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55 572 **3. Extracorporeal shock wave therapy (radial and focal) is safe in the adult population**
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59 573 *- in musculoskeletal disorders, especially in the following conditions:*
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3 574 o Evidence: soft tissue disorders of the lower limbs, knee tendinopathy, Achilles
4
5 575 tendinopathy, osteoarthritis, plantar fasciitis, rotator cuff disease, shoulder tendinopathy and
6
7
8 576 calcifications, acute fracture, orthopedic disorders, consolidation delays, other soft tissue
9
10 577 disorders.
- 11
12
13 578 o Expertise: enthesopathies of the upper and lower limbs, calcifications, epicondylitis,
14
15
16 579 epitrocleitis, muscle injuries, muscle contractures and trigger points.
- 17
18
19 580 - in neurological disorders, especially in the following conditions:
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21
22
23 581 o Evidence: post-stroke lower limb spasticity, multiple sclerosis spasticity.
24
25
26 582 o Expertise: spasticity following head trauma, spasticity following spinal cord injury.
27
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29
30 583 - in pelvis-perineal disorders, especially in the following conditions:
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32
33 584 o Evidence: chronic prostatitis/chronic pelvic pain syndrome.
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37 585 o Expertise: persistent female pelvic pain, Peronye disease.
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- 40 586 Patients should be informed of the potential undesirable effects after applying ESWT. Indeed, a
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42 587 recent literature review showed some expected mild adverse events, such as pain and erythema, at
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45 588 the application site⁷.
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52 590 **4. Laser therapy (e.g., low level laser therapy (LLLT), high level laser therapy (HLLT)) is safe**
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54 591 **in the**
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56 592 **adult population**
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60 593 - in musculoskeletal disorders, especially in the following conditions:

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2
3 594 o Evidence: low back pain, Achilles tendinopathy, rotator cuff disease, capsulitis adhesive,
4
5 595 lower extremity soft tissue disorders, frozen shoulder, carpal tunnel syndrome, knee
6
7
8 596 osteoarthritis, neck pain, whiplash associated disorders.
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10
11 597 o Expertise: upper and lower limb tendinopathy, acute arthropathy, acute muscle and tendon
12
13 598 injuries, acute musculoskeletal pain. Upper and lower limb tendinopathy, acute arthropathy,
14
15 599 acute muscle and tendon injury, and acute musculoskeletal pain.
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19 600 - *in pelvis-perineal disorders (extracavitary LLLT only), especially in the following conditions:*
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21

22
23 601 o Evidence: Urinary incontinence and pelvic organ prolapse, persistent pelvic pain.
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25

26 602 o Expertise: healing (episiotomies, laparotomies, lacerations, etc.), inflammatory pelvic
27
28 603 pain, edema or perineal hematomas.
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31
32 604 - *in lymphatic disorders (LLLT only), especially in the following conditions:*
33
34

35 605 o Evidence: secondary lymphoedema (e.g., breast cancer-related lymphedema).
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39 606 o Expertise: lymphoedema
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41

42 607 - *in neurological disorders (LLLT only), especially in the following conditions:*
43
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45
46 608 o Evidence: Bell's palsy
47
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49 609 o Expertise: stroke, multiple sclerosis, spinal cord injury, head trauma, peripheral nerve
50
51 610 injury.
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55 611 **5. Electromagnetic therapy (e.g., Pulsed ElectroMagnetic Field Therapy (PEMFT), repetitive**
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57 612 **Peripheral Magnetic Stimulation (rPMS)) is safe in the adult population**
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613 - *in musculoskeletal disorders, especially in the following conditions:*

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3 614 o Evidence: neck pain, fractures, consolidation delays.

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6 615 o Expertise: osteoporosis, bone oedema, algodystrophy, arthrosis.

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10 616 - in pelvis-perineal disorders, especially in the following conditions:

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14 617 o Evidence: persistent pelvic pain and urinary incontinence.

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17 618 o Expertise: faecal incontinence, prolapse, descending perineum syndrome, perineal

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19 619 hypotonia, vesicico-sphincteric or anorectal dyssynergia, pudendal neuralgia, pelvic pain

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22 620 acute, erectile dysfunction, premature ejaculation, diastasis recti.

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25 621 **6. Diathermy (e.g., Short Wave Tecar Therapy) is safe in the adult population**

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29 622 - in musculoskeletal disorders, especially in the following conditions:

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32 623 o Evidence: rotator cuff disease, knee osteoarthritis.

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35 624 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-

36

37

38 625 acute), osteoarthritis, muscle contractures, trigger points.

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41 626 - in pelvis-perineal disorders, especially in the following conditions:

42

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45 627 o Evidence: inflammatory pelvic pain, persistent pelvic pain, sexual dysfunction (Peronye's
46 628 disease).

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50 629 o Expertise: prolapse, stress urinary incontinence, scarring (episiotomies, laparotomies,

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53 630 lacerations, etc.), perineal edema or hematoma, vulvovaginal dystrophy and dryness,

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59 632 **7. Hot thermal agent modalities (e.g., drug-free heatwrap) are safe in the adult population**

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3 633 - *in musculoskeletal disorders, especially in the following conditions:*

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6 634 o Evidence: groin pain, low back pain.

7
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10 635 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-
11
12 636 acute), osteoarthritis

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19 638 **8. Cryotherapy (e.g, ice or liquid nitrogen) is safe in the adult population**

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23 639 - *in musculoskeletal disorders, especially in the following conditions:*

24
25
26 640 o Evidence: arthroscopy, reconstruction of the anterior cruciate ligament, post-surgery.

27
28
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30 641 o Expertise: Delayed Onset Muscle Soreness (DOMS)/Delayed Onset Muscle Soreness
31
32 642 (DOMER), post-surgery, post trauma (48h).

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39 644 **9. Therapeutic Ultrasound is safe in the adult population**

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42 645 - *in musculoskeletal disorders, especially in the following conditions:*

43
44
45
46 646 o Evidence: back pain, neck pain, carpal tunnel, rotator cuff disorder, lower limb soft-tissue
47
48 647 disorder, knee osteoarthritis, fracture, acute fracture, ankle fracture, ankle and knee sprains,

49
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51 648 o Expertise: hand and foot osteoarthritis, calcifications, enthesitis.

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55 649 **General note and considerations related to subgroups:**

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58 650 Following a confirmed clinical prescription, the applications of the above physical therapies are safe
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61 in the adult population (>18 years) under the supervision of an expert operator. For precautionary

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652 reasons, these indications are not extended to other subgroups of patients (e.g., children,
653 adolescents, frail, etc.) since insufficient literature is available.

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Establishment of the Steering Committee and Panel of Experts

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Generation of indications

- Comprehensive and evidence-based approach by a published scoping review of existing systematic reviews

Voting indications

- Online National Delphi Survey with all panel experts to identify any additional indications and to assess importance of candidate indications

Workshop meeting

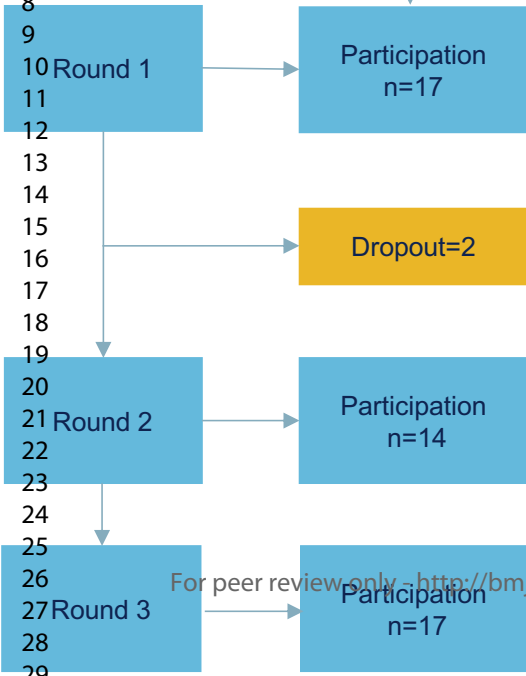
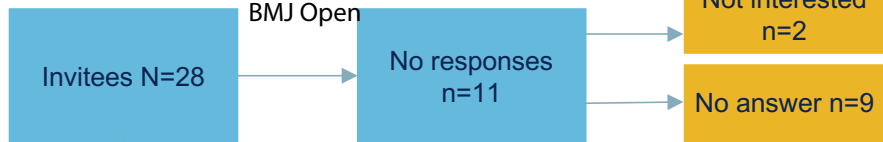
- Finalization of the indications by online meeting with all panel experts

Dissemination

- Publication of good practice indications in national registries (e.g., SNLG, AGENAS)

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- Scientific and Technical Societies (STS)**
- Cittadinanzattiva APS
 - SIN (Società Italiana di Neurologia)
 - FMSI (Federazione Medico Sportiva Italiana)
 - SIUD (Società Italiana di Urodinamica)
 - SICuPP (Società Italiana Delle Cure Primarie Pediatriche)
 - SIMG (Società Italiana di Medicina Generale e delle cure primarie)
 - SIRN (Società Italiana di Riabilitazione Neurologica)
 - SIMLA (Società Italiana di Medicina Legale e delle Assicurazioni)
 - AOGOI (Associazione Ostetrici Ginecologi Ospedalieri Italiani)
 - SIR (Società italiana di Reumatologia)
 - FIASF (Federazione Italiana delle Associazioni Scientifiche di Fisioterapia)
 - SIFL (Società Italiana di Flebologia)
 - AIUG (Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico)
 - SIGO (Società Italiana Di Ginecologia E Ostetricia)
 - SISC (Società Italiana per lo Studio delle Cefalee)
 - OTODI (Ortopedi e Traumatologi Ospedalieri D'Italia)
 - Società Italiana di Pediatria (SIP)

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5 **Supplementary Files**
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7 *Supplementary File 1. Ethical considerations*2

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9 *Supplementary File 2. Physical agent modalities description*2

10 **REFERENCES**.....6
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Supplementary File 1. Ethical considerations

Participation in the Delphi survey is voluntary and by invitation. The questionnaire includes a beginning section to acquire consent and privacy for data processing. Participants are informed that the responses will have 'remained total confidentiality according to the Regulation on the protection of personal data' 679/2016 of the European Union, and that the results will be used for research purposes and a document shared at the corporate level¹. The interested party may be interested in the rights provided for by art. 15, 16, 17, 18, 20, 21 and 22 of the Regulation mentioned above.

Database randomization and differential privacy access were achieved. In addition, "anonymization" by generalizing was performed.² The study project and data collection were managed and anonymously entrusted by the Unit of Clinical Epidemiology of IRCCS Istituto Ortopedico Galeazzi based in Milano. The data subject cannot be re-identified and is therefore outside the scope of the data protection law³.

The row dataset was accessible to two researchers (SG, SB) excluded from participation in Delphi for the quantitative and qualitative analyses. This practice complies with the European standards for the use of aggregative data where the data subject cannot be re-identified, are not personal data and are therefore outside the scope of data protection law³. The final report only contains aggregate data. In the final document, we reported the names of the participants who have completed all rounds and gave their consent to disclose their names.

Supplementary File 2. Physical agent modalities description

1) **Electrical stimulation:** electrotherapeutic currents and waveforms to facilitate neuromuscular or sensory activity to improve muscle strength and reeducate muscle function.⁴

- Neuromuscular electrical stimulation (NMES): use of pulsed currents to stimulate motor nerves, which in turn produce tetanic contractions of the neuromuscular spindles, with or without joint movement.⁵
- Functional Electrical Stimulation (FES) uses electrical pulses to stimulate motor neurons or denervated muscle fibers directly to elicit a contraction during a functional activity (e.g., gait). FES is used in the treatment of orthopedic and neurological conditions.⁶

2) **Neuromodulation, analgic and interferential electrical currents :** electrotherapeutic currents and waveforms to influence physiological effects on the patient's body structures and functions aiming to modulate pain.⁴

- Transcutaneous electrical nerve stimulation (TENS): delivers electrical stimulation via electrodes placed over the intact skin surface near the source of pain to produce analgesia or hypoalgesia. A wide variety of pulsed waveforms are used, with frequencies typically in the range of 1-100Hz. The intensities are set to produce sensory stimulations alone or in combination with motor stimulations to produce muscle twitches (acupuncture-like TENS).⁷
- Transcutaneous Tibialis Posterior Stimulation (TTNS): a form of neuromodulation involving the use of electrical impulses to address urinary symptoms (e.g. overactive bladder) with inhibitory action on neurons of the spinothalamic tract (S2–S3).⁸
- Interferential current (IC): involves crossing two medium frequency currents (most commonly 4000 Hz), which reportedly generates a low-frequency 'beating' (amplitude-modulated) effect at between 0 and 150 Hz in the deep tissues.⁹ These beat frequencies are believed to decrease pain, increase circulation and block nerve conduction.

3) **Extracorporeal shock wave therapy:** a nonsurgical treatment that uses the phenomenon of mechanotransduction (i.e., adapting cells biochemical activity, influencing cells migration, proliferation, differentiation and apoptosis)^{10 11} to treat various musculoskeletal conditions (e.g., plantar fasciitis; tennis elbow). Shock wave therapy can be either extracorporeal or radial.¹²

- Extracorporeal shock wave therapy (ESWT) involves passing sound waves (or shock waves) through the skin to the affected area. Shock waves are single pulsed acoustic or sonic waves, which dissipate mechanical energy at the interface of two substances with different acoustic impedance.¹³ They are produced by generators of an electrical energy source and require an electroacoustic conversion mechanism and a focusing

1
2
3 device. Three types of systems can be distinguished based upon the sound source:
4 electrohydraulic, electromagnetic and piezoelectric systems. Various doses appear to
5 be used, with no apparent consensus on the minimum therapeutic dose. As defined
6 defined by Cacchio 2006¹⁴ as low-energy shock waves is less than 0.1 mJ/mm² and
7 high-energy shock waves: is 0.2 mJ/mm² to 0.4 mJ/mm²).

- 8
9 - Radial shock wave therapy (RSWT) is generated through the acceleration of a
10 projectile inside the handpiece of the treatment device and then transmitted radially
11 from the tip of the applicator to the target zone. Radial shock waves show a lower
12 peak pressure and a considerably longer rise time than extracorporeal shock waves.
13 In RSWT, the focal point is not centred on a target zone, as occurs in focal ESWT,
14 but on the tip of the applicator.¹⁴

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16
17 **4) Laser therapy:** light source treatment, non-invasive, widely used to treat various
18 musculoskeletal conditions.

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20
21 - Low-level laser therapy (LLLT) generates a beam of light with a particular
22 wavelength that can deliver light energy to tissue depths below the dermis¹⁵.
23 Studies suggest that LLLT contributes to pain relief by reducing pro-inflammatory
24 cytokines¹⁶. The effects of LLLT are considered to be dependent on dosage,
25 wavelength, site and duration of treatment.^{15 16}
- 26
27
28 - high level laser therapy (HLLT): laser with an output power greater than 500 mW
29 or 0.5 Watts. HLLT creates heat on the surface of the skin due to their higher power
30 density (irradiance).¹⁷

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33
34 **5) Electromagnetic therapy:** based on Faraday's law of electromagnetic induction, to promote
35 bone healing, treat osteoarthritis and inflammatory diseases of the musculoskeletal system,
36 alleviate pain, enhance healing of ulcers and reduce spasticity¹⁸.

37
38 - Pulsed Electromagnetic Field therapy (PEMF), which involves the delivery of pulsing (that
39 is 'on-off') low-frequency magnetic fields through the body, which is believed to provide
40 temporary pain relief by influencing tissue generation and cell proliferation.¹⁹

41
42 - Repetitive magnetic stimulation (rMS), which allows the transcutaneous induction of nerve
43 stimulating electric currents. This technique requires extremely strong and sharp magnetic
44 impulses (for example 15,000 amperes peak current; 2.5 T field strength; < 1 msec) applied
45 by specially designed coils (< 10 cm) over the target area. Modern devices allow the repetition
46 of up to 60 impulses per second. Mainly developed to study and influence brain functions,
47 rMS also stimulates spinal chord fibres and peripheral nerves. Initial studies used peripheral
48 rMS for therapeutic reasons, such as in myofascial pain syndrome²⁰. Since the resulting small
49 electric impulses are the nerve stimulating factor, rMS effects may be similar to TENS.
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55 **6) Shortwave and microwave Diathermy**

- 56 - Tecartherapy or radiofrequency diathermy (RFD) is a non-invasive therapy and
57 consists in the emission of high-frequency electromagnetic waves which increase
58 tissue metabolism. This process promotes tissue repair and affects pain
59 sensitivity.^{21 22 23}
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- Microwave diathermy: a deep heating modality that converts electromagnetic energy to thermal energy. Frequencies approved for therapeutic microwave are 915 MHz (wavelength 33 cm) and 2,456 MHz (wavelength 12 cm). The lower frequency has the advantage of increased depth of penetration but also the disadvantages of greater beam dispersion and the requirement of larger applicators. If muscle heating is primary objective, 915-MHz applicators are preferable to 2,456-MHz applicators. Average temperatures of approximately 41°C at a depth of 1–3 cm have been demonstrated²⁴

- 7) **Hot thermal agents:** heat transferred from an object with direct contact to the body. Heat therapy include hot packs, heatwraps, hot/warm water immersion, sauna. Heat treatment increases metabolism in tissues, promotes blood circulation and reduces pain. The temperature of the heat therapy is generally 35–40°C.^{25 26}
- 8) **Cryotherapy:** cold is transferred from an object with direct contact to the body. Examples include cold packs, cold-water immersion ($\leq 15^{\circ}\text{C}$), ice massage, the novel modality of cryotherapy. Cryotherapy is a treatment involving very short exposures to extremely cold dry air to the whole patient or a treatment area (mean temperature of the cryotherapy chamber is at -30°C , -80 to -110°C , or $< -110^{\circ}\text{C}$). Cold treatment is thought to reduce swelling and cell metabolism, minimizing oedema, pain and injury.^{25 27}
- 9) **Therapeutic Ultrasound:** delivers energy to deep tissue sites through ultrasonic waves (often at frequencies of 1 or 3 MHz and intensities between 0.1 watts/cm² and 3 watts/cm²) using a crystal sound head. Treatment can be delivered in two forms, continuous (non- stop ultrasonic waves) and pulsed (intermittent ultrasonic waves^{22 28}). The treatment aim to increase tissue temperature and induce non-thermal physiological changes (such as cell permeability and cell growth), which are believed to promote soft tissue healing and muscle relaxation.²⁹

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CREDES Checklist:**Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]****Technology in Palliative Care (TIP): the identification of digital priorities for palliative care research using a modified Delphi method**

Items of reporting	Reported on page
<i>Purpose and rationale.</i> 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.	5 - 6
<i>Expert panel.</i> Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
<i>Description of the methods.</i> 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.	7-10
<i>Procedure.</i> 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.	6-9; Figure 1-2
<i>Definition and attainment of consensus.</i> It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
<i>Results.</i> 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.	10-12; Table 2; Appendix 2
<i>Discussion of limitations.</i> Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
<i>Adequacy of conclusions.</i> 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
<i>Publication and dissemination.</i> 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.	13-14

- 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: 684–706. doi:10.1177/0269216317690685

BMJ Open

Evidence-informed and consensus-based indications about SAFETY of Physical Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE PAMP): a national Delphi of healthcare scientific societies

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-075348.R1
Article Type:	Original research
Date Submitted by the Author:	30-Oct-2023
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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Rehabilitation medicine, Rheumatology, Sports and exercise medicine, Neurology, Urology
Keywords:	Physical Therapy Modalities, REHABILITATION MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, ORTHOPAEDIC & TRAUMA SURGERY, NEUROLOGY

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3 1 **Evidence-informed and consensus-based indications about SAFETY of Physical**
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6 2 **Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE**
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8 3 **PAMP): a national Delphi of healthcare scientific societies**
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3 **43 ABSTRACT: 272 words**
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5 **44 Objective:** A shared consensus on safety about Physical Agent Modalities (PAMs) in physiotherapy
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7 and rehabilitation is lacking. We aimed to develop evidence-informed and consensus-based
8
9 indications about the safety of PAMs.
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12 **47 Study design and setting:** A RAND-modified Delphi rounds' survey was used to reach a consensus.
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14 We established a steering committee of the Italian Association of Physiotherapy (Associazione
15
16 Italiana di Fisioterapia - AIFI) to identify areas and questions for developing indications about the
17
18 safety of the most commonly used PAMs in physiotherapy and rehabilitation. We invited 28 National
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20 Scientific and Technical Societies (STS), including forensics and lay members, as a multidisciplinary
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22 and multi-professional panel of experts to evaluate the proposed indications and formulate additional
23
24 inputs. The level of agreement was measured with a 9-point Likert scale. Consensus in the Delphi
25
26 rounds was assessed using the rating proportion with a threshold of 75%.
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30 **55 Results:** Seventeen (61%) out of 28 STS participated, involving their most representative members.
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32 Experts composing the panel were mainly clinicians (88%) reporting multiple expertise in
33
34 musculoskeletal (47%), pelvic floor (24%), neurological (18%) and lymphatic (6%) disorders with a
35
36 median experience of 30 years (IQR=17-36). Two Delphi rounds were necessary to reach a
37
38 consensus. The final approved criteria list comprised nine indications about the safety in adult patients
39
40 on nine PAMs (i.e., electrical stimulation neuromodulation, extracorporeal shock wave therapy, laser
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42 therapy, electromagnetic therapy, diathermy, hot thermal agents, cryotherapy and therapeutic
43
44 ultrasound) with a general note about populations subgroups.
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49 **63 Conclusions:** The resulting consensus-based indications inform patients, healthcare professionals and
50
51 policy-makers regarding the safe application of PAMs in physiotherapy and rehabilitation. Future
52
53 research is needed to extend this consensus on pediatric and frail patients.
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57 **66 Key Words:** Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation
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59 Medicine, Delphi Technique, Orthopedics, Neurology, Pelvic Floor, Musculoskeletal System
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3 68 **STRENGTH AND LIMITATIONS**
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7 69 • We developed a national electronic survey based on a Rand Delphi technique aiming
8
9 70 to identify, assess and modify indications for safe Physical Agent Modalities (PAMs)
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11 71 in rehabilitation.
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13 72 • Starting from a recent scoping review of the literature we refined evidence-informed
14
15 73 indications of rehabilitation for safe PAMs;
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17 74 • The multi-professional and multidisciplinary panel of experts rated and revised the
18
19 75 agreement of indications for safe PAMs rehabilitation in multiple rounds until
20
21 76 reaching consensus.
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23 77 • Indications were restricted to PAMs safety, not addressing their clinical effectiveness.
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82 INTRODUCTION

83 Physical agent modalities (PAMs) are extensively applied in physiotherapy and rehabilitation to elicit
84 therapeutic effects on tissues, including reducing swelling, alleviating pain, expediting the healing
85 process, and improving muscle tone.(1-4) Healthcare professionals from diverse medical specialties
86 can recommend and administer these treatments alongside other physiotherapy and rehabilitation
87 interventions. However, clinicians and patients must be informed about the safety of the proposed
88 treatments. Previous consensus regarding contraindications and precautions associated with using
89 PAMs from various organizations were released in the early 2000s.(5-7) Still, they have become
90 outdated in light of technological advancements of the last years.(8, 9) A recent scoping review of
91 the literature(10) examined several systematic reviews on the safety of commonly used PAMs (i.e.,
92 cryotherapy, electrical stimulation, transcutaneous electrical nerve stimulation, functional electrical
93 stimulation, extracorporeal shockwave therapy, laser therapy, magnetotherapy, pulsed
94 electromagnetic field and diathermy), revealing no important harm associated with their use.
95 Nevertheless, it is worth noting that adverse events may be underreported in primary studies(11, 12)
96 highlighting the need to integrate expert experience to bridge the current gaps between existing
97 literature and clinical practice. Therefore, the purpose of the SAFETY of Physical Agent Modalities
98 Practice (SAFE PAMP) consensus in physiotherapy and rehabilitation is to develop evidence-
99 informed and expert consensus-based indications about the safety of PAMs through a RAND Delphi
100 procedure. Our goal is to make patients, healthcare professionals and policy-makers aware about the
101 safe application of PAMs in physiotherapy and rehabilitation.

