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## Accepted Manuscript

Title: Physiotherapy for primary frozen shoulder in secondary care: Developing and implementing stand-alone and post-operative protocols for UK FROST and inferences for wider practice

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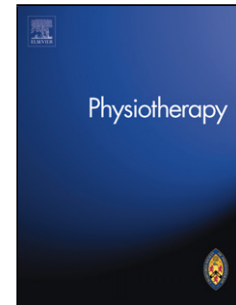
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**Physiotherapy for primary frozen shoulder in secondary care:  
Developing and implementing stand-alone and post-operative  
protocols for UK FROST and inferences for wider practice**

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**Author contribution**

N.C.A. Hanchard: Input into all aspects of methods, Delphi survey development, implementation and analysis; wrote the paper. ☐

L. Goodchild: Input into Delphi survey development, implementation and analysis; revision of manuscript.

S. D. Brealey: Input into Delphi survey development, implementation and analysis; revision of manuscript. ☐

SE. Lamb: revision of manuscript. ☐

A. Rangan: Chief investigator UK FROST; advice on content; revision of manuscript.

**Ethics approval**

*Delphi survey ethics approval* Ethics approval (069/14) for the Delphi survey was obtained from the School of Health and Social Care Research Governance and Ethics Committee of Teesside University on 23<sup>rd</sup> May 2014.

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**Conflicts of interest**

Dr Rangan's department has received educational and research funds from DePuy Ltd outside the submitted work. None of the other authors declare any conflicts.

1 **Physiotherapy for primary frozen shoulder in secondary care:**  
2 **Developing and implementing stand-alone and post-operative**  
3 **protocols for UK FROST and inferences for wider practice**

4

5 **Abstract**

6 **Objectives** The United Kingdom Frozen Shoulder Trial (UK FROST) compares stand-  
7 alone physiotherapy and two operative procedures, both with post-operative  
8 rehabilitation, for primary frozen shoulder in secondary care. We developed  
9 physiotherapy protocols for UK FROST, incorporating best evidence but recognizing  
10 uncertainty and allowing flexibility.

11 **Methods** We screened a UK Department of Health systematic review and UK evidence-  
12 based guidelines<sup>1,2</sup> for recommendations, and previous surveys of UK physiotherapists  
13<sup>3,4</sup> for strong consensus. We conducted a two-stage, questionnaire-based, modified  
14 Delphi survey of shoulder specialist physiotherapists in the UK National Health Service.  
15 This required positive, negative or neutral ratings of possible interventions in four  
16 clinical contexts (stand-alone physiotherapy for, respectively, predominantly painful  
17 and predominantly stiff frozen shoulder; and post-operative physiotherapy for,  
18 respectively, predominantly painful and predominantly stiff frozen shoulder). We  
19 proposed respectively mandating or recommending interventions with 100% and 90%  
20 positive consensus, and respectively disallowing or discouraging interventions with  
21 90% and 80% negative consensus. Other interventions would be optional.

22 **Results** The systematic review and guideline recommended including steroid injection  
23 and manual mobilizations in non-operative care, and we mandated these for stand-  
24 alone physiotherapy. Consensus in the pre-existing surveys strongly favoured advice,  
25 education and home exercises, which we mandated across contexts. The Delphi survey  
26 led to recommendation of some supervised exercise modalities, plus the disallowing or  
27 discouragement—in various contexts—of immobilization and some ‘higher-tech’  
28 electrotherapies and alternative therapies.

29 **Conclusions** We developed physiotherapy protocols despite incomplete empirical  
30 evidence. Their clear structure enabled implementation in data-sheets designed to

31 facilitate recording, monitoring of fidelity and reporting of interventions. Other trials  
32 involving physiotherapy may benefit from this approach.

33

### 34 **Contribution of the paper**

- 35 • Pre-existing reviews and guidelines<sup>1,2</sup> for use of physiotherapy in treatment of  
36 primary frozen shoulder confirmed that the empirical evidence was very limited:  
37 only steroid injections and manual mobilization, both for non-operative care, were  
38 recommended. Previous surveys<sup>3,4</sup> emphasized patient advice, education and  
39 provision of home exercises as key elements of care.
- 40 • A dedicated Delphi survey helped develop physiotherapy protocols to be used in all  
41 three arms of the United Kingdom Frozen Shoulder Trial (UKFROST), comparing  
42 stand-alone physiotherapy and two operative procedures, both with post-operative  
43 rehabilitation, for primary frozen shoulder.
- 44 • Our approach lends itself to the development of structured protocols, enabling  
45 implementation in data-sheets that facilitate recording, monitoring of fidelity and  
46 reporting of interventions in clinical trials.

47

### 48 **Key words**

49 Frozen shoulder, methods, physiotherapy, protocol, UK FROST

50

### 51 **Introduction**

52 Primary frozen shoulder has a prevalence of around 10% in the general population<sup>5</sup> and  
53 causes profound physical and emotional effects.<sup>6</sup> It is idiopathic, and starts with pain in  
54 the shoulder and arm,<sup>7</sup> which increases as stiffness develops. The pain and stiffness may  
55 become severe, causing substantial functional impairments.<sup>6,7</sup> There is a tendency to  
56 resolution, but the natural history is protracted, spanning months or years, and  
57 recovery may be slow or incomplete.<sup>8</sup> Patients' anxieties are fuelled by uncertainties  
58 about their diagnosis, the likely outcome or both, against a background of chronic pain  
59 and disturbed sleep.<sup>6</sup>

60 For patients entering secondary care with primary frozen shoulder, popular  
61 treatments in the UK National Health Service (NHS), include: physiotherapy