102 METHODS

103 Design

104 A RAND-modified Delphi rounds survey process was employed as the facilitation technique for
105 reaching expert consensus.(13, 14) Delphi technique is primarily used when the available knowledge
106 is incomplete or subject to uncertainty.(15) We followed the guidance on "Conducting and REporting
107 of DELphi Studies" (CREDES).(16, 17) This project is exempted from ethical approval according to
108 the "ethics and data protection" regulations of the European Commission.(18) More details are
109 reported in **Supplementary File 1**. The protocol was *a-priori* registered on the Open Science
110 Framework (OSF) online repository.(19)

111 The process consisted of four phases: (i) establishment of the steering committee and invitation of
112 national scientific and technical societies (STS) to constitute the panel of experts; (ii) generation of
113 indications using a comprehensive approach based on a published scoping review of existing
114 systematic reviews on PAMs safety in physiotherapy and rehabilitation medicine(10) as well as on
115 expertise from content experts of the steering committee; (iii) voting of indications from the panel of
116 experts through a national Delphi survey aiming to identify, assess and modify indications importance
117 for each field (e.g., musculoskeletal); (iv) an online workshop meeting to finalize the list of
118 indications reaching the final consensus. Finally, we planned to disseminate the final indications list
119 as good clinical practice (**Figure 1**).

[Figure 1]

123 **Phase I. Establishment of the steering committee and panel of experts**

124 *Steering committee*

125 In June 2022, the project team nominated a steering committee responsible for defining the list of
126 indications of safe PAMs, selecting national STS for expert participants, developing the Delphi
127 questionnaires, and analyzing responses from participants after each round.

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3 128 The steering committee involved 11 content experts from the Italian Association of Physiotherapy
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5 129 (Associazione Italiana di Fisioterapia – AIFI), a member of the World Physiotherapy (20). AIFI is
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8 130 the STS in Italy for the physiotherapy profession recognized by the Italian Minister of Health to
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10 131 produce clinical practice guidelines in the field.(21, 22)

11
12 132 To assure the external validity of the consensus process, the steering committee included two content
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14 133 experts on PAMs (MB, EP), three on rehabilitation of musculoskeletal disorders (GR, VG, SB), one
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17 134 on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF), and
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19 135 four methodologists (SGa, SGi, GC, LP).

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23 24 137 *Panel of experts*

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26 138 It is known that the diversity of a Delphi panel has an impact on the quality of the final
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28 139 recommendations. In contrast, no agreement on the panel size for Delphi studies exists. Panels of 20–
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31 140 30 participants are common.(23, 24) Thus, the steering committee invited all the national
32
33 141 multidisciplinary and multi-professional STS involved in physiotherapy and rehabilitation care
34
35 142 (n=26) and the STS dealing with forensics (n=1). These STS were identified from the published
36
37
38 143 endorsed by the Italian Ministry of Health and are recognized as the ones entitled to generate national
39
40 144 clinical practice guidelines.(21, 22) Each STS delegated their most representative member involved
41
42 145 in physiotherapy and rehabilitation care to join the panel of experts. The panel of expert members
43
44
45 146 was multidisciplinary and multi-professional, including clinicians, researchers, and healthcare
46
47 147 managers from different fields(24) (e.g., orthopedics, neurology). To represent patients' perspectives,
48
49 148 the panel also included a lay member from Cittadinazattiva,(25) the largest Italian patient advocate
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52 149 organization that promotes citizen activism for the protection of rights, the care of common goods,
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54 150 and support for people in conditions of weakness.

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57 58 152 ***Phase II. Generation of indications***

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153 The steering committee formulated indications ensuring that all the potentially relevant topics in the
154 field would be included in the initial list of questions for the first Delphi round. Each indication
155 included a statement regarding safety about the following PAMs:

- 156 1. Electrical stimulation
- 157 2. Neuromodulation, antalgic and interferential electrical currents
- 158 3. Extracorporeal shock wave therapy
- 159 4. Laser therapy
- 160 5. Electromagnetic therapy
- 161 6. Diathermy
- 162 7. Hot thermal agents
- 163 8. Cryotherapy
- 164 9. Therapeutic ultrasound

165 **Supplementary File 2** reported details about each included PAM.

166 Indications were developed for different target conditions/populations. PAMs are delivered by expert
167 healthcare professionals (who had undergone formal education and training) to ensure patient safety
168 in inpatient and outpatient settings. Indications were presented within the relevant rehabilitation field,
169 along with a list of patient conditions in which the PAMs were indicated as safe and supported by
170 evidence and clinical expertise. Evidence was recently summarized in a scoping review(10), which
171 gathered information about the safety of PAMs from 117 systematic reviews in physiotherapy and
172 rehabilitation medicine. Clinical expertise was assured by content experts of AIFI (e.g.,
173 musculoskeletal disorders, orthopedic and neurological physiotherapy and pelvic floor
174 rehabilitation).

176 ***Phase III. Voting of indications through Delphi Rounds***

177 We used an electronic Delphi process, allowing participants to submit responses anonymously and
178 independently without being biased by other participants' identities and responses. The steering

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3 179 committee reached the panel of experts using the SurveyMonkey online platform (Palo Alto, CA,
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5 180 USA; www.surveymonkey.com) and used a blinded electronic voting.

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8 181 The web-based survey consisted of two sections: the first regarded the participants' demographics
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10 182 (e.g., type of profession, the field of expertise, and years of experience), and the second covered how
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12 183 to vote for indications. The panel of experts evaluated the proposed indications and formulated
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14 184 additional comments using a free text box to ensure complete topic coverage. According to the RAND
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17 185 method, the panel of experts used a 9-point Likert scale (i.e., 1-3 = highly inappropriate, 4-6 =
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19 186 undecided, 7-9 = highly appropriate) for rating the level of concordance for each indication.

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21 187 In addition, the experts could abstain from voting, selecting the answer "Not my expertise" for
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24 188 indications they were not familiar with.

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26 189 A summary of results for each Delphi round was provided according to the total number of experts
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28 190 voting as feedback to inform panel members on consensus development with feedback and
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31 191 descriptive statistics incorporated for the next round. The panel of experts were asked to re-rate their
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33 192 evaluation in more rounds only for those indications needing clarification or for indications for which
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35 193 consensus (i.e., $\geq 75\%$ on a 7-9 points scale or 1-3 points scale) was not reached.

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37 194 An anonymous report of each round was provided to each expert, showing the distribution of
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40 195 responses for each indication with all additional comments provided in the free text box. Based on
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42 196 previous voting, indications were modified and presented for the next round. Up to three reminder
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44 197 emails for completion were sent to each component individually. Data collection occurred over 5
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47 198 months (June-November 2022).

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51 200 ***Phase IV. Workshop Meeting as last round***

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53 201 After reaching a consensus, the steering committee joined an online meeting to refine indications
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56 202 according to each expert contribution and to confirm which indications would be included in the final
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58 203 criteria list. Finally, the panel of experts was asked to vote on the final indications list for the closing
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60 204 audit procedure.

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45 206 **Definition and calculation of consensus**

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8 207 In agreement with the RAND appropriateness method, we adopted predefined criteria(26) to assess
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10 208 the consensus in the Delphi method using the proportion of ratings with a threshold of 75%.(27)

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12 209 Particularly:

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17 211 1. Consensus in: $\geq 75\%$ of participants scored the item as "critical" (score 7 to 9), and $< 15\%$
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19 212 scored the item as of "limited importance" (score 1 to 3)
- 20
21 213 2. Consensus out: $\geq 75\%$ of participants scored the item as of "limited importance" (score 1
22
23
24 214 to 3), and $< 15\%$ scored the item as "critical" (score 7 to 9)
- 25
26 215 3. No consensus: All other results.

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31 217 **Statistical Analysis**

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33 218 Descriptive statistics were used to describe general characteristic of participants, summarised as mean
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35 219 and standard deviation (SD) or median and interquartile range (IQR) and counts and percentage (%),
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38 220 as appropriate. Each statement was analysed quantitatively by the percentage of agreement ratings.

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42 222 **Role of the Funding Source**

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44
45 223 AIFI supported this research. The funder played no role in this study's design, conduct, or reporting.

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49 225 **Patient and public involvement**

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51 226 In this study, a patient representative participated in the panel of experts to rate the indications.

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227 RESULTS

228 Participants

229 Out of the 28 STS/organizations that were invited as panel of experts, two declined their interest in
230 participation, while nine did not provide a response. Finally, 17 STS/organizations (61%), each
231 represented by their most representative expert member, were included (**Figure 2**). The majority of
232 experts were clinicians (88.2%), with half having expertise in musculoskeletal disorders (47.1%).
233 Others were specialized in areas such as pelvic floor (23.5%), neurological (17.6%), lymphatic
234 disorders (5.9%), pediatrics (5.9%). The panel also included a forensic and a lay member as patient
235 representative. On average, experts had a median of 30 years of experience (interquartile range [IQR]:
236 17-36) in their respective fields. All general characteristics are reported in **Table 1**. No conflict of
237 interest was present (**Supplementary File 3**).

[Figure 2]

[Table 1]

242 Delphi rounds

243 Two rounds of Delphi were necessary to reach a consensus.

245 Round 1

246 Overall, 17 experts panel participants completed the survey. All indications passed the first round
247 with a consensus of 75% (**Table 2**). Five experts offered justifications for their choices (e.g., examples
248 of clinical practice) and gave important inputs for the indications. In particular, they raised concerns
249 about the safe use of PAMs in children. Additionally, they suggested refining the purpose of the
250 indications, emphasizing that the focus was on patient safety rather than provider safety.

[Table 2]

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3 253 *Round 2*
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5 254 Indications of Round 1 were reviewed according to panel comments for the subsequent assessment
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8 255 in Round 2, with a specific restriction on the adult population and a clearer emphasis on patient safety.
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10 256 Overall, 14 experts panel participants (82%) completed the survey of Round 2, and all the indications
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12 257 passed with a consensus out of 75%. (**Table 2**). One expert provided additional comments that
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14
15 258 included examples of expertise, which were subsequently integrated into the final list of indications.
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20 260 *Workshop Meeting*
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23 261 On September 27, 2022, nine experts panel participants (53%) joined the online meeting to discuss
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26 262 comments, justifications and highlights. A comprehensive digital presentation of Round 1 and Round
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28 263 2 findings were reported during the workshop. Here, the panel of experts suggested introducing a
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30 264 general note making explicit that indications on safety were not extended to different subgroups of
31
32
33 265 the population (e.g., children, adolescents, frail) due to lack of literature.

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35 266 The final list of indications with this general note was shared to reach final approval. All 17 experts
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37 267 panel participants (100%) approved and released the final indications list. One expert voted for the
38
39 268 option "Not my expertise" in the indication of the cryotherapy (**Table 2**). In **Appendix 1**, we reported
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42 269 the final criteria list released for good clinical practice with details of sources (evidence and expertise)
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44 270 and applications in different fields, clinical conditions or population settings.
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1 2 3 271 **DISCUSSION**

4 5 272 **Main findings**

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8 273 This study aimed to develop indications about the safety of PAMs in physical therapy and
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10 274 rehabilitation medicine. These indications were developed by a steering committee (including clinical
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12 275 and methodological experts) of AIFI and informed by 17 national STS with high expertise in different
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14 276 fields related to physiotherapy and rehabilitation (e.g., orthopedics, neurology), including a forensic
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17 277 scientist and a lay member in the representation of patients.

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19 278 The response rate was 61%, defined as a moderate participation.(28) All nine indications were
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22 279 approved in the first round, achieving an important consensus of over 75% agreement. Subsequent
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24 280 adjustments were made, particularly regarding age restrictions (i.e., limited to the adult population)
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26 281 and the refinement of expertise examples during a second round. After a workshop meeting, a general
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28 282 note was added to clarify that the use of PAMs should not be extended to specific population
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30 283 subgroups. All panel experts approved and released the final indications list with overall consensus.
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33 284 In summary, experts agreed on the safety of PAMs in the adult population (>18 years) when
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35 285 prescribed and applied by a healthcare professional (e.g., physiotherapist, physician) who is formed
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38 286 and informed, as required by education and licensure.

39 40 287 41 42 288 **Comparison with literature**

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44 289 This Delphi represents the most recent consensus on the safety of PAMs. Earlier consensus
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47 290 documents from different organizations were published in 2001,(5) 2006, (6) and 2010.(7) The
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49 291 Canadian guideline is the most comprehensive, covering contraindications and precautions for
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51 292 various PAMs. It involved experts from Canada and the United States, drawing on scientific evidence
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54 293 from multiple sources (including textbooks). However, it is important to note that the evidence was
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56 294 not collected by a clear and rigorous systematic process, potentially missing relevant information,
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58 295 and all these documents could be now outdated. Ideally, guidelines should be updated every three to
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60 296 five years or when new information become available.(29, 30) In 2018, the American Occupational

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3 297 Therapy Association issued a position paper(31) clarifying the appropriate use of PAMs in
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5 298 contemporary occupation-based occupational therapy practice, providing clinical case vignettes in
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8 299 their field. Others reported indications and contraindications about specific types of PAMs (e.g.,
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10 300 ESWT (32)). Many other societies, such as National Institute for Clinical Excellence (NICE), also
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12 301 offer specific clinical questions guidelines, and we cannot exclude that they can involve
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15 302 recommendations on PAMs (e.g., NG59 for low back pain(33)).
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17 303 18 19 304 **Implications for clinicians**

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21 305 Healthcare professionals are encouraged to use a comprehensive approach when using this Delphi
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24 306 consensus. Before proposing PAMs to patients, they must collect their medical history (e.g.,
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26 307 comorbidities) during the initial examination to better determine the diagnosis, prognosis, anticipated
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28 308 goals, and expected outcomes for identified impairments, activity limitations, and participation
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31 309 restrictions.(34) Then, they should incorporate the best research evidence, their clinical expertise, and
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33 310 patient values, needs, and preferences to propose effective treatments, balancing effectiveness and
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35 311 safety and informing patients about the possibility of trivial adverse events. For instance, a patient
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37 312 needing ESWT (as additional therapy to optimize clinical outcomes) should be informed about the
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40 313 possible occurrence of pain and erythema(10) at the application site. However, when evidence is
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42 314 lacking or moderate to severe harm is likely, caution is advised, and using PAM may be reconsidered.
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45 315 In fact, for safety purposes, developed indications were not generally extended to other subgroups,
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47 316 such as children, adolescents, and frail people, since limited and insufficient literature on harm is
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49 317 available. Some PAMs could influence the biological tissues in the growth phase in children and
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51 318 adolescents(35). This population has open growth plates, and their ligaments are stronger than the
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54 319 bony attachment sites, where they serve as connectors.(36) As a safety principle, decision-makers
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56 320 adopt precautionary measures when scientific evidence on harms is uncertain, and the population is
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58 321 vulnerable(37) (38, 39) (e.g., people historically considered at risk for being misused in clinical
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60 322 research or for whom a truly voluntary decision may be compromised from a regulatory perspective

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3 323 such as children or frail people). All these indications should be adhered to in conjunction with the
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5 324 guidelines and standards established by professional associations, equipment manufacturers' manuals
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8 325 and regulatory bodies.(40)
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12 327 **Implications for stakeholders**

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14 328 Good practices for the safety of patients should be managed by national agencies with a living
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17 329 monitoring system and shared in international initiatives such as the WHO Global Patient Safety
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19 330 Challenge Medication Safety(41) to strengthen systems and practices adopting corrective action
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22 331 within countries. Our consensus could be implemented into the Good Clinical Practices (GCPs) of
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24 332 the Italian Ministry of Health system by Istituto Superiore di Sanità (ISS) for the production of
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26 333 national guidelines and the National Agency for Regional Health Services (Agenzia Nazionale per i
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28 334 Servizi Sanitari Regionali – AGENAS)(42) for reporting any experience of improvement in patient
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31 335 safety made by healthcare organizations. National and international STS should facilitate
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33 336 disseminating CPG in different strategies. On the one hand, STS can promote local experiences of
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35 337 improvement in patient safety stored in shared repository (i.e., AGENAS)(42) in the light of evidence-
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38 338 based consensus (e.g., SAFE PAMP) to facilitate national collaboration between different
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40 339 institutions.

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42 340 On the other hand, STS can disseminate a plain, patient-oriented version of good clinical practice
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45 341 indications. We planned to develop patient and stakeholder versions of our evidence-informed and
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47 342 consensus-based indications. We aim to use a conceptual framework based on public health
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49 343 digitalization to put people and patients at the center of care delivery, supporting patient
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51 344 empowerment and making the healthcare system more efficient and safer.(43, 44) For example, we
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54 345 can plan stakeholder meetings, webinars, and education and counseling via pamphlets/videos/and
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56 346 social messages.

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348 **Implications for research**

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We believe that indications developed by the multidisciplinary and multi-professionally panel of experts can be generalized worldwide. These results could provide essential information for GCPs to produce national and international guidelines to improve patient safety and decrease avoidable harm related to interventions. Studies should convey their efforts to plan and adequately report adverse events before objectively estimating these harms. We call for multicentric randomized controlled trials based on the core outcome set also for harms and not only for benefit.(45) In addition, specific subgroups of populations should be studied. It is a serious matter to exclude a group from research eligibility, and this must be done only when no less restrictive option is sufficient to ensure protection from undue risk.(46)

Lastly, future studies can better explore our indications to ensure the safest and optimal modality application of the proposed PAMs (e.g., optimal voltage, amperage, frequency, current density, dose), especially for the subgroups mentioned (e.g., age of children).(47)

Strength and limitations

This is the first effort to provide guidance on the safety of PAMs in physiotherapy and rehabilitation. We strictly followed published guidelines for reporting and conduction. In addition, we *a-priori* publicly registered the consensus criterion used to determine agreement within the Delphi process. (26, 48) We adopted one of the most conservative thresholds for obtaining the consensus (75%)(27), and in all rounds, this was reached with a high percentage of agreements. However, some downsides should be acknowledged. We did not cover indications about the clinical effectiveness of PAMs, as our aim was to make patients, healthcare providers and policy-makers aware about the safety application of PAMs in clinical practice. As with all Delphi process, our study rely on national expert response and may not capture the full range of perspectives or experiences.(16, 49) However, we tried to involve multidisciplinary and multi-professional experts (as occurs in clinical practice guidelines) that enable confrontations in anonymity (avoiding negatively influencing outcomes and encouraging balanced consideration of ideas). Then, indications were developed starting from the scoping review,

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375 which mapped and summarized safety in population and intervention areas without assessing the
376 evidence level (e.g., grading of the certainty of evidence).(10) For instance, panel experts were not
377 confident about extending the indications to specific subgroups of patients (e.g., children, adolescents,
378 frail, etc.) for precautionary reasons of the lack of literature retrieved.

379

380 **CONCLUSION**

381 These evidence-based indications inform patients, healthcare professionals, and policy-makers about
382 the safety of a wide range of PAMs used in physiotherapy and rehabilitation after a comprehensive
383 clinical evaluation of patients' needs. This consensus can provide a basis for decision-making and
384 future research.

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3 385 **DECLARATIONS**
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5 386 **Author Contributions**
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7
8 387 Concept/idea/research design: S. Gianola, S. Bargerì, G. Castellini
9

10 388 Writing: S. Gianola, S. Bargerì, G. Castellini
11

12 389 Data collection: S. Gianola, S. Bargerì
13

14
15 390 Data analysis: S. Gianola, S. Bargerì
16

17 391 Project management: S. Gianola, S. Bargerì
18

19 392 Consultation (including review of manuscript before submitting): S. Gianola, S. Bargerì, L.
20

21 393 Pellicciari, S. Gambazza, G. Rossetini, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S.
22

23 394 Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators
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26 395
27
28 396 **Ethics Approval**
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31 397 This study was declared exempt from institutional review board review.
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35 399 **Disclosures**
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37 400 The authors and SAFE PAMP Collaborators declared they had no conflicts of interest.
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42 402 **Funding**
43

44 403 This work was supported and funded by Associazione Italiana di Fisioterapia (AIFI). The APC was
45
46 404 funded by AIFI. This research did not receive specific grant from any funding agency in the public,
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48 405 commercial or not-for-profit sectors.
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53 407 **Data sharing statement**
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56 408 Research data are stored in OSF repository <https://osf.io/w8kgs/> (19)
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60 410 **Manuscript word count:** 3275/4000

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411 **Figure 1.** Phases of the RAND Delphi process

412 **Figure 2.** Flow chart of Delphi process

413 **Table 1.** General characteristics of experts panels

414 **Table 2.** Agreement results for each round.

For peer review only

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3 536 **Tables**

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6 **Table 1. General characteristics of experts panel (n=17)**

Professional profile*	Responses N (%)
Clinicians	15 (88.2)
Researchers	7 (41.2)
Management	4 (23.5)
Field of expertise*	
Musculoskeletal	8 (47.1)
Pelvic floor disorders	4 (23.5)
Neurological	3 (17.6)
Lymphatic disorders	1 (5.9)
Paediatrics	1 (5.9)
Lay member (Patient)	1 (5.9)
Forensic member	1 (5.9)

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539 **Table 2. Agreement results for each round**

Indications about the safety of...	ROUND 1		ROUND 2		FINAL LIST	
	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Approved	NME
Electrical stimulation	85.7	7.1	85.7	0.0	100.0	0.0
Neuromodulation, antalgic, and interferential electrical currents	100.0	0.0	100.0	0.0	100.0	0.0
Extracorporeal shock wave therapy	83.3	0.0	76.9	0.0	100.0	0.0
Laser therapy	84.6	7.7	90.9	0.0	100.0	0.0
Electromagnetic therapy	81.8	9.1	76.9	0.0	100.0	0.0
Diathermy	90.0	10.0	84.6	0.0	100.0	0.0
Hot thermal agents	81.8	9.1	91.7	0.0	100.0	0.0
Cryotherapy	75.0	0.0	90.9	0.0	94.2	5.8
Therapeutic ultrasound	90.9	0.0	91.7	0.0	100.0	0.0
General note [^]	-	-	-	-	100.0	0.0

540 [^]added for the Final Criteria List

541 Abbreviations: NME: not my expertise

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542 **Appendix 1. Final criteria list**

543 **Introduction**

544 The indications are focused on adult population. Each indication was developed based on the
545 scientific literature (i.e., evidence) and experience of content experts of Associazione Italiana di
546 Fisioterapia - AIFI (i.e., expertise) with details for clinical conditions/populations in the relevant
547 rehabilitation fields.

548 *Target group:* indications were developed for adults (> 18 years). Physical agents modalities are
549 delivered by expert healthcare professionals (who had undergone formal education and training) to
550 ensure patient safety in both inpatient and outpatient settings.

551 *Condition/population of application:* indications were presented within the relevant rehabilitation
552 field according to *informed-evidence* and *expertise-based* consensus.

553 *Evidence:* This section has been defined on the basis of a scoping review of the literature conducted
554 by two independent reviewers that focused on safety of PAMs from 117 systematic reviews in
555 physiotherapy and rehabilitation medicine (10).

556 *Expertise:* this section has been formulated by the steering committee which included different
557 content experts of AIFI (e.g., neurological, musculoskeletal, pelvic floor, physical therapies), with
558 additional inputs from the multidisciplinary and multi-professional panel of experts.

559 **Final list of indications**

560 **1. Electrical stimulation (e.g., Functional electrical stimulation (FES), Neuromuscular**
561 **electrical stimulation (NMES), Electrical muscle stimulation (EMS)) is safe in the adult**
562 **population**

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3 563 - *in musculoskeletal disorders, especially in the following conditions:*

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5
6 564 o Evidence: neck pain, knee osteoarthritis, musculoskeletal pain, muscle hypotrophy.

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10 565 o Expertise: spinal osteoarthritis, knee osteoarthritis, musculoskeletal pain, knee
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12 566 osteoarthritis, muscle and joint pain.

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16 567 - *in pelvis-perineal disorders, especially in the following conditions:*

17
18
19 568 o Evidence: urinary incontinence, fecal incontinence, lower urinary tract symptoms in
20
21
22 569 postpartum women, overactive bladder.