62 (permutations of advice, exercises, therapist-applied mobilization techniques and  
63 thermo- and electrotherapies); intra-articular steroid injection(s), which many NHS  
64 physiotherapists are trained to administer; manipulation under anaesthetic (MUA),  
65 repeated if symptoms recur,<sup>9</sup> which may be combined with a steroid injection (MUA  
66 with steroid); and arthroscopic capsular release (ACR), supplemented by MUA (ACR  
67 with MUA).<sup>10</sup> However, it is unknown whether a combination of steroid injection and  
68 physiotherapy (steroid with PT) or either of the operative procedures, each with post-  
69 operative physiotherapy, is more effective.<sup>2</sup> UK FROST is a multi-centre randomized  
70 controlled trial (RCT) that seeks to clarify this at the point in the care pathway when an  
71 operative procedure is being considered. It compares steroid with PT *versus* MUA and  
72 steroid with PT *versus* ACR and MUA with PT. Crucially, all arms of UK FROST involve  
73 physiotherapy, either as part of the stand-alone physiotherapy intervention (designated  
74 as 'structured physiotherapy' in the trial) or as rehabilitation following an operative  
75 procedure ('post-procedural physiotherapy').

76 We aimed to rationalize development and implementation of the physiotherapy  
77 protocols in UK FROST, so as to make the interventions relevant and acceptable beyond  
78 the trial. This would involve:

- 79 • developing physiotherapy protocols that would incorporate 'best practice' insofar  
80 as this could be established, while recognizing uncertainty and accommodating  
81 clinical adaptability;
- 82 • implementing these protocols as graduated models for stand-alone and post-  
83 operative physiotherapy, whereby any possible physiotherapy intervention would  
84 fall into one category on an ordinal scale of 'mandatory', 'optional' or 'not allowed';  
85 and
- 86 • gauging the optimal duration of a course of physiotherapy based on clinical  
87 considerations.

88 In operationalizing the protocols, we further aimed to develop data collection forms  
89 that would facilitate:

- 90 • adherence by trial physiotherapists;
- 91 • quick, comprehensive documentation of treatments; and ultimately
- 92 • comprehensive reporting as recommended by the TiDIER guidelines.<sup>11</sup>

93 While UK FROST motivated these processes, we anticipated that the results would  
94 allow us to cautiously draw more general inferences.

## 95 **Methods**

96 The research team explicitly established *a priori* three fundamental and non-negotiable  
97 standards for the conduct of physiotherapy in the trial. These were that it should be  
98 delivered only by qualified physiotherapists and only in hospital settings (to ensure  
99 accessibility of resources), and that post-operative physiotherapy should ideally  
100 commence within 24 hours of the procedure. We established, too, that treating  
101 physiotherapists would be required to document their grade, as well as the number of  
102 frozen shoulder patients typically treated in their routine practice.

103 We then compiled a list of broadly defined, potentially applicable physiotherapy  
104 interventions from the general literature and discussion and set out to categorize each  
105 on our ordinal scale. Ideally, we based these categorizations on empirical evidence  
106 (from evidence-based clinical guidelines and systematic reviews of RCTs and economic  
107 evaluations) but, if this was unavailable, on existing, published expert consensus or a  
108 Delphi survey of shoulder-specialist physiotherapists that was conducted especially for  
109 UK FROST. Each intervention had to be categorized in four clinical contexts (Figure 1),  
110 which accounted for whether physiotherapy was stand-alone or post-operative and  
111 whether the presentation was 'pain-' or 'stiffness-predominant'. The latter dichotomy,  
112 which is meaningful to clinicians and patients, was developed originally for non-  
113 operatively managed frozen shoulder,<sup>3,4</sup> but we reasoned that it would also apply post-  
114 operatively.

115 **Evidence-based clinical guidelines and systematic reviews of RCTs** We drew on  
116 primary RCTs and economic analyses through two resources previously developed by  
117 our group: the UK national physiotherapy guidelines for frozen shoulder, which were  
118 based on a systematic review;<sup>1,12</sup> and a systematic review and cost-benefit analysis  
119 commissioned by the National Institutes for Health Research (NIHR) Health Technology  
120 Assessment (HTA) programme.<sup>2</sup> These rigorously evaluated the effectiveness of many  
121 applicable physiotherapy interventions (including steroid injection) and detailed the  
122 scheduling and duration of physiotherapy in any studies that showed benefit.

123 Our reviews<sup>1,2,12</sup> revealed no good-quality RCTs or economic analyses on post-  
124 operative physiotherapy. We therefore expanded our scope to include the *GOST*:  
125 *Shoulder and Elbow Guidance for Orthopaedic Surgeons and Therapists*,<sup>13</sup> particularly to  
126 inform the overall duration of our post-operative physiotherapy programmes. This

127 document represents the generally accepted UK standard for post-operative  
128 physiotherapy care.

129 **Expert consensus** Expert consensus was derived from two previous questionnaire  
130 surveys on UK physiotherapists' approaches to stand-alone physiotherapy for frozen  
131 shoulder,<sup>3,4</sup> from which we extrapolated to post-operative care if this was reasonable,  
132 and a Delphi survey of UK shoulder specialist physiotherapists, which addressed stand-  
133 alone and post-operative physiotherapy.

134 **Delphi survey** This was a modified Delphi survey conducted in two rounds. The target  
135 population was NHS shoulder specialist physiotherapists and the sampling frame was  
136 the contact physiotherapists for three major shoulder RCTs recently conducted in the  
137 NHS: CSAW,<sup>14</sup> ProFHER<sup>15</sup> and UKUFF.<sup>16</sup>

138 *Development of the Delphi survey* Two authors, NH and LG, both shoulder specialist  
139 physiotherapists (one academic and one clinical) developed a list of potentially relevant  
140 treatment interventions, erring towards over-inclusivity (Table 1). This list was used to  
141 populate a Delphi questionnaire in which respondents would be required to categorize  
142 the respective interventions as 'should always be used' (i.e. mandatory), 'should not be  
143 used' (not allowed) or 'optional' in each of the four study contexts (Figure 1). Certain  
144 interventions were pre-categorized, based on recommendations of the evidence-based  
145 clinical guidelines and HTA systematic review,<sup>1,12</sup> on strong, previously established  
146 expert consensus,<sup>3,4</sup> or both (italicized items in Table 1, and see Results). The  
147 questionnaire explained these exceptions, and did not require respondents to  
148 categorize them. Spaces were provided for respondents to add any unlisted treatment  
149 interventions that they thought important.