23
24
25 570 o Expertise: prolapse, descending perineum syndrome, perineal hypotonia, bladder-sphincter
26
27 571 or anorectal dyssynergia, erectile dysfunction, premature ejaculation, abdominal diastasis.

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31 572 - *in neurological disorders, especially in the following conditions:*

32
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34 573 o Evidence: migraine, spasticity in multiple sclerosis, stroke, spinal cord injury.

35
36
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38 574 o Expertise: post-stroke urinary incontinence, neurogenic bowel dysfunction in spinal cord
39
40 575 injury, second motor neuron disease (e.g., Amyotrophic Lateral Sclerosis), muscular
41
42 576 dystrophies, head trauma, lesions of the peripheral nervous system.

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49 578 **2. Neuromodulation, antalgic and interferential electrical currents (e.g., TransCutaneous**
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52 579 **Electrical Nerve Stimulation (TENS), Transcutaneous Tibialis Posterior Stimulation (TTNS))**
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54 580 **are safe in the adult population**

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57 581 - *in musculoskeletal disorders, especially in the following conditions:*

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582 o Evidence: low back pain, neck pain, rotator cuff disease, whiplash-associated disorders,
583 fibromyalgia.

584 o Expertise: musculoskeletal pain, spine osteoarthritis, neuropathic pain.

585 - *in pelvis-perineal disorders, especially in the following conditions:*

586 o Evidence: overactive bladder, urinary incontinence, fecal incontinence, persistent pelvic
587 pain.

588 o Expertise: Urinary incontinence, pudendal neuralgia, constipation, urinary retention.

589 - *in neurological disorders, especially in the following conditions:*

590 o Evidence: neuropathic pain, stroke, multiple sclerosis, neurogenic bowel dysfunction after
591 spinal cord injury.

592 o Expertise: neurogenic bladder dysfunction after central and peripheral nervous system
593 injuries.

594 3. Extracorporeal shock wave therapy (radial and focal) is safe in the adult population

596 - *in musculoskeletal disorders, especially in the following conditions:*

597 o Evidence: soft tissue disorders of the lower limbs, knee tendinopathy, Achilles
598 tendinopathy, osteoarthritis, plantar fasciitis, rotator cuff disease, shoulder tendinopathy and
599 calcifications, acute fracture, orthopedic disorders, consolidation delays, other soft tissue
600 disorders.

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3 601 o Expertise: enthesopathies of the upper and lower limbs, calcifications, epicondylitis,
4
5 602 epitrocleitis, muscle injuries, muscle contractures, and trigger points.
6
7

8
9 603 - in neurological disorders, especially in the following conditions:
10
11

12 604 o Evidence: post-stroke lower limb spasticity, multiple sclerosis spasticity.
13
14

15 605 o Expertise: spasticity following head trauma, spasticity following spinal cord injury.
16
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19 606 - in pelvis-perineal disorders, especially in the following conditions:
20
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22

23 607 o Evidence: chronic prostatitis/chronic pelvic pain syndrome.
24
25

26 608 o Expertise: persistent female pelvic pain, Peronye disease.
27
28

29
30 609 Patients should be informed of the potential undesirable effects after applying ESWT. Indeed, a
31
32 610 recent literature review showed some expected mild adverse events, such as pain and erythema, at
33
34 611 the application site.(10)
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41 613 **4. Laser therapy (e.g., low-level laser therapy (LLLT), high-level laser therapy (HLLT)) is**
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43 614 **safe in the adult population**
44
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46
47 615 - in musculoskeletal disorders, especially in the following conditions:
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49

50 616 o Evidence: low back pain, Achilles tendinopathy, rotator cuff disease, capsulitis adhesive,
51
52 lower extremity soft tissue disorders, frozen shoulder, carpal tunnel syndrome, knee
53 617
54
55 618 osteoarthritis, neck pain, whiplash associated disorders.
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3 619 o Expertise: upper and lower limb tendinopathy, acute arthropathy, acute muscle and tendon
4
5 620 injuries, acute musculoskeletal pain. Upper and lower limb tendinopathy, acute arthropathy,
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7
8 621 acute muscle and tendon injury, and acute musculoskeletal pain.

9
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11 622 - *in pelvis-perineal disorders (extracavitary LLLT only), especially in the following conditions:*

12
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15 623 o Evidence: Urinary incontinence and pelvic organ prolapse, persistent pelvic pain.

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18 624 o Expertise: healing (episiotomies, laparotomies, lacerations, etc.), inflammatory pelvic
19
20 625 pain, edema or perineal hematomas.

21
22
23
24 626 - *in lymphatic disorders (LLLT only), especially in the following conditions:*

25
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27 627 o Evidence: secondary lymphoedema (e.g., breast cancer-related lymphedema).

28
29
30
31 628 o Expertise: lymphoedema

32
33
34 629 - *in neurological disorders (LLLT only), especially in the following conditions:*

35
36
37
38 630 o Evidence: Bell's palsy

39
40
41 631 o Expertise: stroke, multiple sclerosis, spinal cord injury, head trauma, peripheral nerve
42
43 632 injury.

44
45
46
47 633 **5. Electromagnetic therapy (e.g., Pulsed ElectroMagnetic Field Therapy (PEMFT), repetitive**
48
49 634 **Peripheral Magnetic Stimulation (rPMS)) is safe in the adult population**

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51
52
53 635 - *in musculoskeletal disorders, especially in the following conditions:*

54
55
56 636 o Evidence: neck pain, fractures, consolidation delays.

57
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59
60 637 o Expertise: osteoporosis, bone edema, algodystrophy, arthrosis.

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3 638 - in pelvis-perineal disorders, especially in the following conditions:
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6
7 639 o Evidence: persistent pelvic pain and urinary incontinence.
8
9

10 640 o Expertise: fecal incontinence, prolapse, descending perineum syndrome, perineal
11
12 641 hypotonia, vesico-sphincteric or anorectal dyssynergia, pudendal neuralgia, pelvic pain
13
14 642 acute, erectile dysfunction, premature ejaculation, diastasis recti.
15
16
17

18 643 **6. Diathermy (e.g., Short Wave Tecar Therapy) is safe in the adult population**

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20

21
22 644 - in musculoskeletal disorders, especially in the following conditions:
23
24

25 645 o Evidence: rotator cuff disease, knee osteoarthritis.
26
27

28
29 646 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-
30
31 647 acute), osteoarthritis, muscle contractures, trigger points.
32
33

34 648 - in pelvis-perineal disorders, especially in the following conditions:
35
36
37

38 649 o Evidence: inflammatory pelvic pain, persistent pelvic pain, sexual dysfunction (Peronye's
39
40 650 disease).
41
42

43
44 651 o Expertise: prolapse, stress urinary incontinence, scarring (episiotomies, laparotomies,
45
46 652 lacerations, etc.), perineal edema or hematoma, vulvovaginal dystrophy and dryness,
47
48 653 abdominal diastasis.
49
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51 654 **7. Hot thermal agent modalities (e.g., drug-free heat wrap) are safe in the adult population**

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55 655 - in musculoskeletal disorders, especially in the following conditions:
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57

58
59 656 o Evidence: groin pain, low back pain.
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- 1
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3 657 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-
4
5 658 acute), osteoarthritis
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12 **8. Cryotherapy (e.g., ice or liquid nitrogen) is safe in the adult population**
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16 661 - *in musculoskeletal disorders, especially in the following conditions:*
17

18
19 662 o Evidence: arthroscopy, reconstruction of the anterior cruciate ligament, post-surgery.
20

21
22
23 663 o Expertise: Delayed Onset Muscle Soreness (DOMS)/Delayed Onset Muscle Soreness
24
25 664 (DOMER), post-surgery, post-trauma (48h).
26

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29 665

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31
32 **9. Therapeutic Ultrasound is safe in the adult population**
33

34
35 667 - *in musculoskeletal disorders, especially in the following conditions:*
36

37
38
39 668 o Evidence: back pain, neck pain, carpal tunnel, rotator cuff disorder, lower limb soft-tissue
40
41 669 disorder, knee osteoarthritis, fracture, acute fracture, ankle fracture, ankle and knee sprains,
42

43
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45 670 o Expertise: hand and foot osteoarthritis, calcifications, enthesitis.
46

47
48 **General notes and considerations related to subgroups:**
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51
52 672 Following a confirmed clinical prescription, applying the above physical therapies is safe in the
53
54 673 adult population (>18 years) under the supervision of an expert operator. For precautionary reasons,
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56 674 these indications are not extended to other subgroups of patients (e.g., children, adolescents, frail,
57
58
59 675 etc.) since insufficient literature is available.
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For peer review only

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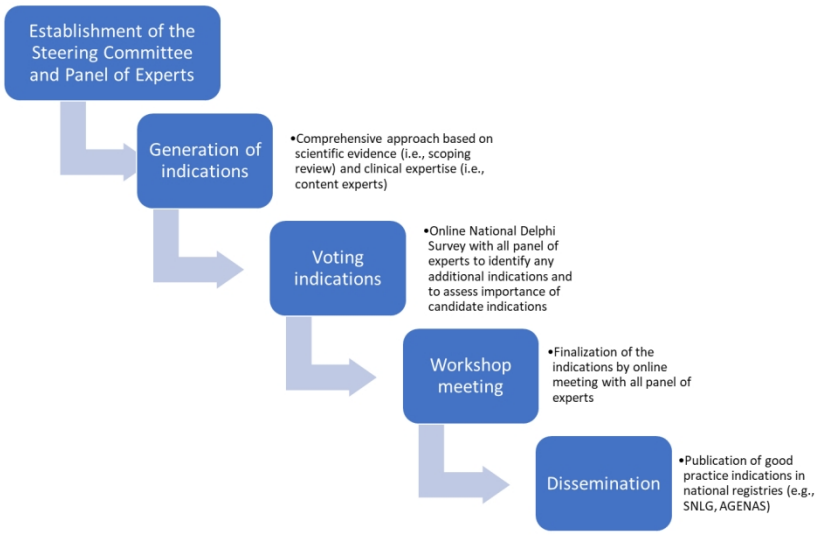


Figure 1

282x150mm (150 x 150 DPI)

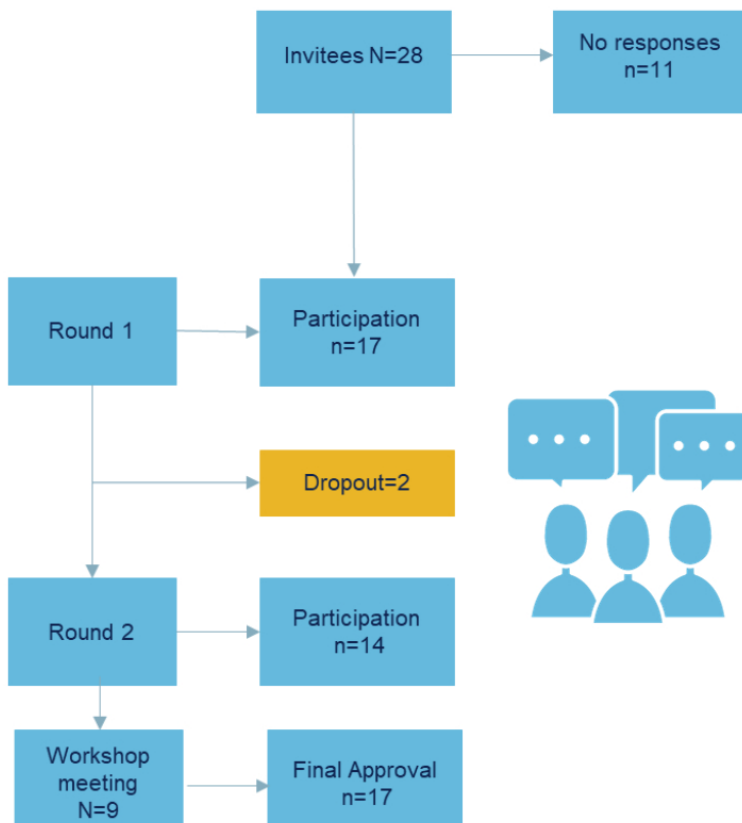


Figure 2

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Supplementary Files

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Supplementary File 1. Ethical considerations

Participation in the Delphi survey is voluntary and by invitation. The questionnaire includes a beginning section to acquire consent and privacy for data processing. Participants are informed that the responses will have 'remained total confidentiality according to the Regulation on the protection of personal data' 679/2016 of the European Union, and that the results will be used for research purposes and a document shared at the corporate level¹. The interested party may be interested in the rights provided for by art. 15, 16, 17, 18, 20, 21 and 22 of the Regulation mentioned above.

Database randomization and differential privacy access were achieved. In addition, "anonymization" by generalizing was performed.² The study project and data collection were managed and anonymously entrusted by the Unit of Clinical Epidemiology of IRCCS Istituto Ortopedico Galeazzi based in Milano. The data subject cannot be re-identified and is therefore outside the scope of the data protection law³.

The row dataset was accessible to two researchers (SG, SB) excluded from participation in Delphi for the quantitative and qualitative analyses. This practice complies with the European standards for the use of aggregative data where the data subject cannot be re-identified, are not personal data and are therefore outside the scope of data protection law³. The final report only contains aggregate data. In the final document, we reported the names of the participants who have completed all rounds and gave their consent to disclose their names.

Supplementary File 2. Physical agent modalities description

1) **Electrical stimulation:** electrotherapeutic currents and waveforms to facilitate neuromuscular or sensory activity to improve muscle strength and reeducate muscle function.⁴

- Neuromuscular electrical stimulation (NMES): use of pulsed currents to stimulate motor nerves, which in turn produce tetanic contractions of the neuromuscular spindles, with or without joint movement.⁵
- Functional Electrical Stimulation (FES) uses electrical pulses to stimulate motor neurons or denervated muscle fibers directly to elicit a contraction during a functional activity (e.g., gait). FES is used in the treatment of orthopedic and neurological conditions.⁶

2) **Neuromodulation, analgic and interferential electrical currents :** electrotherapeutic currents and waveforms to influence physiological effects on the patient's body structures and functions aiming to modulate pain.⁴

- Transcutaneous electrical nerve stimulation (TENS): delivers electrical stimulation via electrodes placed over the intact skin surface near the source of pain to produce analgesia or hypoalgesia. A wide variety of pulsed waveforms are used, with frequencies typically in the range of 1-100Hz. The intensities are set to produce sensory stimulations alone or in combination with motor stimulations to produce muscle twitches (acupuncture-like TENS).⁷
- Transcutaneous Tibialis Posterior Stimulation (TTNS): a form of neuromodulation involving the use of electrical impulses to address urinary symptoms (e.g. overactive bladder) with inhibitory action on neurons of the spinothalamic tract (S2-S3).⁸
- Interferential current (IC): involves crossing two medium frequency currents (most commonly 4000 Hz), which reportedly generates a low-frequency 'beating' (amplitude-modulated) effect at between 0 and 150 Hz in the deep tissues.⁹ These beat frequencies are believed to decrease pain, increase circulation and block nerve conduction.

3) **Extracorporeal shock wave therapy:** a nonsurgical treatment that uses the phenomenon of mechanotransduction (i.e., adapting cells biochemical activity, influencing cells migration, proliferation, differentiation and apoptosis)^{10 11} to treat various musculoskeletal conditions (e.g., plantar fasciitis; tennis elbow). Shock wave therapy can be either extracorporeal or radial.¹²

- Extracorporeal shock wave therapy (ESWT) involves passing sound waves (or shock waves) through the skin to the affected area. Shock waves are single pulsed acoustic or sonic waves, which dissipate mechanical energy at the interface of two substances with different acoustic impedance.¹³ They are produced by generators of an electrical energy source and require an electroacoustic conversion mechanism and a focusing

1
2
3 device. Three types of systems can be distinguished based upon the sound source:
4 electrohydraulic, electromagnetic and piezoelectric systems. Various doses appear to
5 be used, with no apparent consensus on the minimum therapeutic dose. As defined
6 defined by Cacchio 2006¹⁴ as low-energy shock waves is less than 0.1 mJ/mm² and
7 high-energy shock waves: is 0.2 mJ/mm² to 0.4 mJ/mm²).

- 8
9 - Radial shock wave therapy (RSWT) is generated through the acceleration of a
10 projectile inside the handpiece of the treatment device and then transmitted radially
11 from the tip of the applicator to the target zone. Radial shock waves show a lower
12 peak pressure and a considerably longer rise time than extracorporeal shock waves.
13 In RSWT, the focal point is not centred on a target zone, as occurs in focal ESWT,
14 but on the tip of the applicator.¹⁴

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17 **4) Laser therapy:** light source treatment, non-invasive, widely used to treat various
18 musculoskeletal conditions.

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20
21 - Low-level laser therapy (LLLT) generates a beam of light with a particular
22 wavelength that can deliver light energy to tissue depths below the dermis¹⁵.
23 Studies suggest that LLLT contributes to pain relief by reducing pro-inflammatory
24 cytokines¹⁶. The effects of LLLT are considered to be dependent on dosage,
25 wavelength, site and duration of treatment.^{15 16}
- 26
27
28 - high level laser therapy (HLLT): laser with an output power greater than 500 mW
29 or 0.5 Watts. HLLT creates heat on the surface of the skin due to their higher power
30 density (irradiance).¹⁷

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33
34 **5) Electromagnetic therapy:** based on Faraday's law of electromagnetic induction, to promote
35 bone healing, treat osteoarthritis and inflammatory diseases of the musculoskeletal system,
36 alleviate pain, enhance healing of ulcers and reduce spasticity¹⁸.

37
38 - Pulsed Electromagnetic Field therapy (PEMF), which involves the delivery of pulsing (that
39 is 'on-off') low-frequency magnetic fields through the body, which is believed to provide
40 temporary pain relief by influencing tissue generation and cell proliferation.¹⁹

41
42
43 - Repetitive magnetic stimulation (rMS), which allows the transcutaneous induction of nerve
44 stimulating electric currents. This technique requires extremely strong and sharp magnetic
45 impulses (for example 15,000 amperes peak current; 2.5 T field strength; < 1 msec) applied
46 by specially designed coils (< 10 cm) over the target area. Modern devices allow the repetition
47 of up to 60 impulses per second. Mainly developed to study and influence brain functions,
48 rMS also stimulates spinal chord fibres and peripheral nerves. Initial studies used peripheral
49 rMS for therapeutic reasons, such as in myofascial pain syndrome²⁰. Since the resulting small
50 electric impulses are the nerve stimulating factor, rMS effects may be similar to TENS.

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53
54 **6) Shortwave and microwave Diathermy**

- 55
56 - Tecartherapy or radiofrequency diathermy (RFD) is a non-invasive therapy and
57 consists in the emission of high-frequency electromagnetic waves which increase
58 tissue metabolism. This process promotes tissue repair and affects pain
59 sensitivity.^{21 22 23}

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- Microwave diathermy: a deep heating modality that converts electromagnetic energy to thermal energy. Frequencies approved for therapeutic microwave are 915 MHz (wavelength 33 cm) and 2,456 MHz (wavelength 12 cm). The lower frequency has the advantage of increased depth of penetration but also the disadvantages of greater beam dispersion and the requirement of larger applicators. If muscle heating is primary objective, 915-MHz applicators are preferable to 2,456-MHz applicators. Average temperatures of approximately 41°C at a depth of 1–3 cm have been demonstrated²⁴

- 7) **Hot thermal agents:** heat transferred from an object with direct contact to the body. Heat therapy include hot packs, heatwraps, hot/warm water immersion, sauna. Heat treatment increases metabolism in tissues, promotes blood circulation and reduces pain. The temperature of the heat therapy is generally 35–40°C.^{25 26}
- 8) **Cryotherapy:** cold is transferred from an object with direct contact to the body. Examples include cold packs, cold-water immersion ($\leq 15^{\circ}\text{C}$), ice massage, the novel modality of cryotherapy. Cryotherapy is a treatment involving very short exposures to extremely cold dry air to the whole patient or a treatment area (mean temperature of the cryotherapy chamber is at -30°C , -80 to -110°C , or $< -110^{\circ}\text{C}$). Cold treatment is thought to reduce swelling and cell metabolism, minimizing oedema, pain and injury.^{25 27}
- 9) **Therapeutic Ultrasound:** delivers energy to deep tissue sites through ultrasonic waves (often at frequencies of 1 or 3 MHz and intensities between 0.1 watts/cm² and 3 watts/cm²) using a crystal sound head. Treatment can be delivered in two forms, continuous (non- stop ultrasonic waves) and pulsed (intermittent ultrasonic waves^{22 28}). The treatment aim to increase tissue temperature and induce non-thermal physiological changes (such as cell permeability and cell growth), which are believed to promote soft tissue healing and muscle relaxation.²⁹

Supplementary File 3. SAFE PAMP Collaborators

Name and Surname	Affiliations	STS	COI
Armando Perrotta	IRCCS Neuromed, Pozzilli (IS)	Società Italiana per lo Studio delle Cefalee (SISC)	None
Viviana Rosati	A.U.O. Policlinico Umberto I	Società Italiana di Riabilitazione Neurologica (SIRN)	None
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Giancarlo Tancredi	Pediatric Department. Sapienza Università di Roma	Società Italiana di Pediatria (SIP)	None

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Monica Pierattelli	Presidente SICuPP Toscana, Pediatra di libera scelta Campi Bisenzio (FI)	Societa' Italiana Delle Cure Primarie Pediatriche (SICuPP)	None
Carla Berliri	Cittadinanzattiva- APS - Sede Nazionale -Staff area Salute - Tribunale per i Diritti del Malato - Politiche della Salute-	Cittadinanzattiva - APS	None

Abbreviations: COI, Conflict of Interest; STS, Scientific and Technical Societies

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CREDES Checklist:**Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]****Technology in Palliative Care (TIP): the identification of digital priorities for palliative care research using a modified Delphi method**

Items of reporting	Reported on page
<i>Purpose and rationale.</i> 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.	5 - 6
<i>Expert panel.</i> Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
<i>Description of the methods.</i> 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.	7-10
<i>Procedure.</i> 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.	6-9; Figure 1-2
<i>Definition and attainment of consensus.</i> It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
<i>Results.</i> 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.	11-12; Table 2; Appendix 2
<i>Discussion of limitations.</i> Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
<i>Adequacy of conclusions.</i> 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
<i>Publication and dissemination.</i> 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.	13-14

- 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: 684–706. doi:10.1177/0269216317690685

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-075348.R2
Article Type:	Original research
Date Submitted by the Author:	29-Jan-2024
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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Rehabilitation medicine, Rheumatology, Sports and exercise medicine, Neurology, Urology
Keywords:	Physical Therapy Modalities, REHABILITATION MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, ORTHOPAEDIC & TRAUMA SURGERY, NEUROLOGY

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3 1 **Evidence-informed and consensus-based statements about SAFETY of Physical**
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6 2 **Agent Modalities Practice in physiotherapy and rehabilitation medicine (SAFE**
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8 3 **PAMP): a national Delphi of healthcare scientific societies**
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3 46 **ABSTRACT: 280 words**

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5 47 **Objective:** A shared consensus on safety about Physical Agent Modalities (PAMs) practice in
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8 48 physiotherapy and rehabilitation is lacking. We aimed to develop evidence-informed and consensus-
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10 49 based statements about the safety of PAMs.