150 Round two questionnaires replicated those of round one, but reminded  
151 respondents of their respective round-one categorizations as well as presenting the  
152 modal categorizations for all respondents. Thus individual responses were informed by  
153 those of the group and could be modified at this stage.

154 The objectives of the Delphi study were to achieve consensus and to quantify the  
155 level of agreement. We did not require criteria to determine when to stop the Delphi  
156 because we structured the survey to deliver the best possible consensus over 2 rounds.  
157 Consensus criteria are listed in Table 2.

158

159 Piloting of the questionnaires by 10 physiotherapists (seven clinical and three  
160 academic) resulted in addition of a 'don't know' option for categorizations, but no other  
161 changes, and indicated that the round one questionnaire could be completed in 20  
162 minutes or less and round two in 25-30 minutes or less. The definitive questionnaires  
163 were implemented on protected Word® forms.

164 *Delphi survey recruitment strategy* A 'gatekeeper' approach was used. One of us (AR)  
165 knew the site Principal Investigators (usually surgeons) of CSAW, ProFHER and UKUFF,  
166 and emailed each of them (N = 113) to ask that they forward the email to the most  
167 appropriate physiotherapist at their site. We estimated that the sampling frame  
168 comprised between 70 and 100 physiotherapists.

169 *Delphi survey procedure* The email incorporated the covering letter for the invitations to  
170 participate and, as attachments, the Participant Information Sheet and the first round  
171 questionnaire. This email informed the Principal Investigators of our intention to send  
172 routine reminders through them to the potential participants one and two weeks hence,  
173 and asked that those emails be forwarded in the same way. Round one questionnaires  
174 required respondents to provide their names and preferred email addresses, while  
175 round two required names. These data enabled: matching of round one and two  
176 questionnaires; emailing of round two questionnaires directly to participants rather  
177 than *via* 'gatekeepers'; feedback of the survey results; and entry of participants who had  
178 completed and returned both questionnaires into a prize draw for a £50.00 shop  
179 voucher. Up to two weekly reminders were sent for round two.

180 *Delphi survey analysis* Table 2 shows the implementation of Delphi consensus  
181 thresholds in the development of the UK FROST protocol. We decided *a priori* that a  
182 90% consensus of valid respondents who expressed an opinion was convincing. We  
183 duly disallowed interventions with a  $\geq 90\%$  rating of 'should not be used' from UK  
184 FROST. However, we could not apply a corresponding consensus threshold to 'should  
185 always be used' to define mandatory interventions. This would have risked labelling as  
186 mandatory certain interventions that some centres could not deliver, due to lack of  
187 facilities, equipment or specific skills. Pragmatism therefore dictated that consensus for  
188 'should always be used' be set at 100% of valid responders who expressed an opinion.  
189 We defined interventions that met neither the 'should always be used' nor the 'should  
190 not be used' thresholds as 'optional'. Furthermore, we retrospectively decided that, to  
191 make best use of our data, we would stratify the 'optional' category. This involved

192 setting secondary, 80% levels of consensus for ‘should always be used’ and ‘should not  
193 be used’. These would be respectively implemented as ‘recommended’ and  
194 ‘discouraged’ interventions in the protocol.

195 Lastly, as well as informing the UK FROST protocol, we aimed to make our data  
196 directly useful to clinical physiotherapists. This involved a supplementary analysis  
197 redefining consensus as > 50% of valid respondents. We selected > 50% for this  
198 purpose because, as the threshold for the pronoun ‘most’, it is an intuitive and  
199 universally meaningful quantification. Specifically, given the paucity of evidence, we  
200 considered that clinicians could gain much reassurance from an indication of how most  
201 of our expert respondents rated each of the interventions. In the clinical setting, this  
202 level of quantification would provide a more useful benchmark than the 80-90%  
203 required for developing the UK FROST protocol. As valuable as such inferences for  
204 clinical practice may be, however, they are only indicative. This is because they reach  
205 beyond the frame of the Delphi survey, which was couched in the context of UK FROST.  
206 We briefly present this aspect of our analysis in our paper, but further details are  
207 provided in the [supplementary information](#).

## 208 **Results and their application**

209 **Evidence-based clinical guidelines and systematic reviews of RCTs** Our reviews<sup>1,12</sup>  
210 revealed that good-quality empirical evidence for or against effectiveness was very  
211 limited, and that there was none applicable post-operatively. For conservatively  
212 managed frozen shoulder both documents had, however, recommended steroid  
213 injection and adjunctive manual mobilizations. These recommendations were based on  
214 two RCTs—one in secondary care and at low risk of bias,<sup>17</sup> the other in primary care  
215 and at some risk of bias,<sup>18</sup> which collectively provided moderate evidence that a steroid  
216 injection is effective for conservatively managed frozen shoulder, and that  
217 physiotherapist-applied manual mobilizations, adapted to suit differing clinical  
218 presentations, might augment the benefit for some outcomes. We therefore specified  
219 that a steroid injection (unless clearly not indicated or contra-indicated) ‘should always  
220 be used’ as part of structured physiotherapy, as should physiotherapist-applied manual  
221 mobilizations. However, recognizing that there are many different approaches to  
222 manual mobilisations, all influenced by patient presentation, we did not prescribe the  
223 technique or insist that they be given at every session.

224 A further consideration was the number and distribution of sessions. Our primary  
225 sources<sup>17,18</sup> provided nine and twelve physiotherapy sessions respectively, but  
226 distributed them differently (Table 3). We emulated the higher figure but approached  
227 distribution pragmatically, specifying that sessions could be spaced and used at  
228 physiotherapists' discretion over up to 12 weeks. Where progress required fewer  
229 sessions, this was acceptable. We did not prescribe the length of each session. We  
230 applied a similar structure to post-operative physiotherapy delivery. This was  
231 commensurate with the recommendation in *GOST: Shoulder & Elbow* that post-operative  
232 physiotherapy for ACR should be continued for up to 12 weeks. *GOST: Shoulder & Elbow*  
233 did not address MUA as an isolated procedure.<sup>13</sup>

#### 234 **Expert consensus**

235 *Existing literature* Previous surveys of UK physiotherapists involved in treating  
236 frozen shoulder<sup>3,4</sup> revealed that a very large majority favoured provision of advice,  
237 education and exercises. We therefore pre-specified "advice and education" and "home  
238 exercises" as mandatory elements of the stand-alone physiotherapy protocol and  
239 confidently extrapolated this mandatory status to post-operative physiotherapy. We  
240 were unable to provide evidence for specific exercises or dose however, and  
241 determined that these would be delivered throughout the trial on an individual basis  
242 according to clinical judgment.

243 *Delphi survey* There were 46 responses to round one (41% response rate) and 42 to  
244 round two, demonstrating good retention (91%). For one round two respondent, some  
245 responses were void. Forty-five round one respondents (98%) were self-reportedly  
246 shoulder specialist physiotherapists. The detailed results of the Delphi survey are  
247 shown in Figures 2 to 5. These are considered in relation to UK FROST and then, briefly,  
248 more generally. The latter aspect is addressed more extensively in the [supplementary](#)  
249 [information](#).

250 No interventions achieved the 100% consensus criterion for 'should always be  
251 used' in UK FROST, but some, all exercise-related, reached or exceeded 80%, and were  
252 therefore 'recommended' (Figures 3 to 5). These were one-to-one function-based  
253 exercises for structured physiotherapy in the stiffness-predominant phase, one-to-one  
254 gentle active exercises for post-operative physiotherapy in the pain-predominant phase,  
255 and one-to-one gentle active exercise and function-based exercise for post-operative  
256 physiotherapy in the stiffness-predominant phase.

257 Some interventions met or exceeded our 90% consensus criterion for 'should not be  
258 used' and were consequently disallowed by the UK FROST protocol. In this category,  
259 and applicable to all four of the clinical contexts, were deep friction, laser and provision  
260 of a brace. There was also  $\geq 90\%$  consensus that craniosacral therapy, interferential and  
261 shockwave therapy 'should not be used' in the stiffness- predominant phase for either  
262 structured or post-operative physiotherapy when stiffness was the predominant  
263 problem; and that craniosacral therapy 'should not be used' for structured  
264 physiotherapy in the pain-predominant phase. A number of interventions met or  
265 exceeded our 80% consensus criterion for 'should not be used' in one or more of the  
266 four clinical contexts, and the protocol discouraged their use in those contexts. Thus  
267 ultrasound was discouraged in all contexts; Bowen therapy in all contexts except  
268 structured physiotherapy during the stiffness-predominant phase; graded motor  
269 imagery, mirror therapy and shortwave diathermy for stiffness-predominant  
270 presentations, irrespective of whether the physiotherapy was structured or post-  
271 operative; shockwave therapy for structured physiotherapy in the pain-predominant  
272 phase; and craniosacral therapy and electro-acupuncture for post-operative  
273 physiotherapy in the pain- and stiffness-predominant stages, respectively. Most  
274 interventions considered in the Delphi survey fell short of 80% consensus for 'should  
275 always be used' and also for 'should not be used'. These were all allowed by the UK  
276 FROST protocol.

277 As previously stated, to cautiously apply our results more generally, we performed  
278 a supplementary analysis in which we re-defined consensus as a simple majority. There  
279 is no compelling reason to suppose that respondents would have rated interventions  
280 any differently for applications outside of UK FROST. Nonetheless, the fact remains that  
281 ratings were made for the latter, and extrapolation from that context can only be  
282 indicative. Refer to the [supplementary information](#) for more detailed narrative on this  
283 aspect. Briefly, at this level of consensus, most interventions were considered at least  
284 acceptable. The cluster of interventions categorized as 'should always be used'  
285 expanded by gaining additional types of exercise, as well as postural re-education,  
286 across clinical contexts. At the other end of the spectrum, additional interventions rated  
287 as 'should not be used' across all four contexts most notably included the most  
288 'alternative' therapies, higher-tech electro- and thermotherapies, graded motor  
289 imagery, mirror therapy and provision of a brace. As would be expected, the majority of

290 respondents also rated most analgesic modalities and strategies as 'should not be used'  
291 in the stiffness-predominant stage.

### 292 **Operationalising the results of the reviews and expert consensus for UK FROST**

293 Our rational approach to developing the physiotherapy protocols in UK FROST was a  
294 crucial step towards making the interventions relevant and acceptable beyond the trial.  
295 But in operationalizing these there were two other key considerations. First, the data  
296 collection instrument had to capture interventions in sufficient detail to enable  
297 comprehensive reporting as recommended by the TiDIER guidelines<sup>11</sup> and be navigable  
298 by clinicians and researchers alike. Second, in order to optimize participating  
299 physiotherapists' adherence and the reliability of their recording, it had to be clearly  
300 presented and quick and easy to complete, requiring little more than routine record  
301 keeping.