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12 50 **Study design and setting:** A RAND-modified Delphi rounds' survey was used to reach a consensus.
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14 51 We established a steering committee of the Italian Association of Physiotherapy (Associazione
15 52 Italiana di Fisioterapia - AIFI) to identify areas and questions for developing statements about the
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17 52 safety of the most commonly used PAMs in physiotherapy and rehabilitation. We invited 28 National
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19 53 Scientific and Technical Societies, including forensics and lay members, as a multidisciplinary and
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21 54 multi-professional panel of experts to evaluate the nine proposed statements and formulate additional
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23 55 inputs. The level of agreement was measured with a 9-point Likert scale. Consensus in the Delphi
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25 56 rounds was assessed using the rating proportion with a threshold of 75%.
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30 58 **Results:** Seventeen (61%) out of 28 Scientific and Technical Societies participated, involving their
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32 59 most representative members. Experts composing the panel were mainly clinicians (88%) reporting
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34 60 multiple expertise in musculoskeletal (47%), pelvic floor (24%), neurological (18%) and lymphatic
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36 61 (6%) disorders with a median experience of 30 years (IQR=17-36). Two Delphi rounds were
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38 62 necessary to reach a consensus. The final approved criteria list comprised nine statements about the
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40 63 safety in adult patients on nine PAMs (i.e., electrical stimulation neuromodulation, extracorporeal
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42 64 shock wave therapy, laser therapy, electromagnetic therapy, diathermy, hot thermal agents,
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44 65 cryotherapy and therapeutic ultrasound) with a general note about populations subgroups.
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49 66 **Conclusions:** The resulting consensus-based statements inform patients, healthcare professionals and
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51 67 policy-makers regarding the safe application of PAMs in physiotherapy and rehabilitation practice.
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53 68 Future research is needed to extend this consensus on pediatric and frail patients such as
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55 69 immunocompromised patients.
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3 70 **Key Words:** Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation
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5 71 Medicine, Delphi Technique, Orthopedics, Neurology, Pelvic Floor, Musculoskeletal System
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9 72 **STRENGTH AND LIMITATIONS**
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- 12 73 • Starting from a recent scoping review of the literature, we aimed to acknowledge evidence-
13 informed indications of rehabilitation for safe PAMs;
14 74
15 75 • Indications on the safety of physical agents (PAMs) were developed by a steering committee
16 for different target conditions in physiotherapy and rehabilitation practice and supported by
17 76 evidence and clinical expertise
18 77
19 78 • We strictly followed published guidelines for reporting and conduction, with a-priori publicly
20 79 registered protocol to determine agreement within the Delphi process.
21 80
22 81 • The multi-professional and multidisciplinary panel of experts rated and revised the agreement
23 of indications for safe PAMs rehabilitation in multiple rounds until reaching a consensus.
24 82
25 83 • Indications did not cover the clinical effectiveness of PAMs as well as specific subgroups for
26 which evidence and expertise were not available.
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84 INTRODUCTION

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86 Physical agent modalities (PAMs) are extensively applied in physiotherapy and rehabilitation practice
87 to elicit therapeutic effects on tissues, including reducing swelling, alleviating pain, expediting the
88 healing process, and improving muscle tone.(1-4) Healthcare professionals from diverse medical
89 specialties can recommend and administer these treatments alongside other physiotherapy and
90 rehabilitation interventions. However, clinicians and patients must be informed about the safety of
91 the proposed treatments. Previous consensus regarding contraindications and precautions associated
92 with using PAMs from various organizations were released in the early 2000s.(5-7) Still, they have
93 become outdated in light of technological advancements of the last years.(8, 9) A recent scoping
94 review of the literature(10) examined several systematic reviews on the safety of commonly used
95 PAMs (i.e., cryotherapy, electrical stimulation, transcutaneous electrical nerve stimulation, functional
96 electrical stimulation, extracorporeal shockwave therapy, laser therapy, magnetotherapy, pulsed
97 electromagnetic field and diathermy), revealing no important harm associated with their use.
98 Nevertheless, it is worth noting that adverse events may be underreported in primary studies(11, 12)
99 highlighting the need to integrate expert experience to bridge the current gaps between existing
100 literature and clinical practice. Therefore, the purpose of the SAFETY of Physical Agent Modalities
101 Practice (SAFE PAMP) consensus in physiotherapy and rehabilitation is to develop evidence-
102 informed and expert consensus-based statements about the safety of PAMs through a RAND Delphi
103 procedure. Our goal is to make patients, healthcare professionals and policy-makers aware about the
104 safe application of PAMs in physiotherapy and rehabilitation.

105 METHODS

106 Design

107 A RAND-modified Delphi rounds survey process was employed as the facilitation technique for
108 reaching expert consensus.(13, 14) Delphi technique is primarily used when the available knowledge
109 is incomplete or subject to uncertainty.(15) We followed the guidance on "Conducting and REporting
110 of DELphi Studies" (CREDES).(16, 17) This project is exempted from ethical approval according to
111 the "ethics and data protection" regulations of the European Commission.(18) More details are
112 reported in **Supplementary File 1**. The protocol was *a-priori* registered on the Open Science
113 Framework (OSF) online repository.(19)

114 The process consisted of four phases: (i) establishment of the steering committee and invitation of
115 national scientific and technical societies to constitute the panel of experts; (ii) generation of
116 statements using a comprehensive approach based on a published scoping review of existing
117 systematic reviews on PAMs safety in physiotherapy and rehabilitation medicine(10) as well as on
118 expertise from content experts of the steering committee; (iii) rating of statements from the panel of
119 experts through a national Delphi survey aiming to identify, assess and modify statements importance
120 for each field (e.g., musculoskeletal); (iv) an online workshop meeting to finalize the list of statements
121 reaching the final consensus. Finally, we planned to disseminate the final statements list as good
122 clinical practice (**Figure 1**).

[Figure 1]

126 **Phase I. Establishment of the steering committee and panel of experts**

127 *Steering committee*

128 In June 2022, the project team nominated a steering committee responsible for defining the list of
129 statements of safe PAMs, selecting national scientific and technical societies for expert participants,
130 developing the Delphi questionnaires, and analyzing responses from participants after each round.

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3 131 The steering committee involved 11 content experts from the Italian Association of Physiotherapy
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5 132 (Associazione Italiana di Fisioterapia – AIFI), a member of the World Physiotherapy (20). AIFI is
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8 133 the scientific and technical societies in Italy for the physiotherapy profession recognized by the Italian
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10 134 Minister of Health to produce clinical practice guidelines in the field.(21, 22)

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12 135 To assure the external validity of the consensus process, the steering committee included two content
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15 136 experts on PAMs (MB, EP), three on rehabilitation of musculoskeletal disorders (GR, VG, SB), one
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17 137 on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF), and
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19 138 four methodologists (SGa, SGi, GC, LP).

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23 24 140 *Panel of experts*

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26 141 It is known that the diversity of a Delphi panel has an impact on the quality of the final
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29 142 recommendations. In contrast, no agreement on the panel size for Delphi studies exists. Panels of 20–
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31 143 30 participants are common.(23, 24) Thus, the steering committee invited all the national
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33 144 multidisciplinary and multi-professional scientific and technical societies involved in physiotherapy
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35 145 and rehabilitation care (n=26) and the societies dealing with forensics (n=1). These societies were
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38 146 identified from the published endorsed by the Italian Ministry of Health and are recognized as the
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40 147 ones entitled to generate national clinical practice guidelines.(21, 22) Each society delegated their
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42 148 most representative member involved in physiotherapy and rehabilitation care to join the panel of
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45 149 experts. The panel of expert members was multidisciplinary and multi-professional, including
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47 150 clinicians, researchers, and healthcare managers from different fields(24) (e.g., orthopedics,
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49 151 neurology). To represent patients' perspectives, the panel also included a lay member from
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52 152 Cittadinazattiva,(25) the largest Italian patient advocate organization that promotes citizen activism
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54 153 for the protection of rights, the care of common goods, and support for people in conditions of
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56 154 weakness.

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59 60 156 ***Phase II. Generation of statements***

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3 157 Firstly, the steering committee formulated statements aimed at safety based on evidence and clinical
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5 158 expertise. Particularly, evidence was summarized from a published scoping review and its
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8 159 supplementary materials,(10) which gathered information about the safety of the nine PAMs from
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10 160 117 systematic reviews in physiotherapy and rehabilitation medicine (e.g. safety of PAMs for low
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12 161 back pain, osteoarthritis, stroke, urinary incontinence). Clinical expertise was assured by content
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15 162 experts of AIFI (e.g., musculoskeletal disorders, orthopedic and neurological physiotherapy and
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17 163 pelvic floor rehabilitation) adding examples of clinical conditions for which they commonly safely
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19 164 apply PAMs in their specific field. Disagreements between experts were resolved through discussion.
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21
22 165 The steering committee formulated statements for each PAM (with distinction of evidence and
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24 166 expertise) ensuring that all the potentially relevant topics in the field would be included in the initial
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26 167 list of questions for the first Delphi round (**Supplementary File 2** reported details about each included
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28 168 PAM). Each statement included a statement regarding safety about the following PAMs:

- 30 169 1. Electrical stimulation
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33 170 2. Neuromodulation, antalgic and interferential electrical currents
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35 171 3. Extracorporeal shock wave therapy
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38 172 4. Laser therapy
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40 173 5. Electromagnetic therapy
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42 174 6. Diathermy
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44 175 7. Hot thermal agents
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47 176 8. Cryotherapy
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49 177 9. Therapeutic ultrasound
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51 178 Statements were developed for different target conditions. PAMs are delivered by expert healthcare
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54 179 professionals (who had undergone formal education and training) to ensure patient safety in inpatient
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56 180 and outpatient settings. Statements were presented within the relevant rehabilitation field, along with
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58 181 a list of patient conditions in which the PAMs were indicated as safe and supported by evidence and
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60 182 clinical expertise.

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Phase III. Rating of statements through Delphi Rounds

We used an electronic Delphi process, allowing participants to submit responses anonymously and independently without being biased by other participants' identities and responses. The steering committee reached the panel of experts using the SurveyMonkey online platform (Palo Alto, CA, USA; www.surveymonkey.com) and used a blinded electronic rating.

The web-based survey consisted of two sections: the first regarded the participants' demographics (e.g., type of profession, the field of expertise, and years of experience), and the second the rating for statements. The panel of experts evaluated the proposed statements and formulated additional comments using a free text box to ensure complete topic coverage. According to the RAND method, the panel of experts used a 9-point Likert scale (i.e., 1-3 = highly inappropriate, 4-6 = undecided, 7-9 = highly appropriate) for rating the level of concordance for each statement.

In addition, the experts could abstain from rating, selecting the answer "Not my expertise" for statements they were not familiar with.

A summary of results for each Delphi round was provided according to the total number of experts rating as feedback to inform panel members on consensus development with feedback and descriptive statistics incorporated for the next round. The panel of experts were asked to re-rate their evaluation in more rounds only for those statements needing clarification or for statements for which consensus (i.e., $\geq 75\%$ on a 7-9 points scale or 1-3 points scale) was not reached.

An anonymous report of each round was provided to each expert, showing the distribution of responses for each statement with all additional comments provided in the free text box. Based on previous rating, statements were modified and presented for the next round. Up to three reminder emails for completion were sent to each component individually. Data collection occurred over 5 months (June-November 2022).

Phase IV. Workshop Meeting as last round

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3 209 After reaching a consensus, the steering committee joined an online meeting to refine statements
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5 210 according to each expert contribution and to confirm which statements would be included in the final
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8 211 criteria list. Finally, the panel of experts was asked to rate on the final statements list for the closing
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10 212 audit procedure.

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13 14 15 214 **Definition and calculation of consensus**

16
17 215 In agreement with the RAND appropriateness method, we adopted predefined criteria(26) to assess
18
19 216 the consensus in the Delphi method using the proportion of ratings with a threshold of 75%.(27)

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22 217 Particularly:

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26 219 1. Consensus in: $\geq 75\%$ of participants scored the item as "highly appropriate" (score 7 to 9),
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28 220 and $< 15\%$ scored the item as of "highly inappropriate" (score 1 to 3)

29
30 221 2. Consensus out: $\geq 75\%$ of participants scored the item as of "highly inappropriate" (score
31
32 222 1 to 3), and $< 15\%$ scored the item as "highly appropriate" (score 7 to 9)

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34
35 223 3. No consensus: All other results.
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39 40 225 **Statistical Analysis**

41
42 226 Descriptive statistics were used to describe general characteristic of participants, summarised as
43
44 227 median and interquartile range (IQR) and counts and percentage (%), as appropriate. Each statement
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46
47 228 was analysed quantitatively by the percentage of agreement ratings.

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50 51 230 **Role of the Funding Source**

52
53 231 AIFI supported this research. The funder played no role in this study's design, conduct, or reporting.
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57 58 233 **Patient and public involvement**

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60 234 In this study, a patient representative participated in the panel of experts to rate the statements.

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235 RESULTS

236 Participants

237 Out of the 28 scientific and technical societies/organizations that were invited as panel of experts,
238 two declined their interest in participation, while nine did not provide a response. Finally, 17
239 societies/organizations (invitation rate: 61%), each represented by their most representative expert
240 member, were included (**Figure 2**). The majority of experts were clinicians (88.2%), with half having
241 expertise in musculoskeletal disorders (47.1%). Others were specialized in areas such as pelvic floor
242 (23.5%), neurological (17.6%), lymphatic disorders (5.9%), pediatrics (5.9%). The panel also
243 included a forensic and a lay member as patient representative. On average, experts had a median of
244 30 years of experience (IQR 17-36) in their respective fields. All general characteristics are reported
245 in **Table 1**. No conflict of interest was present (**Supplementary File 3**).

[Figure 2]

[Table 1]

250 Delphi rounds

251 Two rounds of Delphi were necessary to reach a consensus.

253 Round 1

254 Overall, 17 experts panel participants completed the survey (participation rate: 100%). All statements
255 passed the first round with a consensus of 75% (**Table 2**). Five experts offered justifications for their
256 choices (e.g., examples of clinical practice) and gave important inputs for the statements. In particular,
257 most of them raised concerns about the safe use of PAMs in children. Additionally, they suggested
258 refining the purpose of the statements, emphasizing that the focus was on patient safety rather than
259 provider safety. Some experts reported uncertainties about safe use of PAMs according to their
260 experiences. For examples, one expert reported the possible mild skin irritation in the hot thermal

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3 261 therapies and another one suggested caution in the use of cryotherapy due to risk of cold burns,
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5 262 especially if the patients are not well informed or supervised. Then, one expert was uncertain about
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8 263 safety in persistent use of electromagnetic therapies for long-terms. Some experts suggested safe use
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10 264 of PAMS in other fields of applications such as the use of diathermia in the dermatological field for
11
12 265 Lichen Sclerosus, that was out of our purposes. All comments were considered in the release of the
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15 266 statements (**Supplementary File 4**).

16
17 267 [Table 2]
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21 269 *Round 2*

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23 270 Statements of Round 1 were reviewed according to panel comments for the subsequent assessment
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26 271 in Round 2, with a specific restriction on the adult population and a clearer emphasis on patient safety.

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28 272 1. Overall, 14 experts panel participants (participation rate: 82%) completed the survey of Round
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30 273 2, and all the statements passed with a consensus out of 75%. (**Table 2**). One expert provided
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32 274 additional comments that included examples of expertise, which were subsequently integrated
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35 275 into the final list of statements. In particular, low level laser therapy could accentuate genital
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37 276 dryness, requiring additional interventions to improve hydration during the treatment period
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39 277 to mitigate certain discomfort to the patients. For other therapies, such as electrical
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42 278 stimulation and extracorporeal shock wave therapy there was uncertainty of applications in
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44 279 some field due to little expertise (Supplementary File 4).
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50 281 *Workshop Meeting*

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53 282 On September 27, 2022, nine experts panel participants (completion rate: 53%) joined the online
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55 283 meeting to discuss comments, justifications and highlights. A comprehensive digital presentation of
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57 284 Round 1 and Round 2 findings were reported during the workshop. Here, the panel of experts
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60 285 suggested introducing a general note making explicit that statements on safety were not extended to

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286 different subgroups of the population (e.g., children, adolescents, immunocompromised) due to lack
287 of literature.

288 The final list of statements with this general note was shared via SurveyMonkey to reach final
289 approval. All 17 experts panel participants (approval rate: 100%) approved and released the final
290 statements list. One expert rated for the option "Not my expertise" in the statement of the cryotherapy
291 (**Table 2**). In **Appendix 1**, we reported the final criteria list released for good clinical practice with
292 details of sources (evidence and expertise) and applications in different fields and clinical conditions.

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293 **DISCUSSION**

294 **Main findings**

295 The SAFE PAMP consensus developed safety statements for Physical Agent Modalities in physical
296 therapy and rehabilitation practice. The multidisciplinary and multiprofessional panel of experts
297 participated with a moderate response rate (61%).(28) All nine statements were approved in two
298 rounds (consensus of over 75% agreement.) and released in a final workshop meeting with some
299 adjustments made (e.g., specific population subgroups). In summary, experts agreed on the safety of
300 PAMs in the adult population (>18 years) when prescribed and applied by a healthcare professional
301 (e.g., physiotherapist, physician) who is formed and informed, as required by education and licensure.

303 **Literature Context**

304 Earlier consensus documents from different organizations were published in 2001,(5) 2006,(6) and
305 2010.(7) In 2018, the American Occupational Therapy Association issued a position paper(29)
306 clarifying the appropriate use of PAMs in contemporary occupation-based occupational therapy
307 practice, providing clinical case vignettes in their field. Others reported indications and
308 contraindications about specific types of PAMs (e.g., extracorporeal shock wave therapy(30)). Many
309 other societies, such as National Institute for Clinical Excellence (NICE), also offer specific clinical
310 questions guidelines, and we cannot exclude that they can involve recommendations on PAMs (e.g.,
311 NG59 for low back pain(31)).

312 Overall, the Canadian document(7) represents the most comprehensive guidance on this topic.
313 However, our Delphi is the most recent consensus on PAMs focusing on statements about safe PAMs
314 application as clinical practice indications (e.g. field) sustained by literature and clinical expertise.
315 This does not mean that the contraindications and precautions mentioned in the Canadian guideline(7)
316 are in contrast to our findings. Simply, we use a complementary perspective. Our Delphi agree to
317 define the common safe applications stratifying by fields/conditions whereas the Canadian one
318 describes the contraindications and precautions about these common applications in particular

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3 319 situations or under certain circumstances. For instance, both documents recognize cryotherapy and
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5 320 electrical stimulation as commonly safe PAMs in musculoskeletal applications, such as treating ankle
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8 321 sprains and osteoarthritis. However, the Canadian guideline recommends precaution when combining
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10 322 compression with cryotherapy to ensure the preservation of circulation and nerves. Furthermore, the
11
12 323 guideline contraindicated the use of electrical stimulation in presence of implanted electronic devices.
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15 324 Although the evidence presented in the Canadian guideline was not systematically collected (Canada
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17 325 and the United States experts in conjunction with multiple sources such as textbooks), it is reasonable
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19 326 to assume that many precautions and contraindications still remain applicable. Nevertheless, it is
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22 327 important to note that guidelines should be updated every three to five years or when new information
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24 328 becomes available.(32, 33)
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Implications for clinicians

Healthcare professionals are encouraged to use a comprehensive approach when using this Delphi consensus. Before proposing PAMs to patients, they must collect their medical history (e.g., comorbidities) to better determine the diagnosis, prognosis, anticipated goals, and expected outcomes.(34) Then, they should incorporate the best research evidence, clinical expertise, patient values, needs, and preferences to propose effective treatments, balancing effectiveness and safety and informing patients about the possibility of trivial adverse events (e.g., pain and erythema at the application site(10) using extracorporeal shock wave therapy). However, when evidence is lacking and moderate to severe harm is likely, caution is advised, and using PAM may be reconsidered. In fact, for precautionary purpose. (35-37) developed statements were not generally extended to other subgroups, such as children and adolescents (due to biological tissue in growth phases(38, 39)), and frail people (e.g., immunocompromised patients), since limited and insufficient literature on harm is available. Generally, all these statements should be adhered to in conjunction with precautions and contraindications under specific circumstances referring to equipment manufacturers' manuals and

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3 344 regulatory bodies(40) as well as to previous guidelines(7) and standards established by professional
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5 345 associations.

10 347 **Implications for stakeholders**

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12 348 Good practices for the safety of patients should be managed by national agencies with a living
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14 349 monitoring system and shared in international initiatives such as the WHO Global Patient Safety
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16 350 Challenge Medication Safety(41) to strengthen systems and practices adopting corrective action
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18 351 within countries. For instance, national and international scientific and technical societies should
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20 352 facilitate disseminating CPGs adopting different strategies, such as storing good clinical practices in
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22 353 shared repository(42) as well as disseminating plain, patient-oriented versions of good clinical
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24 354 practice statements, supporting patient empowerment and making the healthcare system more
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26 355 efficient, tailored and safer.(43, 44) We intend to organize meetings with stakeholders and patients,
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28 356 conduct webinars, and provide education and counseling through pamphlets, videos, and social
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30 357 messages.

37 359 **Implications for research**

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39 360 We believe that statements developed by the multidisciplinary and multi-professionally panel of
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41 361 experts can be generalized worldwide. These results could provide essential information to produce
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43 362 national (e.g., Good Clinical Practices of the Italian Ministry of Health(45)) and international
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45 363 guidelines to improve patient safety and decrease avoidable harm related to interventions. Studies
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47 364 should convey their efforts to plan and adequately report adverse events before objectively estimating
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49 365 these harms. We call for multicentric randomized controlled trials based on the core outcome set also
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51 366 for harms and not only for benefit.(46) In addition, specific subgroups of populations should be
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53 367 studied. It is a serious matter to exclude a group from research eligibility, and this must be done only
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55 368 when no less restrictive option is sufficient to ensure protection from undue risk.(47)

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3 369 Lastly, future studies can better expand our statements to ensure the safest and optimal modality
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5 370 application of the proposed PAMs (e.g., optimal voltage, amperage, frequency, current density, dose),
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8 371 contraindications and precautions, especially for the subgroups mentioned (e.g., children,
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10 372 immunocompromised people).(48)

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14 374 **Strength and limitations**

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17 375 This is the first effort to provide guidance on the safety of PAMs in physiotherapy and rehabilitation.
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19 376 We strictly followed published guidelines for reporting and conduction. In addition, we *a-priori*
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22 377 publicly registered the consensus criterion used to determine agreement within the Delphi process.
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24 378 (26, 49) We adopted one of the most conservative thresholds for obtaining the consensus (75%)(27),
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26 379 and in all rounds, this was reached with a high percentage of agreements. However, some downsides
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28 380 should be acknowledged. We did not cover statements about the clinical effectiveness of PAMs, as
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31 381 our aim was to make patients, healthcare providers and policy-makers aware about the safety
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33 382 application of PAMs in clinical practice. As well, we did not aim to report specific contraindications
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35 383 as we started collecting evidence from systematic reviews that reported safety outcomes from primary
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38 384 studies, which may not always encompass real-world conditions, such as the presence of
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40 385 comorbidities (e.g., active deep vein thrombosis). In addition, evidence-informed by systematic
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42 386 reviews did not find enough information about risk for a specific population (e.g., hemato-oncological
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45 387 patients with severe immunocompromised or coagulopathy). However, based on the principle of
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47 388 precaution, the panel agreed to add as a general note about precaution in specific subgroups of the
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49 389 population, in the absence of literature. As with all Delphi process, our study relies on national expert
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51 390 response and may not capture the full range of perspectives or experiences.(16, 50) However, we tried
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54 391 to involve multidisciplinary and multi-professional experts (as occurs in clinical practice guidelines)
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56 392 that enable confrontations in anonymity (avoiding negatively influencing outcomes and encouraging
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58 393 balanced consideration of ideas). Then, statements were developed starting from the scoping
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60 394 review(10), which mapped and summarized safety in population and intervention areas without

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3 395 assessing the certainty of evidence (e.g., grading of the certainty of evidence).(10) Lastly, even if we
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5 396 generated statements starting from the latest available evidence, we should recognize that adverse
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8 397 events may be under-estimated since safety outcome is commonly poor-reported in the literature (11,
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10 398 12, 51).

11 12 399 13 14 **CONCLUSION**

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17 401 These evidence-based statements inform patients, healthcare professionals, and policy-makers about
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19 402 the safety of a wide range of PAMs in field and conditions of physiotherapy and rehabilitation practice
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22 403 after a comprehensive clinical evaluation of patients' needs. All these statements should be associated
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24 404 to precautions and contraindications for specific cases referring to previous guidelines, equipment
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26 405 manufacturers' manual and regulatory bodies. This consensus can provide a basis for decision-making
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28 406 and future research.
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3 407 **DECLARATIONS**

4
5 408 **Author Contributions**

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7 409 Concept/idea/research design: S. Gianola, S. Bargerì, G. Castellini

8
9 410 Writing: S. Gianola, S. Bargerì, G. Castellini

10
11 411 Data collection: S. Gianola, S. Bargerì

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13 412 Data analysis: S. Gianola, S. Bargerì

14
15 413 Project management: S. Gianola, S. Bargerì

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17 414 Consultation (including review of manuscript before submitting): S. Gianola, S. Bargerì, L.