302 We developed two log sheets, one for structured physiotherapy sessions and one  
303 for post-operative physiotherapy sessions (Figures 6 and 7 in the [supplementary](#)  
304 [information](#)), which were collated into patient-specific logbooks. The log sheets served  
305 as *aides-memoire* and forms for quickly documenting key session characteristics. Each  
306 required a judgment as to whether, on that particular day, pain or stiffness  
307 predominated. The physiotherapist was then directed to a corresponding column on the  
308 form. This listed the interventions that were disallowed or discouraged for clear  
309 reference. It specified and highlighted the interventions that were mandatory or  
310 encouraged in a tick box format to facilitate recording. To further enhance the ease of  
311 recording, the checkbox lists were extended to include a limited number of additional  
312 interventions that we expected to be frequently used, these being derived from the  
313 remaining Delphi items with the highest levels of acceptability (the 'should always be  
314 used' and 'should be optional' categories combined). This last process involved  
315 screening out broadly equivalent terms to avoid redundancy, and clustering highly  
316 related interventions provided that doing so would not cause confusion, that the  
317 interventions' acceptability was high and homogeneous, that there was clinical  
318 justification, and that any clustered data were sufficient for our research aims. Such  
319 judgements were made on a context specific basis. There was no requirement for  
320 physiotherapists to use any of these additional interventions, which were provided only  
321 for ease of recording; and they were free to use any others, unless they were disallowed

322 or—to a lesser degree—discouraged. Space was provided for other interventions to be  
323 recorded in longhand.

## 324 **Discussion**

325 We used composite methodology to evaluate a wide range of physiotherapy  
326 interventions for stand-alone (structured) and post-operative physiotherapy for  
327 primary frozen shoulder. This was mainly motivated by the requirement to develop  
328 ‘best practice’ physiotherapy protocols for UK FROST. Standardization of complex  
329 interventions like physiotherapy in clinical trials is problematic, because empirical  
330 evidence is patchy, opinions differ, and different contexts may demand different  
331 approaches. Rigid standardization may over-reach from the evidence, fail to  
332 accommodate contextual factors, alienate clinicians and patients—and possibly impact  
333 upon outcomes—by limiting choice and adaptability, and lack relevance to real-life  
334 practice. Conversely, inadequate standardization may lead to trial treatment provision  
335 that is un-evidenced, hard or impossible to define, and not replicable.<sup>19</sup> Clearly, in trials  
336 such as UK FROST, a position between these extremes, which respectively characterize  
337 explanatory and pragmatic research, would be desirable. In practice, this has seldom  
338 been achieved: a recent, large systematic review of surgical trial interventions  
339 (comparably complex to interventions in physiotherapy trials) revealed that fewer than  
340 one third were reportedly standardized, and fewer than one third were monitored for  
341 adherence, regardless of whether the trials were claimed to be explanatory or  
342 pragmatic.<sup>20</sup> The design, conduct, monitoring and reporting of rehabilitation in surgical  
343 trials has been particularly poor, but the recent ProFHER (Proximal Fracture of  
344 Humerus Evaluation by Randomisation) trial, a surgical trial with a physiotherapy  
345 intervention group, set foundational standards in these regards.<sup>21</sup> They used paper-  
346 based (thus universally available) forms listing the likeliest interventions alongside tick  
347 boxes, and provided space in which other interventions could be recorded longhand.  
348 Their forms were well completed,<sup>21</sup> and we sought to replicate their properties. Listing  
349 all of the interventions derived from empirical evidence, established best practice and  
350 the Delphi survey was an option; but these would have numbered 50 or more per  
351 context, making the forms cumbersome and burdensome to use, not least because many  
352 of the Delphi items were not mutually exclusive. A further option now available would  
353 be electronic data collection. Electronic note keeping has become common since the

354 inception of UK FROST, and data collection could readily be ported to that medium; but  
355 the same limitations apply. In order to achieve proper balance in our own trial, we  
356 identified possible physiotherapy interventions and classified them as 'mandatory',  
357 'recommended', 'optional', 'discouraged' or 'not allowed', according to available  
358 empirical evidence, clinical guidelines or expert opinion, as applicable. Alongside  
359 guidance on the number and distribution of physiotherapy sessions, this provided a  
360 clearly defined treatment framework, and facilitated monitoring of treatment fidelity as  
361 well as recording of the interventions given. This approach is broadly commensurate  
362 with the strategy for standardizing complex surgical interventions that has  
363 subsequently been recommended.<sup>22</sup>

364 On implementing our approach, we could derive only limited data from existing  
365 empirical evidence and/or clinical guidelines. This informed the number and  
366 distribution of treatment sessions in UK FROST (stand-alone and post-operative  
367 physiotherapy) and enabled us to designate a small number of core interventions (for  
368 stand-alone physiotherapy only); but the dearth of data placed a premium on our  
369 Delphi survey, in which responders were free to consider all but a handful of pre-stated  
370 core interventions. Applying our stringent consensus criteria (Table 2) to further  
371 inform the physiotherapy protocols for UK FROST, no intervention reached the pre-  
372 specified consensus threshold to be deemed mandatory; while few reached the  
373 thresholds at which to be encouraged, discouraged or disallowed. Most interventions  
374 were therefore categorized as optional. It is noteworthy that even among this sample of  
375 shoulder-specialist physiotherapists there was only a single instance of complete  
376 consensus. This highlights the level of uncertainty that exists.