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19 415 Pellicciari, S. Gambazza, G. Rossetini, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S.

20
21 416 Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators

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24
25 418 **Ethics Approval**

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27 419 This study was declared exempt from institutional review board review.

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31 421 **Disclosures**

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33 422 The authors and SAFE PAMP Collaborators declared they had no conflicts of interest.

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37 424 **Funding**

38
39 425 This work was supported and funded by Associazione Italiana di Fisioterapia (AIFI). The APC was

40
41 426 funded by AIFI. This research did not receive specific grant from any funding agency in the public,

42
43 427 commercial or not-for-profit sectors.

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47 429 **Data sharing statement**

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49 430 Research data are stored in OSF repository <https://osf.io/w8kgs/> (19)

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53 432 **Manuscript word count: 3275/4000**

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433 **Figure 1.** Phases of the RAND Delphi process

434 **Figure 2.** Flow chart of Delphi process

435 **Table 1.** General characteristics of experts panels

436 **Table 2.** Agreement results for each round.

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569 **Tables**

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Table 1. General characteristics of experts panel (n=17)

Professional profile*	Responses N (%)
Clinicians	15 (88.2)
Researchers	7 (41.2)
Management	4 (23.5)
Field of expertise*	
Musculoskeletal	8 (47.1)
Pelvic floor disorders	4 (23.5)
Neurological	3 (17.6)
Lymphatic disorders	1 (5.9)
Paediatrics	1 (5.9)
Lay member (Patient)	1 (5.9)
Forensic member	1 (5.9)

*More than one answer was possible

572 **Table 2. Agreement results for each round**

Statements about the safety of...	ROUND 1		ROUND 2		FINAL LIST	
	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Approved	NME
Electrical stimulation	85.7	7.1	85.7	0.0	100.0	0.0
Neuromodulation, antalgic, and interferential electrical currents	100.0	0.0	100.0	0.0	100.0	0.0
Extracorporeal shock wave therapy	83.3	0.0	76.9	0.0	100.0	0.0
Laser therapy	84.6	7.7	90.9	0.0	100.0	0.0
Electromagnetic therapy	81.8	9.1	76.9	0.0	100.0	0.0
Diathermy	90.0	10.0	84.6	0.0	100.0	0.0
Hot thermal agents	81.8	9.1	91.7	0.0	100.0	0.0
Cryotherapy	75.0	0.0	90.9	0.0	94.2	5.8
Therapeutic ultrasound	90.9	0.0	91.7	0.0	100.0	0.0
General note [^]	-	-	-	-	100.0	0.0

573 [^]added for the Final Criteria List

574 Abbreviations: NME: not my expertise

575 **Appendix 1. Final criteria list**

576 **Introduction**

577 The statements are focused on adult population. Each statement was developed based on the scientific
578 literature (i.e., evidence) and experience of content experts of Associazione Italiana di Fisioterapia -
579 AIFI (i.e., expertise) with details for clinical conditions/populations in the relevant rehabilitation
580 fields.

581 *Target group:* statements were developed for adults (> 18 years). Physical agents modalities are
582 delivered by expert healthcare professionals (who had undergone formal education and training) to
583 ensure patient safety in both inpatient and outpatient settings.

584 *Conditions of application:* statements were presented within the relevant rehabilitation field
585 according to *informed-evidence* and *expertise-based* consensus.

586 *Evidence:* This section has been defined on the basis of a scoping review of the literature conducted
587 by two independent reviewers that focused on safety of PAMs from 117 systematic reviews in
588 physiotherapy and rehabilitation medicine (10).

589 *Expertise:* this section has been formulated by the steering committee which included different
590 content experts of AIFI (e.g., neurological, musculoskeletal, pelvic floor, physical therapies), with
591 additional inputs from the multidisciplinary and multi-professional panel of experts.

592 **Final list of statements**

593 **1. Electrical stimulation (e.g., Functional electrical stimulation (FES), Neuromuscular**
594 **electrical stimulation (NMES), Electrical muscle stimulation (EMS)) is safe in the adult**
595 **population**

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3 596 - *in musculoskeletal disorders, especially in the following conditions:*

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7 597 o Evidence: neck pain, knee osteoarthritis, musculoskeletal pain, muscle hypotrophy.

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10 598 o Expertise: spinal osteoarthritis, knee osteoarthritis, musculoskeletal pain, knee

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12 599 osteoarthritis, muscle and joint pain.

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16 600 - *in pelvis-perineal disorders, especially in the following conditions:*

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19 601 o Evidence: urinary incontinence, fecal incontinence, lower urinary tract symptoms in

20

21 602 postpartum women, overactive bladder.

22

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24

25 603 o Expertise: prolapse, descending perineum syndrome, perineal hypotonia, bladder-sphincter

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27 604 or anorectal dyssynergia, erectile dysfunction, premature ejaculation, abdominal diastasis.

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30 605 - *in neurological disorders, especially in the following conditions:*

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34 606 o Evidence: migraine, spasticity in multiple sclerosis, stroke, spinal cord injury.

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37 607 o Expertise: post-stroke urinary incontinence, neurogenic bowel dysfunction in spinal cord

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39 608 injury, second motor neuron disease (e.g., Amyotrophic Lateral Sclerosis), muscular

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41 609 dystrophies, head trauma, lesions of the peripheral nervous system.

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49 611 **2. Neuromodulation, antalgic and interferential electrical currents (e.g., TransCutaneous**

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51 612 **Electrical Nerve Stimulation (TENS), Transcutaneous Tibialis Posterior Stimulation (TTNS))**

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53 613 **are safe in the adult population**

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57 614 - *in musculoskeletal disorders, especially in the following conditions:*

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3 615 o Evidence: low back pain, neck pain, rotator cuff disease, whiplash-associated disorders,
4
5 616 fibromyalgia.

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9 617 o Expertise: musculoskeletal pain, spine osteoarthritis, neuropathic pain.

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12 618 - *in pelvis-perineal disorders, especially in the following conditions:*

13
14
15
16 619 o Evidence: overactive bladder, urinary incontinence, fecal incontinence, persistent pelvic
17
18 620 pain.

19
20
21
22 621 o Expertise: Urinary incontinence, pudendal neuralgia, constipation, urinary retention.

23
24
25 622 - *in neurological disorders, especially in the following conditions:*

26
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29 623 o Evidence: neuropathic pain, stroke, multiple sclerosis, neurogenic bowel dysfunction after
30
31 624 spinal cord injury.

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34 625 o Expertise: neurogenic bladder dysfunction after central and peripheral nervous system
35
36 626 injuries.

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44 628 **3. Extracorporeal shock wave therapy (radial and focal) is safe in the adult population**

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47 629 - *in musculoskeletal disorders, especially in the following conditions:*

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50 630 o Evidence: soft tissue disorders of the lower limbs, knee tendinopathy, Achilles
51
52
53 631 tendinopathy, osteoarthritis, plantar fasciitis, rotator cuff disease, shoulder tendinopathy and
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55 632 calcifications, acute fracture, orthopedic disorders, consolidation delays, other soft tissue
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57 633 disorders.

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634 o Expertise: enthesopathies of the upper and lower limbs, calcifications, epicondylitis,
635 epitrocleitis, muscle injuries, muscle contractures, and trigger points.

636 - in neurological disorders, especially in the following conditions:

637 o Evidence: post-stroke lower limb spasticity, multiple sclerosis spasticity.

638 o Expertise: spasticity following head trauma, spasticity following spinal cord injury.

639 - in pelvis-perineal disorders, especially in the following conditions:

640 o Evidence: chronic prostatitis/chronic pelvic pain syndrome.

641 o Expertise: persistent female pelvic pain, Peronye's disease.

642 Patients should be informed of the potential undesirable effects after applying ESWT. Indeed, a
643 recent literature review showed some expected mild adverse events, such as pain and erythema, at
644 the application site.(10)

646 **4. Laser therapy (e.g., low-level laser therapy (LLLT), high-level laser therapy (HLLT)) is**
647 **safe in the adult population**

648 - in musculoskeletal disorders, especially in the following conditions:

649 o Evidence: low back pain, Achilles tendinopathy, rotator cuff disease, capsulitis adhesive,
650 lower extremity soft tissue disorders, frozen shoulder, carpal tunnel syndrome, knee
651 osteoarthritis, neck pain, whiplash associated disorders.

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3 652 o Expertise: upper and lower limb tendinopathy, acute arthropathy, acute muscle and tendon

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5 653 injuries, acute musculoskeletal pain. Upper and lower limb tendinopathy, acute arthropathy,

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7 654 acute muscle and tendon injury, and acute musculoskeletal pain.

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655 - *in pelvis-perineal disorders (extracavitary LLLT only), especially in the following conditions:*

656 o Evidence: Urinary incontinence and pelvic organ prolapse, persistent pelvic pain.

657 o Expertise: healing (episiotomies, laparotomies, lacerations, etc.), inflammatory pelvic

658 pain, edema or perineal hematomas.

659 - *in lymphatic disorders (LLLT only), especially in the following conditions:*

660 o Evidence: secondary lymphoedema (e.g., breast cancer-related lymphedema).

661 o Expertise: lymphoedema

662 - *in neurological disorders (LLLT only), especially in the following conditions:*

663 o Evidence: Bell's palsy

664 o Expertise: stroke, multiple sclerosis, spinal cord injury, head trauma, peripheral nerve

665 injury.

666 **5. Electromagnetic therapy (e.g., Pulsed ElectroMagnetic Field Therapy (PEMFT), repetitive**

667 **Peripheral Magnetic Stimulation (rPMS)) is safe in the adult population**

668 - *in musculoskeletal disorders, especially in the following conditions:*

669 o Evidence: neck pain, fractures, consolidation delays.

670 o Expertise: osteoporosis, bone edema, algodystrophy, arthrosis.

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3 671 - in pelvis-perineal disorders, especially in the following conditions:

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7 672 o Evidence: persistent pelvic pain and urinary incontinence.

8

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10 673 o Expertise: fecal incontinence, prolapse, descending perineum syndrome, perineal

11

12 674 hypotonia, vesico-sphincteric or anorectal dyssynergia, pudendal neuralgia, pelvic pain

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15 675 acute, erectile dysfunction, premature ejaculation, diastasis recti.

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18 676 **6. Diathermy (e.g., Short Wave Tecar Therapy) is safe in the adult population**

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22 677 - in musculoskeletal disorders, especially in the following conditions:

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25 678 o Evidence: rotator cuff disease, knee osteoarthritis.

26

27

28 679 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-

29

30 680 acute), osteoarthritis, muscle contractures, trigger points.

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34 681 - in pelvis-perineal disorders, especially in the following conditions:

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38 682 o Evidence: inflammatory pelvic pain, persistent pelvic pain, sexual dysfunction (Peronye's
39 disease).

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43 684 o Expertise: prolapse, stress urinary incontinence, scarring (episiotomies, laparotomies,

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46 685 lacerations, etc.), perineal edema or hematoma, vulvovaginal dystrophy and dryness,

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48 686 abdominal diastasis.

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52 687 **7. Hot thermal agent modalities (e.g., drug-free heat wrap) are safe in the adult population**

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55 688 - in musculoskeletal disorders, especially in the following conditions:

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59 689 o Evidence: groin pain, low back pain.

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3 690 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-
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5 691 acute), osteoarthritis
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12 693 **8. Cryotherapy (e.g., ice or liquid nitrogen) is safe in the adult population**

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16 694 *- in musculoskeletal disorders, especially in the following conditions:*

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19 695 o Evidence: arthroscopy, reconstruction of the anterior cruciate ligament, post-surgery.
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23 696 o Expertise: Delayed Onset Muscle Soreness (DOMS)/Delayed Onset Muscle Soreness
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25 697 (DOMER), post-surgery, post-trauma (48h).
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32 699 **9. Therapeutic Ultrasound is safe in the adult population**

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35 700 *- in musculoskeletal disorders, especially in the following conditions:*

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39 701 o Evidence: back pain, neck pain, carpal tunnel, rotator cuff disorder, lower limb soft-tissue
40
41 702 disorder, knee osteoarthritis, fracture, acute fracture, ankle fracture, ankle and knee sprains,
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45 703 o Expertise: hand and foot osteoarthritis, calcifications, enthesitis.
46
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48 704 **General notes and considerations related to subgroups:**

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51 705 Following a confirmed clinical prescription, applying the above physical therapies is safe in the
52
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54 706 adult population (>18 years) under the supervision of an expert operator. For precautionary reasons,
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56 707 these statements are not extended to other subgroups of patients (e.g., children, adolescents, frail
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58 708 population, etc.) since insufficient literature is available.
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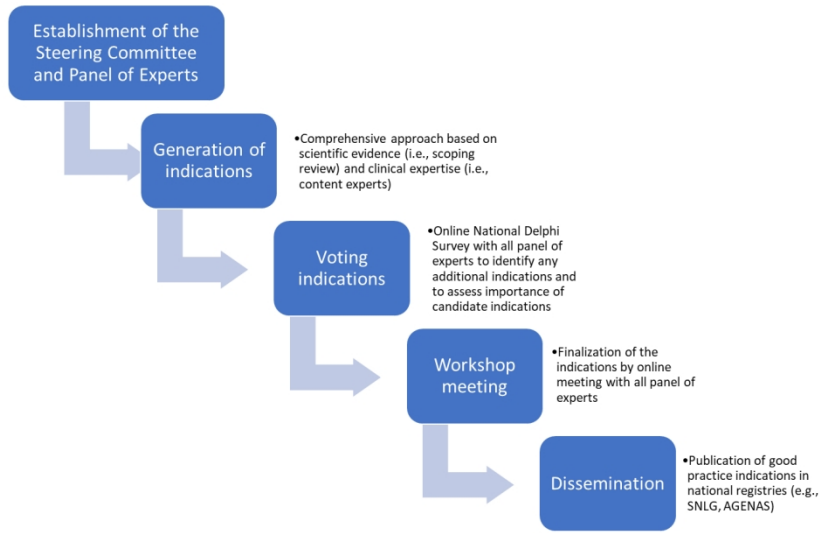


Figure 1

282x150mm (150 x 150 DPI)

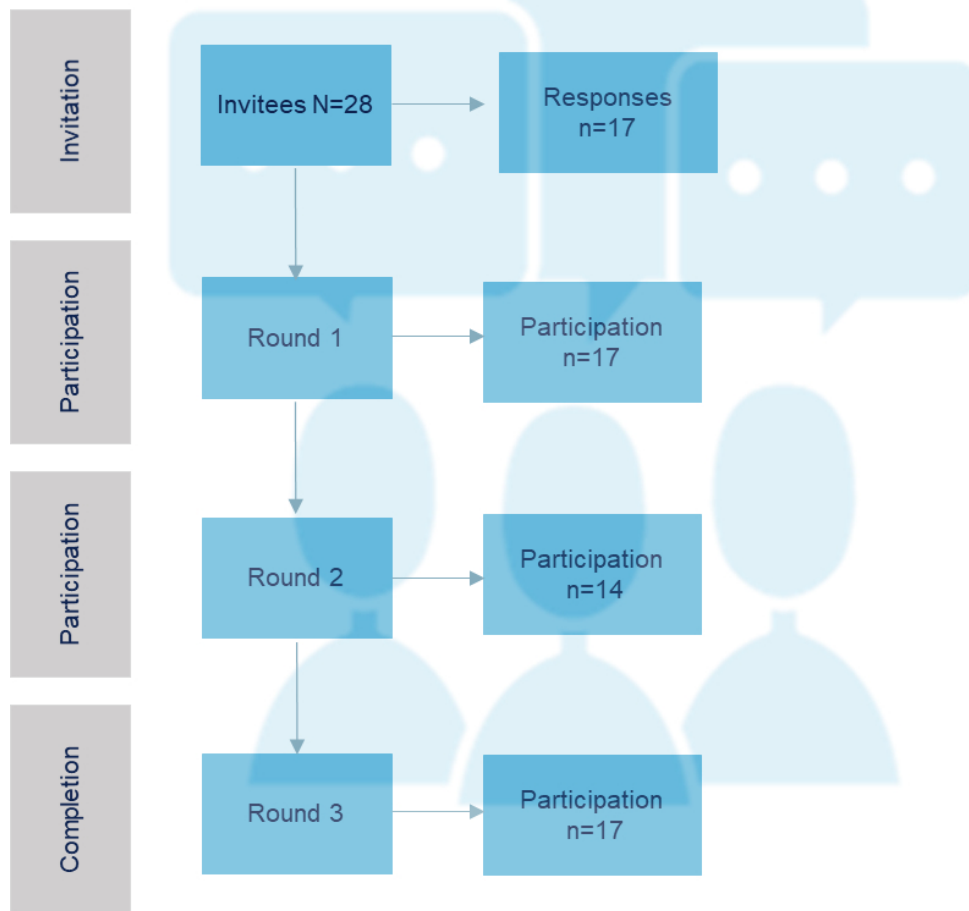


Figure 2

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Supplementary Files

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For peer review only

Supplementary File 1. Ethical considerations

Participation in the Delphi survey is voluntary and by invitation. The questionnaire includes a beginning section to acquire consent and privacy for data processing. Participants are informed that the responses will have 'remained total confidentiality according to the Regulation on the protection of personal data' 679/2016 of the European Union, and that the results will be used for research purposes and a document shared at the corporate level¹. The interested party may be interested in the rights provided for by art. 15, 16, 17, 18, 20, 21 and 22 of the Regulation mentioned above.

Database randomization and differential privacy access were achieved. In addition, "anonymization" by generalizing was performed.² The study project and data collection were managed and anonymously entrusted by the Unit of Clinical Epidemiology of IRCCS Istituto Ortopedico Galeazzi based in Milano. The data subject cannot be re-identified and is therefore outside the scope of the data protection law³.

The row dataset was accessible to two researchers (SG, SB) excluded from participation in Delphi for the quantitative and qualitative analyses. This practice complies with the European standards for the use of aggregative data where the data subject cannot be re-identified, are not personal data and are therefore outside the scope of data protection law³. The final report only contains aggregate data. In the final document, we reported the names of the participants who have completed all rounds and gave their consent to disclose their names.

Supplementary File 2. Physical agent modalities description

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6 **1) Electrical stimulation:** electrotherapeutic currents and waveforms to facilitate neuromuscular or
7 sensory activity to improve muscle strength and reeducate muscle function.⁴
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- Neuromuscular electrical stimulation (NMES): use of pulsed currents to stimulate motor nerves, which in turn produce tetanic contractions of the neuromuscular spindles, with or without joint movement.⁵
 - Functional Electrical Stimulation (FES) uses electrical pulses to stimulate motor neurons or denervated muscle fibers directly to elicit a contraction during a functional activity (e.g., gait). FES is used in the treatment of orthopedic and neurological conditions.⁶

23
24 **2) Neuromodulation, analgic and interferential electrical currents :** electrotherapeutic currents
25 and waveforms to influence physiological effects on the patient's body structures and functions
26 aiming to modulate pain.⁴
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- Transcutaneous electrical nerve stimulation (TENS): delivers electrical stimulation via electrodes placed over the intact skin surface near the source of pain to produce analgesia or hypoalgesia. A wide variety of pulsed waveforms are used, with frequencies typically in the range of 1-100Hz. The intensities are set to produce sensory stimulations alone or in combination with motor stimulations to produce muscle twitches (acupuncture-like TENS).⁷
 - Transcutaneous Tibialis Posterior Stimulation (TTNS): a form of neuromodulation involving the use of electrical impulses to address urinary symptoms (e.g. overactive bladder) with inhibitory action on neurons of the spinothalamic tract (S2-S3).⁸
 - Interferential current (IC): involves crossing two medium frequency currents (most commonly 4000 Hz), which reportedly generates a low-frequency 'beating' (amplitude-modulated) effect at between 0 and 150 Hz in the deep tissues.⁹ These beat frequencies are believed to decrease pain, increase circulation and block nerve conduction.

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3) Extracorporeal shock wave therapy: a nonsurgical treatment that uses the phenomenon of mechanotransduction (i.e., adapting cells biochemical activity, influencing cells migration, proliferation, differentiation and apoptosis)^{10 11} to treat various musculoskeletal conditions (e.g., plantar fasciitis; tennis elbow). Shock wave therapy can be either extracorporeal or radial.¹²

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- Extracorporeal shock wave therapy (ESWT) involves passing sound waves (or shock waves) through the skin to the affected area. Shock waves are single pulsed acoustic or sonic waves, which dissipate mechanical energy at the interface of two substances with different acoustic impedance.¹³ They are produced by generators of an electrical energy source and require an electroacoustic conversion mechanism and a focusing

1
2
3 device. Three types of systems can be distinguished based upon the sound source:
4 electrohydraulic, electromagnetic and piezoelectric systems. Various doses appear to
5 be used, with no apparent consensus on the minimum therapeutic dose. As defined
6 defined by Cacchio 2006¹⁴ as low-energy shock waves is less than 0.1 mJ/mm² and
7 high-energy shock waves: is 0.2 mJ/mm² to 0.4 mJ/mm²).

- 8
9 - Radial shock wave therapy (RSWT) is generated through the acceleration of a
10 projectile inside the handpiece of the treatment device and then transmitted radially
11 from the tip of the applicator to the target zone. Radial shock waves show a lower
12 peak pressure and a considerably longer rise time than extracorporeal shock waves.
13 In RSWT, the focal point is not centred on a target zone, as occurs in focal ESWT,
14 but on the tip of the applicator.¹⁴

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17 **4) Laser therapy:** light source treatment, non-invasive, widely used to treat various
18 musculoskeletal conditions.

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21 - Low-level laser therapy (LLLT) generates a beam of light with a particular
22 wavelength that can deliver light energy to tissue depths below the dermis¹⁵.
23 Studies suggest that LLLT contributes to pain relief by reducing pro-inflammatory
24 cytokines¹⁶. The effects of LLLT are considered to be dependent on dosage,
25 wavelength, site and duration of treatment.^{15 16}
- 26
27
28 - high level laser therapy (HLLT): laser with an output power greater than 500 mW
29 or 0.5 Watts. HLLT creates heat on the surface of the skin due to their higher power
30 density (irradiance).¹⁷

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34 **5) Electromagnetic therapy:** based on Faraday's law of electromagnetic induction, to promote
35 bone healing, treat osteoarthritis and inflammatory diseases of the musculoskeletal system,
36 alleviate pain, enhance healing of ulcers and reduce spasticity¹⁸.

- 37
38 - Pulsed Electromagnetic Field therapy (PEMF), which involves the delivery of pulsing (that
39 is 'on-off') low-frequency magnetic fields through the body, which is believed to provide
40 temporary pain relief by influencing tissue generation and cell proliferation.¹⁹

41
42
43 - Repetitive magnetic stimulation (rMS), which allows the transcutaneous induction of nerve
44 stimulating electric currents. This technique requires extremely strong and sharp magnetic
45 impulses (for example 15,000 amperes peak current; 2.5 T field strength; < 1 msec) applied
46 by specially designed coils (< 10 cm) over the target area. Modern devices allow the repetition
47 of up to 60 impulses per second. Mainly developed to study and influence brain functions,
48 rMS also stimulates spinal chord fibres and peripheral nerves. Initial studies used peripheral
49 rMS for therapeutic reasons, such as in myofascial pain syndrome²⁰. Since the resulting small
50 electric impulses are the nerve stimulating factor, rMS effects may be similar to TENS.