377 Our Delphi respondents were asked to rate interventions specifically in the context  
378 of UK FROST, and our rather stringent criteria for consensus were set with that in mind.  
379 However, as a supplementary step, we re-analyzed the Delphi survey using a less  
380 stringent criterion (>50%) for consensus as to whether interventions 'should always be  
381 used', either 'always be used' or 'optional' in combination (i.e. at least acceptable), or  
382 'should not be used'. This was to increase the relevance of our paper to clinical  
383 physiotherapists, for whom the weight of expert opinion may seem more relevant than  
384 the high consensus thresholds used in developing UK FROST. Viewed in these terms, the  
385 Delphi survey revealed a relatively small nucleus of interventions (approximately 5 to  
386 10%, according to context) that were favoured. More (approximately 25-50%) were

387 considered unacceptable; and more still (approximately 40 to 70%) were rated as at  
388 least acceptable options. The distribution broadly agrees with our previous single-  
389 round questionnaire surveys,<sup>3, 4</sup> although those surveys did not include post-operative  
390 physiotherapy. To our knowledge, no previous study has sought physiotherapists'  
391 opinions on the post-operative rehabilitation of frozen shoulder.

392 **Limitations** With only a 41% response rate and 46 participants the Delphi survey may  
393 not represent the majority of clinical opinion. Higher response rates are desirable but  
394 prove difficult to achieve. We offered the opportunity to win a high street voucher as an  
395 incentive, and purposefully made involvement with the Delphi process as  
396 straightforward as possible both to maximize participation and—anticipating that **most**  
397 **participants would also be asked to take part in to UK FROST itself—to minimize**  
398 **respondent fatigue**. To these ends we developed the survey to achieve consensus and  
399 quantify the level of agreement in just two rounds. **Two rounds are relatively few but**  
400 **were expected to be sufficient for the purposes of protocol development; and, though**  
401 **possible, it is doubtful whether further rounds would have substantively altered the**  
402 **consensus that most interventions should be optional.**

403 While our supplementary analysis of the Delphi data using the >50% level of  
404 consensus increases the relevance of our paper to clinical physiotherapists, the fact  
405 remains that the Delphi respondents were asked to rate the interventions for UK FROST  
406 specifically, and so due caution must be exercised when extrapolating the results to  
407 wider practice.

408

## 409 **Conclusions**

410 We used a composite methodology to inform stand-alone and post-operative  
411 physiotherapy interventions in UK FROST, which is comparing injection with  
412 physiotherapy; and two surgical options with physiotherapy for primary frozen  
413 shoulder in secondary care. This facilitated development of a structured, flexible  
414 protocol that reflects best evidence but recognizes uncertainty and variations in  
415 preference, expertise and context. In implementing the protocol, we sought to optimize  
416 recording, monitoring and reporting of the physiotherapy interventions. Supplementary  
417 analysis of the Delphi survey, cautiously extrapolating beyond UK FROST, revealed a  
418 picture in which most interventions were at least acceptable, but exercises were

419 generally favoured; and immobilization, higher-tech electrotherapies and most  
420 alternative therapies were generally viewed negatively by shoulder specialist  
421 physiotherapists in the UK.

422

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491

492 **Table 1. Interventions considered in the Delphi questionnaires (including those added by**  
 493 **respondents).** Pre-specified mandatory interventions for UK FROST are shown in italics, where †  
 494 is based on empirical evidence and ‡ on our previous questionnaire surveys; *PT* applies to stand-  
 495 alone physiotherapy, *Post-op* to post-operative physiotherapy, *Pain* to pain- predominant and  
 496 *Stiff* to stiffness-predominant.

Category	Intervention	
Education and re-education	<i>Advice and education (‡, PT, (Post-op), Pain, Stiff)</i>	
	Alexander technique	
	CBT	
	Explain pain	
	Graded motor imagery	
	Mirror therapy	
	Posture re-education	
	Relaxation techniques	
Injection	<i>Intra-articular steroid injection (†, ‡, PT, Pain)</i>	
Hands-on techniques	<i>Manual mobilisations (†, ‡, PT, Pain, Stiff)</i>	
	Bowen therapy	
	Craniosacral therapy	
	Effleurage for pain	
	Mobilisations with Movement (MWMs)	
	Muscle energy techniques	
	Myofascial release	
	PNF	
	Spinal/scapulothoracic manual therapy	
	Therapist-assisted end range mobilisations	
	Tool-assisted soft tissue techniques	
	1-to-1 function based exercises	
	1-to-1 gentle active exercises	
	1-to-1 sustained stretching exercises	
Active assisted exercises with scapula control		
Exercises	Facilitation/strength training of rotator cuff/scapula	
	Gentle pulley exercises	
	Hydrotherapy	
	Land-based exercise class	
	Pain-relieving self-mobilizations	
	Passive assisted exercises	
	Scapula setting	
	Neural dynamics	Neural dynamics
	Electro- and thermotherapies	Laser
		Interferential
Shortwave diathermy		
Shockwave therapy		
Superficial cold		
Superficial heat		
TENS		
Ultrasound		
Acupuncture and related	Acupressure	
	Acupuncture	
	Dry needling	
	Electro-acupuncture	
	Trigger-point therapy	
	Deep tendon friction	
	Effleurage	
	Myofascial release	
Taping techniques	Conventional taping	
	Kinesiotaping	
Immobilization	Brace	
Other	Aromatherapy	
	OT or combined assessment	

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498 **Table 2. Consensus criteria.** \*"Don't know" responses were excluded from the consensus  
 499 calculations.

Definition of consensus	Consensus threshold	Implementation of intervention in UK FROST protocol	
'Should always be used'	100%	Mandatory	
'Should always be used'*	80%	Encouraged	Optional
—	—	—	
'Should not be used'*	80%	Discouraged	
'Should not be used'*	90%	Not allowed	

500

501 **Table 3. Scheduling and duration of physiotherapy in the primary RCTs that showed**  
 502 **benefit.**

Study	Session length (min)	Sessions per week	Number of weeks	Sessions total
Carette	60	1	12	12
Ryans	Not reported	2	4	8

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[Supplementary information](#)**536 Delphi results in the general context (Figures 2 to 5)**

537 As stated in the main text, in order to apply the results more generally, consensus was  
538 re-defined as a simple majority: that is, > 50% of the valid responders who expressed an  
539 opinion. The median of responders who expressed an opinion on the stand-alone  
540 physiotherapy interventions was 95% for both the pain and stiffness predominant  
541 phases, and on the post-operative physiotherapy interventions was 98% for both the  
542 pain and stiffness predominant phases.