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54 **6) Shortwave and microwave Diathermy**

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56 - Tecartherapy or radiofrequency diathermy (RFD) is a non-invasive therapy and
57 consists in the emission of high-frequency electromagnetic waves which increase
58 tissue metabolism. This process promotes tissue repair and affects pain
59 sensitivity.^{21 22 23}

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- Microwave diathermy: a deep heating modality that converts electromagnetic energy to thermal energy. Frequencies approved for therapeutic microwave are 915 MHz (wavelength 33 cm) and 2,456 MHz (wavelength 12 cm). The lower frequency has the advantage of increased depth of penetration but also the disadvantages of greater beam dispersion and the requirement of larger applicators. If muscle heating is primary objective, 915-MHz applicators are preferable to 2,456-MHz applicators. Average temperatures of approximately 41°C at a depth of 1–3 cm have been demonstrated²⁴

- 7) **Hot thermal agents:** heat transferred from an object with direct contact to the body. Heat therapy include hot packs, heatwraps, hot/warm water immersion, sauna. Heat treatment increases metabolism in tissues, promotes blood circulation and reduces pain. The temperature of the heat therapy is generally 35–40°C.^{25 26}
- 8) **Cryotherapy:** cold is transferred from an object with direct contact to the body. Examples include cold packs, cold-water immersion ($\leq 15^{\circ}\text{C}$), ice massage, the novel modality of cryotherapy. Cryotherapy is a treatment involving very short exposures to extremely cold dry air to the whole patient or a treatment area (mean temperature of the cryotherapy chamber is at -30°C , -80 to -110°C , or $< -110^{\circ}\text{C}$). Cold treatment is thought to reduce swelling and cell metabolism, minimizing oedema, pain and injury.^{25 27}
- 9) **Therapeutic Ultrasound:** delivers energy to deep tissue sites through ultrasonic waves (often at frequencies of 1 or 3 MHz and intensities between 0.1 watts/cm² and 3 watts/cm²) using a crystal sound head. Treatment can be delivered in two forms, continuous (non- stop ultrasonic waves) and pulsed (intermittent ultrasonic waves^{22 28}). The treatment aim to increase tissue temperature and induce non-thermal physiological changes (such as cell permeability and cell growth), which are believed to promote soft tissue healing and muscle relaxation.²⁹

Supplementary File 3. Declaration of interest

Name and Surname	Affiliation	Scientific and Technical Societies	Conflict of interest declared
Armando Perrotta	IRCCS Neuromed, Pozzilli (IS)	Società Italiana per lo Studio delle Cefalee (SISC)	none
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Supplementary File 4. Panel of experts comments

ROUND	Electrical Stimulation	Neuromodulation, antalgic and interferential electrical currents	Extracorporeal shock wave therapy	Laser therapy	Electromagnetic therapy	Diathermy	Hot thermal agent modalities	Cryotherapy	Ultrasound
Round 1	My Likert Scale rating of 9 stems not only from the numerous evidence but also from the results of my clinical experience. In cases of perineal hypotonia and sphincter deficits, electrical stimulation has facilitated recovery times by enhancing manual work and proprioception during the learning phase.	The primary application of TTNS in my practice, aside from addressing bladder disorders (overactivity), is in the management of painful syndromes, such as spasms of peri-urethral muscles in patients with recurrent post-coital cystitis, vulvodynia, and pudendal neuralgia.	In this case, my assessment requires specificity: In many instances, women experiencing resistant pelvic pain may not readily accept the use of shock waves, as it is an impactful therapy that can cause initial discomfort. Among various instrumental approaches for this patient group, it would not be my first choice. On the other hand, my perspective on shock waves for the treatment of male pelvic pain or erectile dysfunction is quite different; in this case, I positively endorse the statement.	completely agree.	I cannot provide a judgment as I lack the appropriate training and experience in its use.	Thanks to the use of diathermy, I can achieve excellent results in the treatment of dermatological conditions affecting the genital mucosa, such as Lichen Sclerosus. In pelvic pain, patients appreciate the mild heat generated by the diathermy probe, allowing for more effective therapy in the area. Currently, this treatment is consistently integrated into all treatment plans, irrespective of individual clinical situations, without causing discomfort or triggering sensitivity reactions	Limited experience in menstrual pain for just the efficacy. However it is related to other type of hot thermal agents (e.g, infrared therapy)	Agreed, but the patient must be adequately instructed in advance on the use and timing of cryotherapy, for example, ice packs postpartum or in inflammatory hemorrhoidal syndromes. Discourage self ice application, and encourage the use of devices designed for healthcare purposes. It is a very useful and easily administered therapy but potentially 'dangerous' if mishandled at home, for instance, the risk of cold burns	For my expertise US is safe in pelvic disorders.
	In the absence of expertise in the pelvic-perineal and neurological domains, the opinion is limited to the musculoskeletal field	In the absence of expertise in the pelvic-perineal and neurological domains, the opinion is limited to the musculoskeletal context only.	Shock waves are not recommended in individuals during the developmental age since their tissues and cartilage are still in the developmental phase	In the absence of expertise in pelvic-perineal, lymphatic, and neurological domains, the opinion is limited to the musculoskeletal context only	In the absence of expertise in pelvic-perineal areas, the opinion is confined to the musculoskeletal context only. The indicated median score pertains to uncertainty regarding the safety of persistent use (long term), as I am not aware of literature data on adverse events for such durations. For treatment cycles falling within the time frames investigated in the	In the absence of expertise in the pelvic-perineal domain, the opinion is confined to the musculoskeletal context only. The moderate agreement with the safety statement primarily concerns uncertainties regarding the operator's safety with high daily exposure to the equipment, especially if potential risk factors are present (e.g., pregnancy or	In my experience, I have observed several cases of mild and transient skin irritations.	It is the only treatment I have seen used in younger age groups	For my expertise US is safe in pelvic disorders.

					available RCTs, the judgment is certain	the presence of oncological pathologies, even if unrecognized). I am not aware of studies monitoring the health of operators exposed to moderate or high levels of possible electromagnetic fields generated by the equipment. Regarding the equipment's safety for the patient, the judgment of agreement is certain.			
	NMES is widely used to address certain types of pharyngeal dysfunction in adults with dysphagia, but there is limited evidence demonstrating its effectiveness or appropriateness for pediatric patients. Reference: Andreoli S et al. Int J Pediatr Otorhinolaryngol 2019;127:109646. doi: 10.1016/j.ijporl.2019.109646.	NA in some pelvi-perineal and neurological disorders	NA in some pelvi-perineal and neurological disorders	Adulthood or in individuals with skeletal maturity	PEMF therapy is not recommended for children who have not yet completed their growth phases	It is not recommended for children as their biological tissues are still in the growth phase	I suggest emphasizing more strongly that the use is specifically intended for non-acute arthropathies	Risk of cold burn	Rarely used in adolescents after sports-related traumas
	NA in some perineal neurological disorders	For my experience mainly for neurological disorders		NA in some neurological and perineal disorders	NA for some perineal disorders	NA for some perineal disorders	for my expertise, uncertain in groin pain		
	For my expertise mainly in migraine			LLLT expertise in some neurological conditions (e.g, migraine)	for my expertise mainly used in migraine				
Round 2	Limited in some neurological setting	Useful also for vulvodynia, rectal spasms with anal pain	Uncertainty in some neurological disorders	limited evidence in some neurological disorders		I additionally include post-genital ulcer treatment, hypertonicity, and genital swelling in patients with pelvic pain	Limited experience in menstrual pain for just the efficacy. However it is related to other type of hot thermal agents (e.g, infrared therapy)	Cryotherapy in pelvic floor rehabilitation is used for the treatment of pain from hemorrhoidal inflammation, postpartum contusion, postpartum hypotonia with pronounced laxity, and for some patients, it	For my expertise US is safe in pelvic disorders.

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									is beneficial in addressing the sensation of genital swelling in chronic pelvic pain
				I do not have the right clinical experience to rate it with confidence. In my clinical practice, patients who have undergone LLLT have shown a greater tendency towards increased genital dryness. Therefore, the treatment requires additional measures such as enhanced hydration, for example, through the use of serums/ointments/suppositories during the treatment period, to mitigate certain side effects that may cause discomfort to the patients.					

For peer review only

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CREDES Checklist:**Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]**

Items of reporting	Reported on page
<i>Purpose and rationale.</i> 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.	5 - 6
<i>Expert panel.</i> Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
<i>Description of the methods.</i> 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.	7-10
<i>Procedure.</i> 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.	6-9; Figure 1-2
<i>Definition and attainment of consensus.</i> It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
<i>Results.</i> 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.	10-12; Table 2; Appendix 2
<i>Discussion of limitations.</i> Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
<i>Adequacy of conclusions.</i> 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
<i>Publication and dissemination.</i> 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.	13-14

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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-075348.R3
Article Type:	Original research
Date Submitted by the Author:	01-Mar-2024
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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Rehabilitation medicine, Rheumatology, Sports and exercise medicine, Neurology, Urology
Keywords:	Physical Therapy Modalities, REHABILITATION MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, ORTHOPAEDIC & TRAUMA SURGERY, NEUROLOGY

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3 1 **Evidence-informed and consensus-based statements about SAFETY of Physical**
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8 3 **PAMP): a national Delphi of healthcare scientific societies**
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20 35 *Giuseppe Botta, on behalf of SIFL (Società Italiana di Flebologia)*
21

22 36 *Luigi Nappi, on behalf of SIGO (Società Italiana Di Ginecologia E Ostetricia)*
23

24 37 *Gianmarco Rea, on behalf of SIMG (Società Italiana di Medicina Generale e delle cure primarie)*
25

26 38 *Enrico Marinelli, on behalf of SIMLA (Società Italiana di Medicina Legale e delle Assicurazioni)*
27

28 39 *Fabio Bandini, on behalf of SIN (Società Italiana di Neurologia)*
29

30 40 *Roberto Bortolotti, on behalf of SIR (Società Italiana di Reumatologia)*
31

32 41 *Viviana Rosati, on behalf of SIRN (Società Italiana di Riabilitazione Neurologica)*
33

34 42 *Armando Perrotta, on behalf of SISC (Società Italiana per lo Studio delle Cefalee)*
35

36 43 *Gianfranco Lamberti, on behalf of SIUD (Società Italiana di Urodinamica)*
37

38 44 *Monica Pierattelli, on behalf of SICuPP (Società Italiana Delle Cure Primarie Pediatriche)*
39

40 45 *Giancarlo Tancredi, on behalf of SIP (Società Italiana di Pediatria).*
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3 **46 ABSTRACT: 280 words**
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5 **47 Objective:** A shared consensus on the safety about Physical Agent Modalities (PAMs) practice in
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8 **48** physiotherapy and rehabilitation is lacking. We aimed to develop evidence-informed and consensus-
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10 **49** based statements about the safety of PAMs.
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12 **50 Study design and setting:** A RAND-modified Delphi Rounds' survey was used to reach a consensus.
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14 **51** We established a steering committee of the Italian Association of Physiotherapy (Associazione
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16
17 **52** Italiana di Fisioterapia - AIFI) to identify areas and questions for developing statements about the
18
19 **53** safety of the most commonly used PAMs in physiotherapy and rehabilitation. We invited 28 National
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21 **54** Scientific and Technical Societies, including forensics and lay members, as a multidisciplinary and
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23
24 **55** multi-professional panel of experts to evaluate the nine proposed statements and formulate additional
25
26 **56** inputs. The level of agreement was measured using a 9-point Likert scale, with consensus in the
27
28 **57** Delphi Rounds was assessed using the rating proportion with a threshold of 75%.
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30 **58 Results:** Seventeen (61%) out of 28 Scientific and Technical Societies participated, involving their
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32
33 **59** most representative members. The panel of experts mainly consisted of clinicians (88%) with
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35 **60** expertise in musculoskeletal (47%), pelvic floor (24%), neurological (18%) and lymphatic (6%)
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37 **61** disorders with a median experience of 30 years (IQR=17-36). Two Delphi Rounds were necessary to
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40 **62** reach a consensus. The final approved criteria list comprised nine statements about the safety of nine
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42 **63** PAMs (i.e., electrical stimulation neuromodulation, extracorporeal shock wave therapy, laser therapy,
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44 **64** electromagnetic therapy, diathermy, hot thermal agents, cryotherapy and therapeutic ultrasound) in
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47 **65** adult patients with a general note about populations subgroups.
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49 **66 Conclusions:** The resulting consensus-based statements inform patients, healthcare professionals and
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51 **67** policy-makers regarding the safe application of PAMs in physiotherapy and rehabilitation practice.
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54 **68** Future research is needed to extend this consensus on pediatric and frail populations, such as
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56 **69** immunocompromised patients.
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3 70 **Key Words:** Physical Therapy Modalities, Safety, Rehabilitation, Physical and Rehabilitation
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5 71 Medicine, Delphi Technique, Orthopedics, Neurology, Pelvic Floor, Musculoskeletal System
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9 72 **STRENGTH AND LIMITATIONS**
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- 12 73 • Starting from a recent scoping review of the literature, we aimed to acknowledge evidence-
13 informed indications of rehabilitation for safe PAMs;
14 74
15 75 • Indications on the safety of physical agents (PAMs) were developed by a steering committee
16 for different target conditions in physiotherapy and rehabilitation practice and supported by
17 76 evidence and clinical expertise
18 77
19 78 • We strictly followed published guidelines for reporting and conduction, with a-priori publicly
20 registered protocol to determine agreement within the Delphi process.
21 79
22 80 • The multi-professional and multidisciplinary panel of experts rated and revised the agreement
23 of indications for safe PAMs rehabilitation in multiple rounds until reaching a consensus.
24 81
25 82 • Indications did not cover the clinical effectiveness of PAMs as well as specific subgroups for
26 which evidence and expertise were not available.
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3 84 **INTRODUCTION**

4 85
5 86 Physical agent modalities (PAMs) are extensively applied in physiotherapy and rehabilitation practice
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8 87 by targeting tissues to reduce swelling, alleviate pain, enhance healing, and improve muscle tone.(1-
9
10 88 4) These treatments, recommended and administered by healthcare professionals across various
11
12 89 medical fields, are often integrated with other physiotherapy and rehabilitation interventions. (5)
13
14 90 However, ensuring the safety of these treatments is fundamental for both clinicians and patients.
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17 91 Previous consensus on contraindications and precautions associated with using PAMs from various
18
19 92 organizations were released in the early 2000s.(6-8) Still, they have become outdated in light of
20
21 93 technological advancements of the last years.(9, 10) A recent scoping review of the literature(5)
22
23 94 examined several systematic reviews on the safety of commonly used PAMs. This scoping review,
24
25 95 encompassing treatments such as cryotherapy, electrical stimulation, transcutaneous electrical nerve
26
27 96 stimulation, functional electrical stimulation, extracorporeal shockwave therapy, laser therapy,
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29 97 magnetotherapy, pulsed electromagnetic field and diathermy, revealed no important harm associated
30
31 98 with their use. Nevertheless, it is worth noting that adverse events may be underreported in primary
32
33 99 studies(11, 12) highlighting the need to integrate expert experience to bridge the current gaps between
34
35 100 existing literature and clinical practice. Therefore, the purpose of the SAFETY of Physical Agent
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37 101 Modalities Practice (SAFE PAMP) consensus in physiotherapy and rehabilitation is to develop
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39 102 evidence-informed and expert consensus-based statements about the safety of PAMs through a
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41 103 RAND Delphi procedure. Our goal is to make patients, healthcare professionals and policy-makers
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46 104 aware about the safe application of PAMs in physiotherapy and rehabilitation.
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METHODS

Design

A RAND-modified Delphi Rounds survey process was employed as the facilitation technique for reaching expert consensus.(13, 14) The Delphi technique is primarily used when the available knowledge is incomplete or subject to uncertainty.(15) We followed the guidance on "Conducting and REporting of DELphi Studies" (CREDES).(16, 17) This project is exempted from ethical approval according to the "ethics and data protection" regulations of the European Commission.(18) More details are reported in **Supplementary File 1**. The protocol was *a-priori* registered on the Open Science Framework (OSF) online repository.(19)

The process consisted of four phases: (i) establishment of the steering committee and invitation of national scientific and technical societies to constitute the panel of experts; (ii) generation of statements using a comprehensive approach based on a published scoping review of existing systematic reviews on PAMs safety in physiotherapy and rehabilitation medicine(5) as well as on expertise from content experts of the steering committee; (iii) rating of statements from the panel of experts through a national Delphi survey aiming to identify, assess and modify statement importance for each field (e.g., musculoskeletal); (iv) an online workshop meeting to finalize the list of statements reaching the final consensus. Finally, we planned to disseminate the final statements list as good clinical practice (**Figure 1**).

[Figure 1]

Phase I. Establishment of the steering committee and panel of experts

Steering committee

In June 2022, the project team nominated a steering committee responsible for defining the list of statements of safe PAMs, selecting national scientific and technical societies for expert participants, developing the Delphi questionnaires, and analyzing responses from participants after each round.

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3 131 The steering committee involved 11 content experts from the Italian Association of Physiotherapy
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5 132 (Associazione Italiana di Fisioterapia – AIFI), a member of the World Physiotherapy (20). AIFI is
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8 133 the scientific and technical society in Italy for the physiotherapy profession recognized by the Italian
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10 134 Minister of Health to produce clinical practice guidelines in the field.(21, 22)

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12 135 To assure the external validity of the consensus process, the steering committee included two content
13
14
15 136 experts on PAMs (MB, EP), three on rehabilitation of musculoskeletal disorders (GR, VG, SB), one
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17 137 on neurological physiotherapy and neuroscience (AT), one on pelvic floor rehabilitation (AF), and
18
19 138 four methodologists (SGa, SGi, GC, LP).

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23 24 140 *Panel of experts*

25
26 141 It is known that the diversity of a Delphi panel has an impact on the quality of the final
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29 142 recommendations. In contrast, no agreement on the panel size for Delphi studies exists. Panels of 20–
30
31 143 30 participants are common.(23, 24) Thus, the steering committee invited all the national
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33 144 multidisciplinary and multi-professional scientific and technical societies involved in physiotherapy
34
35 145 and rehabilitation care (n=26) and the societies dealing with forensics (n=1). These societies were
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38 146 identified from the published endorsed by the Italian Ministry of Health and are recognized as the
39
40 147 ones entitled to generate national clinical practice guidelines.(21, 22) Each society delegated their
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42 148 most representative member involved in physiotherapy and rehabilitation care to join the panel of
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45 149 experts. The panel of expert members was multidisciplinary and multi-professional, including
46
47 150 clinicians, researchers, and healthcare managers from different fields(24) (e.g., orthopedics,
48
49 151 neurology). To represent patients' perspectives, the panel also included a lay member from
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52 152 Cittadinazattiva,(25) the largest Italian patient advocate organization that promotes citizen activism
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54 153 for the protection of rights, the care of common goods, and support for people in conditions of
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56 154 weakness.

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59 60 156 ***Phase II. Generation of statements***

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3 157 Firstly, the steering committee formulated statements aimed at safety based on evidence and clinical
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5 158 expertise. Particularly, evidence was summarized from a published scoping review and its
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8 159 supplementary materials,(5) which gathered information about the safety of the nine PAMs from 117
9
10 160 systematic reviews in physiotherapy and rehabilitation medicine (e.g. safety of PAMs for low back
11
12 161 pain, osteoarthritis, stroke, urinary incontinence). Clinical expertise was assured by content experts of
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14
15 162 AIFI (e.g., musculoskeletal disorders, orthopedic and neurological physiotherapy and pelvic floor
16
17 163 rehabilitation) adding examples of clinical conditions for which they commonly safely apply PAMs
18
19 164 in their specific field. Disagreements between experts were resolved through discussion.

20
21 165 The steering committee formulated statements for each PAM (with distinction of evidence and
22
23
24 166 expertise) ensuring that all the potentially relevant topics in the field would be included in the initial
25
26 167 list of questions for the first Delphi round (**Supplementary File 2** reported details about each included
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28 168 PAM). Each statement included a statement regarding safety about the following PAMs:

- 30 169 1. Electrical stimulation
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33 170 2. Neuromodulation, antalgic and interferential electrical currents
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35 171 3. Extracorporeal shock wave therapy
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38 172 4. Laser therapy
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40 173 5. Electromagnetic therapy
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42 174 6. Diathermy
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44 175 7. Hot thermal agents
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47 176 8. Cryotherapy
- 48
49 177 9. Therapeutic ultrasound
- 50

51 178 Statements were developed for different target conditions. PAMs are delivered by expert healthcare
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54 179 professionals (who had undergone formal education and training) to ensure patient safety in inpatient
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56 180 and outpatient settings. Statements were presented within the relevant rehabilitation field, along with
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58 181 a list of patient conditions in which the PAMs were indicated as safe and supported by evidence and
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60 182 clinical expertise.

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Phase III. Rating of statements through Delphi Rounds

We employed an electronic Delphi process, allowing participants to submit responses anonymously and independently without being biased by other participants' identities and responses. The steering committee reached out to the panel of experts using the SurveyMonkey online platform (Palo Alto, CA, USA; www.surveymonkey.com) and utilized a blinded electronic rating.

The web-based survey comprised two sections: the first concerned the participants' demographics (e.g., type of profession, field of expertise, and years of experience), and the second involved rating the statements. The panel of experts evaluated the proposed statements and provided additional comments using a free text box to ensure complete coverage of the topics. According to the RAND method, the panel of experts used a 9-point Likert scale (i.e., 1-3 = highly inappropriate, 4-6 = undecided, 7-9 = highly appropriate) to rate the level of concordance for each statement.

In addition, experts could abstain from rating by selecting the answer "Not my expertise" for statements they were not familiar with.

A summary of results for each Delphi round was shared as feedback to update panel members on the progress of consensus development, including descriptive statistics, to guide subsequent rounds. The panel of experts were asked to re-rate their evaluation in subsequent rounds only for those statements needing clarification or for statements for which consensus (i.e., $\geq 75\%$ on a 7-9 points scale or 1-3 points scale) was not reached.

An anonymous report of each round was provided to each expert, showing the distribution of responses for each statement, along with all additional comments provided in the free text box. Based on previous ratings, statements were modified and presented for the next round. Up to three reminder emails for completion were sent to each participant individually. Data collection occurred over 5 months (June-November 2022).

Phase IV. Workshop Meeting as last round

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3 209 After reaching a consensus, the steering committee joined an online meeting to refine statements
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5 210 according to each expert's contribution and confirm which statements would be included in the final
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8 211 criteria list. Finally, the panel of experts was asked to rate the final statements list for the closing audit
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10 212 procedure.

11 12 213 13 14 214 **Definition and calculation of consensus**

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17 215 In agreement with the RAND appropriateness method, we adopted predefined criteria(26) to assess
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19 216 the consensus in the Delphi method, using the proportion of ratings with a threshold of 75%.(27)
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21 Specifically:
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26 219 1. Consensus in: $\geq 75\%$ of participants scored the item as "highly appropriate" (score 7 to 9),
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28 220 and $< 15\%$ scored the item as of "highly inappropriate" (score 1 to 3)
- 29
30 221 2. Consensus out: $\geq 75\%$ of participants scored the item as of "highly inappropriate" (score
31
32 222 1 to 3), and $< 15\%$ scored the item as "highly appropriate" (score 7 to 9)
- 33
34 223 3. No consensus: All other results.
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39 40 225 **Statistical Analysis**

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42 226 Descriptive statistics were used to describe general characteristic of participants, summarised as
43
44 227 median and interquartile range (IQR) and counts and percentage (%), as appropriate. Each statement
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46
47 228 was analysed quantitatively by the percentage of agreement ratings.
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50 51 230 **Role of the Funding Source**

52
53 231 AIFI supported this research. The funder played no role in this study's design, conduct, or reporting.
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57 58 233 **Patient and public involvement**

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60 234 In this study, a patient representative participated in the panel of experts to rate the statements.

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235 RESULTS

236 Participants

237 Out of the 28 scientific and technical societies/organizations that were invited as panel of experts,
238 two declined their interest in participation, while nine did not provide a response. Finally, 17
239 societies/organizations (invitation rate: 61%), each represented by their most representative expert
240 member, were included (**Figure 2**). The majority of experts were clinicians (88.2%), with half having
241 expertise in musculoskeletal disorders (47.1%). Others were specialized in areas such as pelvic floor
242 (23.5%), neurological (17.6%), lymphatic disorders (5.9%), pediatrics (5.9%). The panel also
243 included a forensic and a lay member as patient representative. On average, experts had a median of
244 30 years of experience (IQR 17-36) in their respective fields. All general characteristics are reported
245 in **Table 1**. No conflict of interest was present (**Supplementary File 3**).

[Figure 2]

[Table 1]

250 Delphi rounds

251 Two Delphi Rounds were necessary to reach a consensus.

253 Round 1

254 Overall, 17 experts panel participants completed the survey (participation rate: 100%). All statements
255 passed the first round with a consensus of 75% (**Table 2**). Five experts offered justifications for their
256 choices (e.g., examples of clinical practice) and provided important inputs for the statements. In
257 particular, most of them raised concerns about the safe use of PAMs in children. Additionally, they
258 suggested refining the purpose of the statements, emphasizing that the focus was on patient safety
259 rather than provider safety. Some experts reported uncertainties about safe use of PAMs based on
260 their experiences. For example, one expert mentioned the possibility of mild skin irritation in hot

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3 261 thermal therapies, and another suggested caution in the use of cryotherapy due to risk of cold burns,
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5 262 especially if patients are not well informed or supervised. Then, one expert expressed uncertainty
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8 263 about the safety of long-term use of electromagnetic therapies. Some experts suggested the safe use
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10 264 of PAMs in other fields of applications such as the use of diathermia in the dermatology for Lichen
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12 265 Sclerosus, which was out of our purposes. All comments were considered in the release of the
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14
15 266 statements (**Supplementary File 4**).

16
17 267 [Table 2]
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21 269 *Round 2*

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23 270 The statements from Round 1 were reviewed based on panel comments for the subsequent assessment
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25
26 271 in Round 2, with a specific restriction on the adult population and a clearer emphasis on patient safety.
27
28 272 In Round 2, a total of 14 expert panel participants completed the survey (participation rate: 82%), and
29
30 273 all the statements achieved consensus out of the 75% threshold. (**Table 2**). One expert provided
31
32 274 additional comments including examples of expertise, which were subsequently integrated into the
33
34
35 275 final list of statements. In particular, low-level laser therapy could exacerbate genital dryness,
36
37 276 necessitating additional interventions to improve hydration during the treatment period and mitigate
38
39 277 discomfort for patients. Additionally, there was uncertainty regarding the application of other
40
41
42 278 therapies, such as electrical stimulation and extracorporeal shock wave therapy, in certain fields due
43
44 279 to limited expertise (**Supplementary File 4**).
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46 280 47 48 49 281 *Workshop Meeting*

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52 282 On September 27, 2022, nine experts panel participants (completion rate: 53%) joined the online
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55 283 meeting to discuss comments, justifications and highlights. A comprehensive digital presentation of
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57 284 the findings from Round 1 and Round 2 were reported during the workshop. During the meeting, the
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59 285 panel of experts suggested introducing a general note explicitly stating that statements on safety were

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286 not extended to different subgroups of the population (e.g., children, adolescents,
287 immunocompromised individuals) due to lack of literature.

288 The final list of statements, along with this general note, was shared via SurveyMonkey for final
289 approval. All 17 experts panel participants (approval rate: 100%) approved and released the final list
290 of statements. One expert selected the option "Not my expertise" for the statement on cryotherapy
291 (**Table 2**). In **Appendix 1**, we reported the final criteria list released for good clinical practice with
292 details of sources (evidence and expertise) and applications in different fields and clinical conditions.

For peer review only

293 **DISCUSSION**

294 **Main findings**

295 The SAFE PAMP consensus developed safety statements for Physical Agent Modalities in physical
296 therapy and rehabilitation practice. The multidisciplinary and multiprofessional panel of experts
297 participated with a moderate response rate (61%).(28) All nine statements were approved in two
298 Rounds (consensus of over 75% agreement.) and released in a final workshop meeting with some
299 adjustments made (e.g., specific population subgroups). In summary, experts agreed on the safety of
300 PAMs in the adult population (>18 years) when prescribed and applied by a healthcare professional
301 (e.g., physiotherapist, physician) who is adequately trained and informed, as required by education
302 and licensure.

304 **Literature Context**

305 Earlier consensus documents from different organizations were published in 2001,(6) 2006,(7) and
306 2010.(8) In 2018, the American Occupational Therapy Association issued a position paper(29)
307 clarifying the appropriate use of PAMs in contemporary occupation-based occupational therapy
308 practice, providing clinical case vignettes in their field. Others reported indications and
309 contraindications about specific types of PAMs (e.g., extracorporeal shock wave therapy(30)). Many
310 other societies, such as National Institute for Clinical Excellence (NICE), also offer specific clinical
311 questions guidelines, and we cannot exclude that they can involve recommendations on PAMs (e.g.,
312 NG59 for low back pain(31)).

313 Overall, the Canadian document(8) represents the most comprehensive guidance on this topic.
314 However, our Delphi is the most recent consensus on PAMs focusing on statements about safe PAMs
315 application as clinical practice indications (e.g., field) sustained by literature and clinical expertise.
316 This does not mean that the contraindications and precautions mentioned in the Canadian guideline(8)
317 are in contrast to our findings. Simply, we use a complementary perspective. Our Delphi agrees to
318 define the common safe applications stratifying by fields/conditions whereas the Canadian one

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3 319 describes the contraindications and precautions about these common applications in particular
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5 320 situations or under certain circumstances. For instance, both documents recognize cryotherapy and
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8 321 electrical stimulation as commonly safe PAMs in musculoskeletal applications, such as treating ankle
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10 322 sprains and osteoarthritis. However, the Canadian guideline recommends precaution when combining
11
12 323 compression with cryotherapy to ensure the preservation of circulation and nerves. Furthermore, the
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14
15 324 guideline contraindicated the use of electrical stimulation in presence of implanted electronic devices.
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17 325 Although the evidence presented in the Canadian guideline was not systematically collected (Canada
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19 326 and the United States experts in conjunction with multiple sources such as textbooks), it is reasonable
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22 327 to assume that many precautions and contraindications still remain applicable. Nevertheless, it is
23
24 328 important to note that guidelines should be updated every three to five years or when new information
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26 329 becomes available.(32, 33)
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31 331 **Implications for clinicians**

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33 332 Healthcare professionals are encouraged to use a comprehensive approach when using this Delphi
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35 333 consensus. Prior to proposing PAMs to patients, they must collect their medical history (e.g.,
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38 334 comorbidities) to better determine the diagnosis, prognosis, anticipated goals, and expected
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40 335 outcomes.(34) Then, they should incorporate the best research evidence, clinical expertise, patient
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42 336 values, needs, and preferences to propose effective treatments, balancing effectiveness and safety. It
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44
45 337 is imperative that patients are informed about the possibility of trivial adverse events (e.g., pain and
46
47 338 erythema at the application site(5) using extracorporeal shock wave therapy). However, in situations
48
49 339 when evidence is lacking and there is a likelihood of moderate to severe harm, caution is advised, and
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51 340 the use of PAM may be reconsidered. In fact, for precautionary reasons (35-37) the developed
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54 341 statements were not generally extended to other subgroups, such as children and adolescents (due to
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56 342 biological tissue in growth phases(38, 39)), and frail individuals (e.g., immunocompromised
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58 343 patients), given the limited and insufficient literature on potential harm. It is important to adhere to
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60 344 these statements in conjunction with precautions and contraindications under specific circumstances,

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3 345 referring to equipment manufacturers' manuals and regulatory bodies(40) as well as previous
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5 346 guidelines(8) and standards established by professional associations.
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9 10 348 **Implications for stakeholders**

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12 349 Good practices for patients safety should be managed by national agencies with a living monitoring
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14 350 system and shared through international initiatives such as the WHO Global Patient Safety Challenge
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16 Medication Safety(41) to enhance systems and practices adopting corrective action within countries.
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19 352 For instance, national and international scientific and technical societies should facilitate the
20
21 353 dissemination of CPGs through various strategies, such as storing good clinical practices in shared
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23 repository(42) as well as disseminating plain, patient-oriented versions of good clinical practice
24 354
25 statements. This supports patient empowerment and contributes to making the healthcare system more
26 355
27 efficient, tailored and safer.(43, 44) We plan to organize meetings with stakeholders and patients,
28 356
29 conduct webinars, and provide education and counseling through pamphlets, videos, and social media
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31 messages.
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36 37 360 **Implications for research**

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40 361 We believe that the statements developed by the multidisciplinary and multi-professionally panel of
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42 362 experts can be generalized worldwide. These results could provide essential information to produce
43
44 363 national guidelines (e.g., Good Clinical Practices of the Italian Ministry of Health(45)) and
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46 international guidelines to improve patient safety and decrease avoidable harm related to
47 364
48 interventions. Studies should convey their efforts to plan and adequately report adverse events before
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50 objectively estimating these harms. We call for multicentric randomized controlled trials based on a
51 366
52 core outcome set, including harms in addition to benefits.(46) In addition, specific subgroups of
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54 populations should be studied. It is a serious matter to exclude a group from research eligibility, and
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56 this should only be done when no less restrictive option is sufficient to ensure protection from undue
57 369
58 risk.(47)
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3 371 Lastly, future studies can better expand our statements to ensure the safest and most optimal modality
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5 372 application of the proposed PAMs (e.g., optimal voltage, amperage, frequency, current density, dose),
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8 373 as well as contraindications and precautions, especially for the mentioned subgroups (e.g., children,
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10 374 immunocompromised individuals).(48)

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14 15 376 **Strength and limitations**

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17 377 This represents the first effort to provide guidance on the safety of PAMs in physiotherapy and
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19 378 rehabilitation. We strictly followed published guidelines for reporting and conduction. In addition,
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22 379 we *a-priori* publicly registered the consensus criterion used to determine agreement within the Delphi
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24 380 process. (26, 49) We adopted one of the most conservative thresholds for obtaining the consensus
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26 381 (75%)(27), and in all rounds, this threshold was reached with a high percentage of agreements.
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29 382 However, some downsides should be acknowledged. We did not cover statements about the clinical
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31 383 effectiveness of PAMs, as our aim was to make patients, healthcare providers and policy-makers
32
33 384 aware about the safety application of PAMs in clinical practice. As well, we did not aim to report
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35 385 specific contraindications as we started collecting evidence from systematic reviews that reported
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38 386 safety outcomes from primary studies, which may not always encompass real-world conditions, such
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40 387 as the presence of comorbidities (e.g., active deep vein thrombosis). Furthermore, evidence-informed
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42 388 by systematic reviews did not find enough information about the risk for specific population (e.g.,
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45 389 hemato-oncological patients with severe immunocompromised or coagulopathy). However, based on
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47 390 the principle of precaution, the panel agreed to add as a general note about precautions in specific
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49 391 subgroups of the population, in the absence of literature. As with all Delphi process, our study relies
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51 392 on national expert response and may not capture the full range of perspectives or experiences.(16, 50)
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54 393 Nevertheless, we tried to involve multidisciplinary and multi-professional experts (as occurs in
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56 394 clinical practice guidelines) enabling confrontations in anonymity (avoiding negatively influencing
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58 395 outcomes and encouraging balanced consideration of ideas). Then, statements were developed
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60 396 starting from the scoping review(5), which mapped and summarized safety in population and

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3 397 intervention areas without assessing the certainty of evidence (e.g., grading of the certainty of
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5 398 evidence).(5) Lastly, even though we generated statements based on the latest available evidence, we
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8 399 should recognize that adverse events may be under-estimated since safety outcome is commonly
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10 400 poorly reported in the literature (11, 12, 51).
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12 401 13 14 **CONCLUSION** 15 402

16
17 403 These evidence-based statements inform patients, healthcare professionals, and policy-makers about
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19 404 the safety of a wide range of PAMs in various fields and conditions of physiotherapy and
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22 405 rehabilitation practice, following comprehensive clinical evaluation of patients' needs. All of these
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24 406 statements should be associated to precautions and contraindications for specific cases, referring to
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26 407 previous guidelines, equipment manufacturers' manual and regulatory bodies. This consensus can
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28 408 provide a basis for decision-making and future research.
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3 409 **DECLARATIONS**

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5 410 **Author Contributions**

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8 411 Concept/idea/research design: S. Gianola, S. Bargerì, G. Castellini

9
10 412 Writing: S. Gianola, S. Bargerì, G. Castellini

11
12 413 Data collection: S. Gianola, S. Bargerì

13
14 414 Data analysis: S. Gianola, S. Bargerì

15
16 415 Project management: S. Gianola, S. Bargerì

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18
19 416 Consultation (including review of manuscript before submitting): S. Gianola, S. Bargerì, L.

20
21 417 Pellicciari, S. Gambazza, G. Rossetti, A. Fulvio, V. Genovese, M. Benedini, E. Proverbio, S.

22
23 418 Cecchetto, G. Castellini, A. Turolla, and SAFE PAMP Collaborators

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26 419
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28 420 **Ethics Approval**

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30 421 This study was declared exempt from institutional review board review.

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33 422
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35 423 **Disclosures**

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37 424 The authors and SAFE PAMP Collaborators declared they had no conflicts of interest.

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42 426 **Funding**

43
44 427 This work was supported and funded by Associazione Italiana di Fisioterapia (AIFI). The APC was
45
46 428 funded by AIFI. This research did not receive specific grant from any funding agency in the public,
47
48 429 commercial or not-for-profit sectors.

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53 431 **Data sharing statement**

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55 432 Research data are stored in OSF repository <https://osf.io/w8kgs/> (19)

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58 433
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60 434 **Manuscript word count: 3275/4000**

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435 **Figure 1.** Phases of the RAND Delphi process

436 **Figure 2.** Flow chart of Delphi process

437 **Table 1.** General characteristics of experts panels

438 **Table 2.** Agreement results for each round.

For peer review only

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571 **Tables**

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Table 1. General characteristics of experts panel (n=17)

Professional profile*	Responses N (%)
Clinicians	15 (88.2)
Researchers	7 (41.2)
Management	4 (23.5)
Field of expertise*	
Musculoskeletal	8 (47.1)
Pelvic floor disorders	4 (23.5)
Neurological	3 (17.6)
Lymphatic disorders	1 (5.9)
Paediatrics	1 (5.9)
Lay member (Patient)	1 (5.9)
Forensic member	1 (5.9)

*More than one answer was possible

573

574 **Table 2. Agreement results for each round**

Statements about the safety of...	ROUND 1		ROUND 2		FINAL LIST	
	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Percentage of agreement (7-9 points on the Likert scale)	Percentage of disagreement (1-3 points on the Likert scale)	Approved	NME
Electrical stimulation	85.7	7.1	85.7	0.0	100.0	0.0
Neuromodulation, antalgic, and interferential electrical currents	100.0	0.0	100.0	0.0	100.0	0.0
Extracorporeal shock wave therapy	83.3	0.0	76.9	0.0	100.0	0.0
Laser therapy	84.6	7.7	90.9	0.0	100.0	0.0
Electromagnetic therapy	81.8	9.1	76.9	0.0	100.0	0.0
Diathermy	90.0	10.0	84.6	0.0	100.0	0.0
Hot thermal agents	81.8	9.1	91.7	0.0	100.0	0.0
Cryotherapy	75.0	0.0	90.9	0.0	94.2	5.8
Therapeutic ultrasound	90.9	0.0	91.7	0.0	100.0	0.0
General note [^]	-	-	-	-	100.0	0.0

575 [^]added for the Final Criteria List

576 Abbreviations: NME: not my expertise

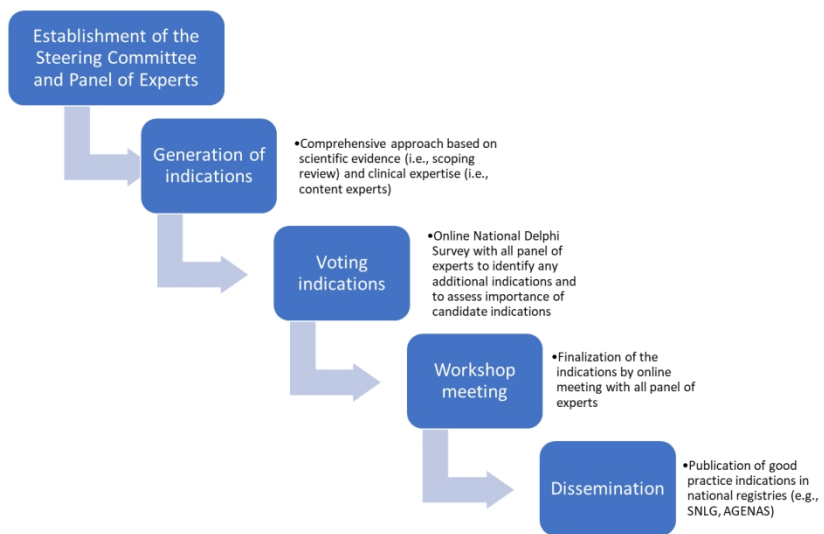


Figure 1

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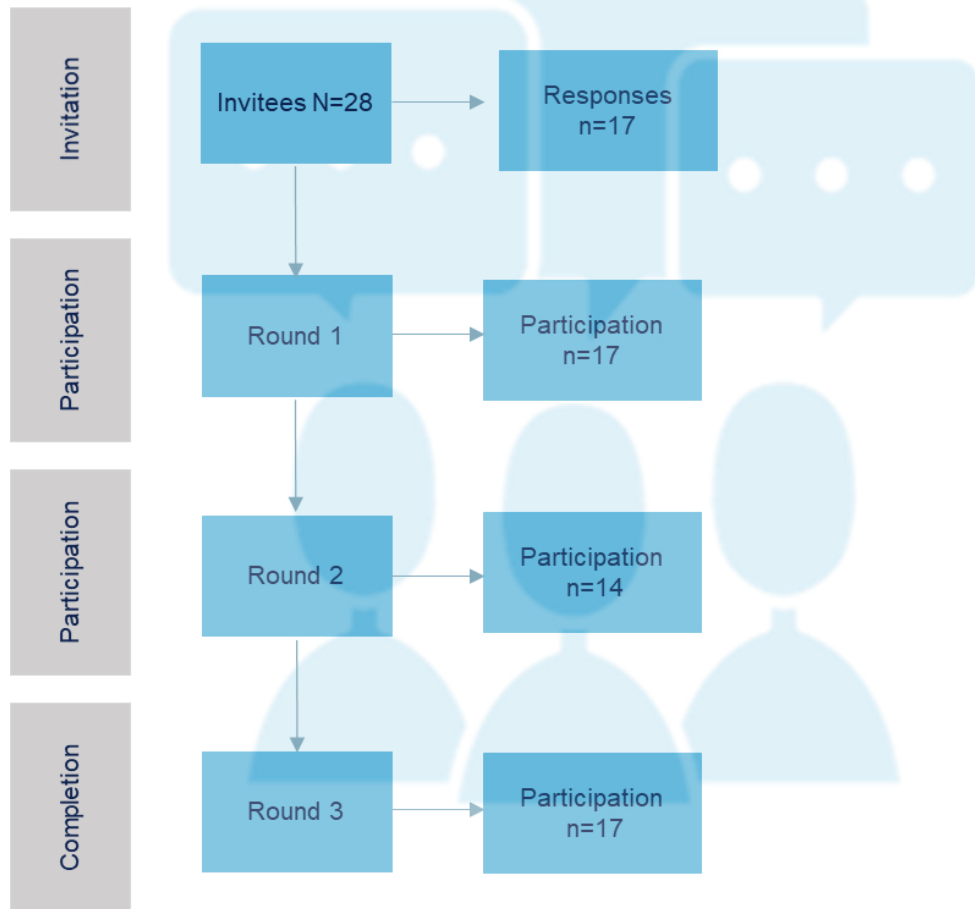


Figure 2

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1 **Appendix 1. Final criteria list**

2 **Introduction**

3 The statements are focused on the adult population. Each statement was developed based on the
4 scientific literature (i.e., evidence) and the experience of content experts from the Associazione
5 Italiana di Fisioterapia - AIFI (i.e., expertise) with details for clinical conditions in the relevant
6 rehabilitation fields.

7 *Target group:* statements were developed for adults (> 18 years). Physical agents modalities (PAMs)
8 are delivered by expert healthcare professionals (who had undergone formal education and training)
9 to ensure patient safety in both inpatient and outpatient settings.

10 *Conditions of application:* statements were presented within the relevant rehabilitation field
11 according to *informed-evidence* and *expertise-based* consensus.

12 *Evidence:* this section has been defined based on a scoping review of the literature conducted by
13 two independent reviewers focusing on the safety of PAMs from 117 systematic reviews in
14 physiotherapy and rehabilitation medicine (5).

15 *Expertise:* this section has been formulated by the steering committee, which included different
16 content experts from AIFI (e.g., neurological, musculoskeletal, pelvic floor, physical therapies), with
17 additional inputs from the multidisciplinary and multi-professional panel of experts.

18 **Final list of statements**

19 **1. Electrical stimulation (e.g., Functional electrical stimulation (FES), Neuromuscular**
20 **electrical stimulation (NMES), Electrical muscle stimulation (EMS)) is safe in the adult**
21 **population**

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2
3 22 - *in musculoskeletal disorders, especially in the following conditions:*

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5
6 23 o Evidence: neck pain, knee osteoarthritis, musculoskeletal pain, muscle hypotrophy.

7
8
9
10 24 o Expertise: spinal osteoarthritis, knee osteoarthritis, musculoskeletal pain, knee
11
12 25 osteoarthritis, muscle and joint pain.

13
14
15
16 26 - *in pelvis-perineal disorders, especially in the following conditions:*

17
18
19 27 o Evidence: urinary incontinence, fecal incontinence, lower urinary tract symptoms in
20
21 28 postpartum women, overactive bladder.

22
23
24
25 29 o Expertise: prolapse, descending perineum syndrome, perineal hypotonia, bladder-sphincter
26
27 30 or anorectal dyssynergia, erectile dysfunction, premature ejaculation, abdominal diastasis.

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31 31 - *in neurological disorders, especially in the following conditions:*

32
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34 32 o Evidence: migraine, spasticity in multiple sclerosis, stroke, spinal cord injury.

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38 33 o Expertise: post-stroke urinary incontinence, neurogenic bowel dysfunction in spinal cord
39
40 34 injury, second motor neuron disease (e.g., Amyotrophic Lateral Sclerosis), muscular
41
42 35 dystrophies, head trauma, lesions of the peripheral nervous system.

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46 36
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49 37 **2. Neuromodulation, antalgic and interferential electrical currents (e.g., TransCutaneous**

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51 38 **Electrical Nerve Stimulation (TENS), Transcutaneous Tibialis Posterior Stimulation (TTNS))**

52
53
54 39 **are safe in the adult population**

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56
57 40 - *in musculoskeletal disorders, especially in the following conditions:*

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2
3 41 o Evidence: low back pain, neck pain, rotator cuff disease, whiplash-associated disorders,
4
5 42 fibromyalgia.
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8
9 43 o Expertise: musculoskeletal pain, spine osteoarthritis, neuropathic pain.
10
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12 44 - *in pelvis-perineal disorders, especially in the following conditions:*
13
14

15 45 o Evidence: overactive bladder, urinary incontinence, fecal incontinence, persistent pelvic
16
17 46 pain.
18
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20
21 47 o Expertise: Urinary incontinence, pudendal neuralgia, constipation, urinary retention.
22
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24
25 48 - *in neurological disorders, especially in the following conditions:*
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28 49 o Evidence: neuropathic pain, stroke, multiple sclerosis, neurogenic bowel dysfunction after
29
30 50 spinal cord injury.
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34 51 o Expertise: neurogenic bladder dysfunction after central and peripheral nervous system
35
36 52 injuries.
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43 54 **3. Extracorporeal shock wave therapy (radial and focal) is safe in the adult population**
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47 55 - *in musculoskeletal disorders, especially in the following conditions:*
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49

50 56 o Evidence: soft tissue disorders of the lower limbs, knee tendinopathy, Achilles
51
52 57 tendinopathy, osteoarthritis, plantar fasciitis, rotator cuff disease, shoulder tendinopathy and
53
54 58 calcifications, acute fracture, orthopedic disorders, consolidation delays, other soft tissue
55
56 59 disorders.
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3 60 o Expertise: enthesopathies of the upper and lower limbs, calcifications, epicondylitis,
4
5 61 epitrocleitis, muscle injuries, muscle contractures, and trigger points.