543 **Stand-alone physiotherapy intervention, pain predominant phase (Figure 2)** By  
544 this more liberal (> 50%) criterion, there was consensus that posture re-education, one-  
545 to-one function based exercises and one-to-one gentle active exercises 'should always  
546 be used'. (Steroid injection and manual mobilisations were pre-specified for stand-alone  
547 physiotherapy and not included in the questionnaire.) Passive assisted exercises fell  
548 short of consensus for 'should always be used', but combining this with the 'should be  
549 optional' rating revealed it to be a very acceptable intervention.

550 There was consensus that the majority of interventions 'should be optional'.  
551 Specifically, these included some education and re-education (CBT, explain pain and  
552 relaxation techniques); some hands-on techniques (MWMs, myofascial release, scapula-  
553 thoracic manual therapy and tool-assisted soft tissue techniques); some  
554 exercises/exercise settings (active-assisted exercises with scapula control,  
555 facilitation/strength training, gentle pulley exercises, hydrotherapy, land-based  
556 exercise class, pain-relieving self-mobilisations, PNF, proprioceptive rehabilitation and  
557 scapula setting); neural dynamics; superficial cold and heat and TENS; most  
558 acupuncture and related interventions (acupressure, acupuncture, dry needling,  
559 electro-acupuncture and trigger-point therapy); and conventional- and kinesio-taping.

560 Opinion on effleurage for pain was equally split between 'should be optional' and  
561 'should not be used'.

562 Consensus on 'should not be used' included some forms of education and re-  
563 education (Alexander technique, graded motor imagery and mirror therapy); some  
564 hands-on techniques (craniosacral therapy and therapist-assisted end range  
565 mobilisations); one-to-one sustained stretching exercises; most electro- and  
566 thermotherapy (interferential, laser, shockwave therapy, shortwave diathermy and

567 ultrasound); some massage (Bowen therapy and deep friction); provision of a brace;  
568 and aromatherapy.

569 **Stand-alone physiotherapy intervention, stiffness predominant phase (Figure 3)** There was  
570 consensus that posture re-education, one-to-one function based exercises, one-to-one  
571 gentle active exercises and one-to-one sustained stretching exercises “Should always be  
572 used”. (Steroid injection and manual mobilisations were pre-specified and not included in  
573 the questionnaire.) Facilitation/strength training and active exercises with scapula control  
574 fell just short of consensus for ‘should always be used’, but combining these with their  
575 ‘should be optional’ ratings revealed them to be very acceptable interventions.

576 Consensus on ‘should be optional’ included some of the hands-on techniques  
577 (effleurage for pain, MWMs, myofascial release, spinal/scapula-thoracic manual  
578 therapy, tool-assisted soft-tissue techniques) and some exercises/exercise settings  
579 (gentle pulley exercises, scapula setting, hydrotherapy, land-based exercise class, PNF,  
580 therapist-assisted end-range mobilisations); superficial heat and TENS; and—alone in  
581 the ‘acupuncture and related’ group—trigger point therapy.

582 Consensus on interventions that ‘should not be used’ included some forms of  
583 education and re-education (Alexander technique, CBT, explain pain, graded motor  
584 imagery and mirror therapy); some hands-on techniques (Bowen therapy, craniosacral  
585 therapy and deep friction); most acupuncture and related interventions (acupuncture,  
586 acupressure, electro-acupuncture and dry needling); conventional- and kinesio-taping;  
587 most electro- and thermotherapies (interferential, laser, shockwave therapy, shortwave  
588 diathermy, superficial cold and ultrasound); provision of a brace; and aromatherapy.

589 **Post-operative physiotherapy intervention, pain predominant phase (Figure 4)**

590 There was consensus that one-to-one function based exercises and one-to-one gentle  
591 active exercises ‘should always be used’. Posture re-education fell just short of  
592 consensus for ‘should always be used’, but combining this with the ‘should be optional’  
593 rating revealed it to be a very acceptable intervention.

594 Consensus on ‘should be optional’ included some forms of education and re-  
595 education (CBT, explain pain and relaxation techniques); some hands-on techniques  
596 (effleurage for pain and manual joint mobilisations, muscle energy techniques, MWMs,  
597 myofascial release, spinal/scapula-thoracic manual therapy, therapist-assisted end-  
598 range mobilisations and tool-assisted soft tissue techniques); some exercises/exercise

599 settings (active-assisted exercises with scapular control, closed chain exercises,  
600 facilitation/strength training, gentle pulley exercises, hydrotherapy, land-based  
601 exercise class, one-to-one sustained stretching exercises, passive exercises, PNF,  
602 proprioception rehabilitation and scapula setting); neural dynamics; some electro- and  
603 thermotherapy (superficial cold and heat and TENS); some acupuncture and related  
604 (acupuncture, acupressure, dry needling, electro-acupuncture, trigger point therapy);  
605 conventional- and kinesio-taping; and occupational therapy or combined assessment.

606 Consensus on 'should not be used' included some education and re-education  
607 (Alexander technique, graded motor imagery and mirror therapy) and hands-on  
608 techniques (Bowen therapy, craniosacral therapy and deep friction); most  
609 electrotherapies (interferential, laser, shockwave therapy, shortwave diathermy and  
610 ultrasound); and provision of a brace.