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9 62 - in neurological disorders, especially in the following conditions:

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11
12 63 o Evidence: post-stroke lower limb spasticity, multiple sclerosis spasticity.

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15 64 o Expertise: spasticity following head trauma, spasticity following spinal cord injury.

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19 65 - in pelvis-perineal disorders, especially in the following conditions:

20
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22 66 o Evidence: chronic prostatitis/chronic pelvic pain syndrome.

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25 67 o Expertise: persistent female pelvic pain, Peronye's disease.

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29 68 Patients should be informed of the potential undesirable effects following the application of
30
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32 69 extracorporeal shock wave therapy. Indeed, a recent literature review showed some expected mild
33
34 70 adverse events, such as pain and erythema, at the application site.(5)
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41 72 **4. Laser therapy (e.g., low-level laser therapy (LLLT), high-level laser therapy (HLLT)) is**
42
43 73 **safe in the adult population**

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47 74 - in musculoskeletal disorders, especially in the following conditions:

48
49
50 75 o Evidence: low back pain, Achilles tendinopathy, rotator cuff disease, capsulitis adhesive,
51
52 76 lower extremity soft tissue disorders, frozen shoulder, carpal tunnel syndrome, knee
53
54
55 77 osteoarthritis, neck pain, whiplash associated disorders.
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3 78 o Expertise: upper and lower limb tendinopathy, acute arthropathy, acute muscle and tendon
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5 79 injuries, acute musculoskeletal pain. Upper and lower limb tendinopathy, acute arthropathy,
6
7
8 80 acute muscle and tendon injury, and acute musculoskeletal pain.
9

10
11 81 - *in pelvis-perineal disorders (extracavitary LLLT only), especially in the following conditions:*
12

13
14 82 o Evidence: Urinary incontinence and pelvic organ prolapse, persistent pelvic pain.
15
16

17
18 83 o Expertise: healing (episiotomies, laparotomies, lacerations, etc.), inflammatory pelvic
19
20 84 pain, edema or perineal hematomas.
21
22

23
24 85 - *in lymphatic disorders (LLLT only), especially in the following conditions:*
25

26
27 86 o Evidence: secondary lymphoedema (e.g., breast cancer-related lymphedema).
28
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30
31 87 o Expertise: lymphoedema
32
33

34 88 - *in neurological disorders (LLLT only), especially in the following conditions:*
35

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37
38 89 o Evidence: Bell's palsy
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41 90 o Expertise: stroke, multiple sclerosis, spinal cord injury, head trauma, peripheral nerve
42
43 91 injury.
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45

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47 92 **5. Electromagnetic therapy (e.g., Pulsed ElectroMagnetic Field Therapy (PEMFT), repetitive**
48
49 93 **Peripheral Magnetic Stimulation (rPMS)) is safe in the adult population**
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53 94 - *in musculoskeletal disorders, especially in the following conditions:*
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56 95 o Evidence: neck pain, fractures, consolidation delays.
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60 96 o Expertise: osteoporosis, bone edema, algodystrophy, arthrosis.

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3 97 - *in pelvis-perineal disorders, especially in the following conditions:*

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6 98 o Evidence: persistent pelvic pain and urinary incontinence.

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9
10 99 o Expertise: fecal incontinence, prolapse, descending perineum syndrome, perineal
11
12 100 hypotonia, vesico-sphincteric or anorectal dyssynergia, pudendal neuralgia, pelvic pain
13
14 101 acute, erectile dysfunction, premature ejaculation, diastasis recti.
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18 102 **6. Diathermy (e.g., Short Wave Tecar Therapy) is safe in the adult population**

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21
22 103 - *in musculoskeletal disorders, especially in the following conditions:*

23
24
25 104 o Evidence: rotator cuff disease, knee osteoarthritis.

26
27
28 105 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-
29
30 106 acute), osteoarthritis, muscle contractures, trigger points.
31
32
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34 107 - *in pelvis-perineal disorders, especially in the following conditions:*

35
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38 108 o Evidence: inflammatory pelvic pain, persistent pelvic pain, sexual dysfunction (Peronye's
39
40 109 disease).

41
42
43 110 o Expertise: prolapse, stress urinary incontinence, scarring (episiotomies, laparotomies,
44
45 111 lacerations, etc.), perineal edema or hematoma, vulvovaginal dystrophy and dryness,
46
47 112 abdominal diastasis.
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51 113 **7. Hot thermal agent modalities (e.g., drug-free heat wrap) are safe in the adult population**

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55 114 - *in musculoskeletal disorders, especially in the following conditions:*

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58 115 o Evidence: groin pain, low back pain.
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3 116 o Expertise: sub-acute/persistent muscle injuries, DOMS/DOMER, arthropathies (non-
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5 117 acute), osteoarthritis
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12 119 **8. Cryotherapy (e.g., ice or liquid nitrogen) is safe in the adult population**
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16 120 *- in musculoskeletal disorders, especially in the following conditions:*
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- 19 121 o Evidence: arthroscopy, reconstruction of the anterior cruciate ligament, post-surgery.
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23 122 o Expertise: Delayed Onset Muscle Soreness (DOMS)/Delayed Onset Muscle Soreness
24
25 123 (DOMER), post-surgery, post-trauma (48h).
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32 125 **9. Therapeutic Ultrasound is safe in the adult population**
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35 126 *- in musculoskeletal disorders, especially in the following conditions:*
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39 127 o Evidence: back pain, neck pain, carpal tunnel, rotator cuff disorder, lower limb soft-tissue
40
41 128 disorder, knee osteoarthritis, fracture, acute fracture, ankle fracture, ankle and knee sprains,
42
43

- 44
45 129 o Expertise: hand and foot osteoarthritis, calcifications, enthesitis.
46
47

48 130 **General notes and considerations related to subgroups:**
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51 131 Following a confirmed clinical prescription, applying the above PAMs is safe in the adult
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53

54 132 population (>18 years) under the supervision of an expert operator. For precautionary reasons, these
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56 133 statements are not extended to other subgroups of patients (e.g., children, adolescents, frail
57

58 134 population, etc.) since insufficient literature is available.
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Supplementary Files

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Supplementary File 1. Ethical considerations

Participation in the Delphi survey is voluntary and by invitation. The questionnaire includes a beginning section to acquire consent and privacy for data processing. Participants are informed that the responses will have 'remained total confidentiality according to the Regulation on the protection of personal data' 679/2016 of the European Union, and that the results will be used for research purposes and a document shared at the corporate level¹. The interested party may be interested in the rights provided for by art. 15, 16, 17, 18, 20, 21 and 22 of the Regulation mentioned above.

Database randomization and differential privacy access were achieved. In addition, "anonymization" by generalizing was performed.² The study project and data collection were managed and anonymously entrusted by the Unit of Clinical Epidemiology of IRCCS Istituto Ortopedico Galeazzi based in Milano. The data subject cannot be re-identified and is therefore outside the scope of the data protection law³.

The row dataset was accessible to two researchers (SG, SB) excluded from participation in Delphi for the quantitative and qualitative analyses. This practice complies with the European standards for the use of aggregative data where the data subject cannot be re-identified, are not personal data and are therefore outside the scope of data protection law³. The final report only contains aggregate data. In the final document, we reported the names of the participants who have completed all rounds and gave their consent to disclose their names.

Supplementary File 2. Physical agent modalities description

1) **Electrical stimulation:** electrotherapeutic currents and waveforms to facilitate neuromuscular or sensory activity to improve muscle strength and reeducate muscle function.⁴

- Neuromuscular electrical stimulation (NMES): use of pulsed currents to stimulate motor nerves, which in turn produce tetanic contractions of the neuromuscular spindles, with or without joint movement.⁵
- Functional Electrical Stimulation (FES) uses electrical pulses to stimulate motor neurons or denervated muscle fibers directly to elicit a contraction during a functional activity (e.g., gait). FES is used in the treatment of orthopedic and neurological conditions.⁶

2) **Neuromodulation, analgic and interferential electrical currents :** electrotherapeutic currents and waveforms to influence physiological effects on the patient's body structures and functions aiming to modulate pain.⁴

- Transcutaneous electrical nerve stimulation (TENS): delivers electrical stimulation via electrodes placed over the intact skin surface near the source of pain to produce analgesia or hypoalgesia. A wide variety of pulsed waveforms are used, with frequencies typically in the range of 1-100Hz. The intensities are set to produce sensory stimulations alone or in combination with motor stimulations to produce muscle twitches (acupuncture-like TENS).⁷
- Transcutaneous Tibialis Posterior Stimulation (TTNS): a form of neuromodulation involving the use of electrical impulses to address urinary symptoms (e.g. overactive bladder) with inhibitory action on neurons of the spinothalamic tract (S2-S3).⁸
- Interferential current (IC): involves crossing two medium frequency currents (most commonly 4000 Hz), which reportedly generates a low-frequency 'beating' (amplitude-modulated) effect at between 0 and 150 Hz in the deep tissues.⁹ These beat frequencies are believed to decrease pain, increase circulation and block nerve conduction.

3) **Extracorporeal shock wave therapy:** a nonsurgical treatment that uses the phenomenon of mechanotransduction (i.e., adapting cells biochemical activity, influencing cells migration, proliferation, differentiation and apoptosis)^{10 11} to treat various musculoskeletal conditions (e.g., plantar fasciitis; tennis elbow). Shock wave therapy can be either extracorporeal or radial.¹²

- Extracorporeal shock wave therapy (ESWT) involves passing sound waves (or shock waves) through the skin to the affected area. Shock waves are single pulsed acoustic or sonic waves, which dissipate mechanical energy at the interface of two substances with different acoustic impedance.¹³ They are produced by generators of an electrical energy source and require an electroacoustic conversion mechanism and a focusing

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3 device. Three types of systems can be distinguished based upon the sound source:
4 electrohydraulic, electromagnetic and piezoelectric systems. Various doses appear to
5 be used, with no apparent consensus on the minimum therapeutic dose. As defined
6 defined by Cacchio 2006¹⁴ as low-energy shock waves is less than 0.1 mJ/mm² and
7 high-energy shock waves: is 0.2 mJ/mm² to 0.4 mJ/mm²).

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9 - Radial shock wave therapy (RSWT) is generated through the acceleration of a
10 projectile inside the handpiece of the treatment device and then transmitted radially
11 from the tip of the applicator to the target zone. Radial shock waves show a lower
12 peak pressure and a considerably longer rise time than extracorporeal shock waves.
13 In RSWT, the focal point is not centred on a target zone, as occurs in focal ESWT,
14 but on the tip of the applicator.¹⁴

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17 **4) Laser therapy:** light source treatment, non-invasive, widely used to treat various
18 musculoskeletal conditions.

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21 - Low-level laser therapy (LLLT) generates a beam of light with a particular
22 wavelength that can deliver light energy to tissue depths below the dermis¹⁵.
23 Studies suggest that LLLT contributes to pain relief by reducing pro-inflammatory
24 cytokines¹⁶. The effects of LLLT are considered to be dependent on dosage,
25 wavelength, site and duration of treatment.^{15 16}
- 26
27
28 - high level laser therapy (HLLT): laser with an output power greater than 500 mW
29 or 0.5 Watts. HLLT creates heat on the surface of the skin due to their higher power
30 density (irradiance).¹⁷

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34 **5) Electromagnetic therapy:** based on Faraday's law of electromagnetic induction, to promote
35 bone healing, treat osteoarthritis and inflammatory diseases of the musculoskeletal system,
36 alleviate pain, enhance healing of ulcers and reduce spasticity¹⁸.

37
38 - Pulsed Electromagnetic Field therapy (PEMF), which involves the delivery of pulsing (that
39 is 'on-off') low-frequency magnetic fields through the body, which is believed to provide
40 temporary pain relief by influencing tissue generation and cell proliferation.¹⁹

41
42
43 - Repetitive magnetic stimulation (rMS), which allows the transcutaneous induction of nerve
44 stimulating electric currents. This technique requires extremely strong and sharp magnetic
45 impulses (for example 15,000 amperes peak current; 2.5 T field strength; < 1 msec) applied
46 by specially designed coils (< 10 cm) over the target area. Modern devices allow the repetition
47 of up to 60 impulses per second. Mainly developed to study and influence brain functions,
48 rMS also stimulates spinal chord fibres and peripheral nerves. Initial studies used peripheral
49 rMS for therapeutic reasons, such as in myofascial pain syndrome²⁰. Since the resulting small
50 electric impulses are the nerve stimulating factor, rMS effects may be similar to TENS.

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54 **6) Shortwave and microwave Diathermy**

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56 - Tecartherapy or radiofrequency diathermy (RFD) is a non-invasive therapy and
57 consists in the emission of high-frequency electromagnetic waves which increase
58 tissue metabolism. This process promotes tissue repair and affects pain
59 sensitivity.^{21 22 23}

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- Microwave diathermy: a deep heating modality that converts electromagnetic energy to thermal energy. Frequencies approved for therapeutic microwave are 915 MHz (wavelength 33 cm) and 2,456 MHz (wavelength 12 cm). The lower frequency has the advantage of increased depth of penetration but also the disadvantages of greater beam dispersion and the requirement of larger applicators. If muscle heating is primary objective, 915-MHz applicators are preferable to 2,456-MHz applicators. Average temperatures of approximately 41°C at a depth of 1–3 cm have been demonstrated²⁴

- 7) **Hot thermal agents:** heat transferred from an object with direct contact to the body. Heat therapy include hot packs, heatwraps, hot/warm water immersion, sauna. Heat treatment increases metabolism in tissues, promotes blood circulation and reduces pain. The temperature of the heat therapy is generally 35–40°C.^{25 26}
- 8) **Cryotherapy:** cold is transferred from an object with direct contact to the body. Examples include cold packs, cold-water immersion ($\leq 15^{\circ}\text{C}$), ice massage, the novel modality of cryotherapy. Cryotherapy is a treatment involving very short exposures to extremely cold dry air to the whole patient or a treatment area (mean temperature of the cryotherapy chamber is at -30°C , -80 to -110°C , or $< -110^{\circ}\text{C}$). Cold treatment is thought to reduce swelling and cell metabolism, minimizing oedema, pain and injury.^{25 27}
- 9) **Therapeutic Ultrasound:** delivers energy to deep tissue sites through ultrasonic waves (often at frequencies of 1 or 3 MHz and intensities between 0.1 watts/cm² and 3 watts/cm²) using a crystal sound head. Treatment can be delivered in two forms, continuous (non- stop ultrasonic waves) and pulsed (intermittent ultrasonic waves^{22 28}). The treatment aim to increase tissue temperature and induce non-thermal physiological changes (such as cell permeability and cell growth), which are believed to promote soft tissue healing and muscle relaxation.²⁹

Supplementary File 3. Declaration of interest

Name and Surname	Affiliation	Scientific and Technical Societies	Conflict of interest declared
Armando Perrotta	IRCCS Neuromed, Pozzilli (IS)	Società Italiana per lo Studio delle Cefalee (SISC)	none
Viviana Rosati	A.U.O. Policlinico Umberto I	Società Italiana di Riabilitazione Neurologica (SIRN)	none
Enrico Marinelli	Department of Anatomical, Histological, Forensic, and Orthopedic Sciences, "Sapienza" University of Rome	Società Italiana di Medicina Legale e delle Assicurazioni (SIMLA) - Dipartimento di Scienze Biotechologiche e Medico-chirurgiche Università di Roma Sapienza	none
Bianca Masturzo	Obstetrics and Gynecology department. Ospedale degli infermi. Ponderano (Biella)	Associazione degli Ostetrici e Ginecologi Ospedalieri Italiani (AOGOI)	none
Mauro Roselli	ASL CittadiTorino- Ospedale Martini-S.C. Ortopedia e Traumatologia	Ortopedici Traumatologi Ospedalieri d'Italia (OTODI)	none
Stefano Vercelli	Laboratorio di Ricerca in Riabilitazione 2rLab, Dipartimento Economia Aziendale, Sanità e Sociale. SUPSI. Manno (CH)	Federazione Italiana delle Associazione Scientifiche di Fisioterapia (FIASF)	none
Gianmarco Rea	Asl Latina, 04100 Latina, Italy	Società Italiana di Medicina Generale e delle Cure Primarie (SIMG)	none

Gianfranco Lamberti	Dipartimento Medicina Riabilitativa AUSL Piacenza	Società Italiana di Urodinamica (SIUD)	none
Roberto Bortolotti	UO Reumatologia Ospedale S.Chiera, Trento	Società Italiana di Reumatologia (SIR)	none
Chiara Torresetti	Paideia International Hospital	Associazione Italiana di Urologia Ginecologia e del Pavimento Pelvico (AIUG)	none
Fabio Bandini	Department of Neurology, ASL 3 Genovese, Genova, Italy	Società Italiana Neurologia (SIN)	none
Giuseppe Botta	Istituto Fisioterapico Michelangelo di Arezzo	Società Italiana di Flebolinfologia (SIFL)	none
Giancarlo Tancredi	Pediatric Department. Sapienza Università di Roma	Società Italiana di Pediatria (SIP)	none
Luigi Nappi	Department of Medical and Surgical Sciences Policlinico Riuniti di Foggia UNIVERSITY OF FOGGIA	Società Italiana Di Ginecologia E Ostetricia (SIGO)	none
Marco Scorcu	Servizio di Medicina dello Sport e dell'Esercizio Fisico, Cagliari, ATS	Federazione Medico Sportiva Italiana (FMSI)	none

	Sardegna, Cagliari, Italy		
Monica Pierattelli	Presidente SICuPP Toscana, Pediatra di libera scelta Campi Bisenzio (FI)	Societa' Italiana Delle Cure Primarie Pediatriche (SICuPP)	none
Carla Berliri	Cittadinanzattiva- APS - Sede Nazionale -Staff area Salute - Tribunale per i Diritti del Malato - Politiche della Salute-	Cittadinanzattiva - APS	none

Supplementary File 4. Panel of experts comments

ROUND	Electrical Stimulation	Neuromodulation, antalgic and interferential electrical currents	Extracorporeal shock wave therapy	Laser therapy	Electromagnetic therapy	Diathermy	Hot thermal agent modalities	Cryotherapy	Ultrasound
Round 1	My Likert Scale rating of 9 stems not only from the numerous evidence but also from the results of my clinical experience. In cases of perineal hypotonia and sphincter deficits, electrical stimulation has facilitated recovery times by enhancing manual work and proprioception during the learning phase.	The primary application of TTNS in my practice, aside from addressing bladder disorders (overactivity), is in the management of painful syndromes, such as spasms of peri-urethral muscles in patients with recurrent post-coital cystitis, vulvodynia, and pudendal neuralgia.	In this case, my assessment requires specificity: In many instances, women experiencing resistant pelvic pain may not readily accept the use of shock waves, as it is an impactful therapy that can cause initial discomfort. Among various instrumental approaches for this patient group, it would not be my first choice. On the other hand, my perspective on shock waves for the treatment of male pelvic pain or erectile dysfunction is quite different; in this case, I positively endorse the statement.	completely agree.	I cannot provide a judgment as I lack the appropriate training and experience in its use.	Thanks to the use of diathermy, I can achieve excellent results in the treatment of dermatological conditions affecting the genital mucosa, such as Lichen Sclerosus. In pelvic pain, patients appreciate the mild heat generated by the diathermy probe, allowing for more effective therapy in the area. Currently, this treatment is consistently integrated into all treatment plans, irrespective of individual clinical situations, without causing discomfort or triggering sensitivity reactions	Limited experience in menstrual pain for just the efficacy. However it is related to other type of hot thermal agents (e.g, infrared therapy)	Agreed, but the patient must be adequately instructed in advance on the use and timing of cryotherapy, for example, ice packs postpartum or in inflammatory hemorrhoidal syndromes. Discourage self ice application, and encourage the use of devices designed for healthcare purposes. It is a very useful and easily administered therapy but potentially 'dangerous' if mishandled at home, for instance, the risk of cold burns	For my expertise US is safe in pelvic disorders.
	In the absence of expertise in the pelvic-perineal and neurological domains, the opinion is limited to the musculoskeletal field	In the absence of expertise in the pelvic-perineal and neurological domains, the opinion is limited to the musculoskeletal context only.	Shock waves are not recommended in individuals during the developmental age since their tissues and cartilage are still in the developmental phase	In the absence of expertise in pelvic-perineal, lymphatic, and neurological domains, the opinion is limited to the musculoskeletal context only	In the absence of expertise in pelvic-perineal areas, the opinion is confined to the musculoskeletal context only. The indicated median score pertains to uncertainty regarding the safety of persistent use (long term), as I am not aware of literature data on adverse events for such durations. For treatment cycles falling within the time frames investigated in the	In the absence of expertise in the pelvic-perineal domain, the opinion is confined to the musculoskeletal context only. The moderate agreement with the safety statement primarily concerns uncertainties regarding the operator's safety with high daily exposure to the equipment, especially if potential risk factors are present (e.g., pregnancy or	In my experience, I have observed several cases of mild and transient skin irritations.	It is the only treatment I have seen used in younger age groups	For my expertise US is safe in pelvic disorders.

					available RCTs, the judgment is certain	the presence of oncological pathologies, even if unrecognized). I am not aware of studies monitoring the health of operators exposed to moderate or high levels of possible electromagnetic fields generated by the equipment. Regarding the equipment's safety for the patient, the judgment of agreement is certain.			
	NMES is widely used to address certain types of pharyngeal dysfunction in adults with dysphagia, but there is limited evidence demonstrating its effectiveness or appropriateness for pediatric patients. Reference: Andreoli S et al. Int J Pediatr Otorhinolaryngol 2019;127:109646. doi: 10.1016/j.ijporl.2019.109646.	NA in some pelvi-perineal and neurological disorders	NA in some pelvi-perineal and neurological disorders	Adulthood or in individuals with skeletal maturity	PEMF therapy is not recommended for children who have not yet completed their growth phases	It is not recommended for children as their biological tissues are still in the growth phase	I suggest emphasizing more strongly that the use is specifically intended for non-acute arthropathies	Risk of cold burn	Rarely used in adolescents after sports-related traumas
	NA in some perineal neurological disorders	For my experience mainly for neurological disorders		NA in some neurological and perineal disorders	NA for some perineal disorders	NA for some perineal disorders	for my expertise, uncertain in groin pain		
	For my expertise mainly in migraine			LLLT expertise in some neurological conditions (e.g, migraine)	for my expertise mainly used in migraine				
Round 2	Limited in some neurological setting	Useful also for vulvodynia, rectal spasms with anal pain	Uncertainty in some neurological disorders	limited evidence in some neurological disorders		I additionally include post-genital ulcer treatment, hypertonicity, and genital swelling in patients with pelvic pain	Limited experience in menstrual pain for just the efficacy. However it is related to other type of hot thermal agents (e.g, infrared therapy)	Cryotherapy in pelvic floor rehabilitation is used for the treatment of pain from hemorrhoidal inflammation, postpartum contusion, postpartum hypotonia with pronounced laxity, and for some patients, it	For my expertise US is safe in pelvic disorders.

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									is beneficial in addressing the sensation of genital swelling in chronic pelvic pain
				I do not have the right clinical experience to rate it with confidence. In my clinical practice, patients who have undergone LLLT have shown a greater tendency towards increased genital dryness. Therefore, the treatment requires additional measures such as enhanced hydration, for example, through the use of serums/ointments/suppositories during the treatment period, to mitigate certain side effects that may cause discomfort to the patients.					

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CREDES Checklist:**Recommendations for the Conducting and REporting of DElphi Studies (CREDES)[1]**

Items of reporting	Reported on page
<i>Purpose and rationale.</i> 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.	5 - 6
<i>Expert panel.</i> Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported.	7
<i>Description of the methods.</i> 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.	7-10
<i>Procedure.</i> 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.	6-9; Figure 1-2
<i>Definition and attainment of consensus.</i> It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus.	9-10
<i>Results.</i> 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.	10-12; Table 2; Appendix 2
<i>Discussion of limitations.</i> Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance.	15-16
<i>Adequacy of conclusions.</i> 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
<i>Publication and dissemination.</i> 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.	13-14

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