611 **Post-operative physiotherapy intervention, stiffness predominant phase (Figure**

612 **5)** There was consensus that 1-to-1 gentle active exercises, 1-to-1 function-based  
613 exercises, 1-to-1 sustained stretching exercises, active exercises with scapular control,  
614 facilitation/strength training and manual joint mobilisations 'should always be used'.

615 Consensus on 'should be optional' included some education and re-education  
616 (posture re-education and relaxation techniques), hands-on techniques (muscle energy  
617 techniques, MWMs, myofascial release, PNF, spinal/scapula-thoracic manual therapy,  
618 therapist-assisted end-range mobilisations and tool-assisted soft tissue techniques) and  
619 exercises (closed chain exercises, gentle pulley exercises, hydrotherapy, land-based  
620 exercise class, passive assisted exercises, proprioception rehabilitation and scapula  
621 setting); neural dynamics; superficial cold and heat; acupressure and trigger-point  
622 therapy; and occupational therapy or combined assessment.

623 Consensus on 'should not be used' included some education and re-education  
624 (Alexander technique, CBT, explain pain, graded motor imagery, mirror therapy),  
625 hands-on techniques (Bowen therapy, craniosacral therapy, deep friction, effleurage for  
626 pain); most electro- and thermotherapy (interferential, laser, shockwave therapy,  
627 shortwave diathermy, TENS, ultrasound), some acupuncture and related interventions  
628 (acupuncture, dry needling, electro-acupuncture); conventional- and kinesio-taping;  
629 and provision of a brace.

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### Structured Physiotherapy (SP) Treatment Log

Please complete this form as soon as possible after each treatment session.

Date  /  /  Session No  Duration of session (mins)

Name of physiotherapist  Staff grade (Please cross one box only)  5  6  7  ≥8

How many non-surgical frozen shoulders do you treat in a typical month? (Please place a cross in one box only)  0 - 1  2 - 3  4 or more

Ask the patient which of the following is their main problem today. (Please place a cross in one box only and proceed as indicated.)

Pain more than stiffness?  Pain and stiffness equally?  Stiffness more than pain?

**PAIN IS PREDOMINANT**  
Use the **YELLOW** column

**STIFFNESS IS PREDOMINANT**  
Use the **GREEN** column

**IMPORTANT!** Interventions marked ★★ **must** be given as part of the overall SP package (but not necessarily at every session) unless contraindicated. Interventions marked ★ are not essential but are encouraged.

Please place a cross in the box beside any treatments given in this session. To record any treatments that are not listed, please use the free-text box provided.

Use this column if **PAIN IS PREDOMINANT**

- Advice and education ★★
- Manual shoulder mobilization ★★
- Home exercises (instruction/review) ★★
- Acupuncture, TENS or trigger-point therapy
- Hydrotherapy
- Posture correction
- Relaxation techniques
- Spinal/scapulothoracic manual therapy
- Superficial heat
- Supervised exercises (function-based)
- Supervised exercises (gentle active/self-assisted)

**TREATMENTS THAT ARE NOT ALLOWED:**  
Brace, craniosacral therapy, deep friction, laser.  
**TREATMENTS THAT ARE DISCOURAGED:**  
Bowen therapy, shockwave therapy, ultrasound.

Use this column if **STIFFNESS IS PREDOMINANT**

- Advice and education ★★
- Manual shoulder mobilization ★★
- Home exercises (instruction/review) ★★
- Supervised exercises (function-based) ★
- Hydrotherapy
- Posture correction
- Soft-tissue techniques
- Spinal/scapulothoracic manual therapy
- Supervised exercises (active/self-assisted)
- Supervised exercises (strengthening)
- Supervised exercises (sustained stretching)

**TREATMENTS THAT ARE NOT ALLOWED:**  
Brace, craniosacral therapy, deep friction, interferential, laser, shockwave therapy.  
**TREATMENTS THAT ARE DISCOURAGED:**  
Bowen therapy, graded motor imagery, mirror therapy, SWD, ultrasound.

Please record any other treatments given  
(e.g. gym class, neural dynamics, referral to another specialty such as Occupational Therapy).

Do you feel the patient has done his /her home exercises adequately?  Yes  No  
(Please place a cross in one box only)

Comments:

Please record any serious adverse effects of treatment (e.g. joint infection) and notify the Research Nurse:

Please record and give reasons for any substantial deviation from the UK FROST SP Instructions (in terms of treatments given/not given, or number of sessions) and notify the Research Nurse:

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Figure 6. Structured (stand-alone) physiotherapy log sheet

### Post-Procedural Physiotherapy (PPP) Treatment Log

Please complete this form as soon as possible after each treatment session.

Date  /  /  Session No  Duration of session (mins)

Name of physiotherapist  Staff grade (Please cross one box only)  5  6  7  >8

How many post-surgical frozen shoulders do you treat in a typical month? (Please place a cross in one box only)  0 - 1  2 - 3  4 or more

Ask the patient which of the following is their main problem today. (Please place a cross in one box only and proceed as indicated.)

Pain more than stiffness?  Pain and stiffness equally?  Stiffness more than pain?

**PAIN IS PREDOMINANT**  
Use the **YELLOW** column

**STIFFNESS IS PREDOMINANT**  
Use the **GREEN** column

**IMPORTANT!** Interventions marked ★ ★ **must** be given as part of the overall PPP package (but not necessarily at every session) unless contraindicated. Interventions marked ★ are not essential but are encouraged.

Please place a cross in the box beside any treatments given in this session. To record any treatments that are not listed, please use the free-text box provided.

Use this column if **PAIN IS PREDOMINANT**

- Advice and education ★ ★
- Home exercises (instruction/review) ★ ★
- Supervised exercises (gentle active/self-assisted) ★
- Supervised exercises (function-based)
- Hydrotherapy
- Relaxation techniques
- Manual shoulder mobilization
- Superficial cold
- TENS
- Trigger point therapy
- Posture correction

**TREATMENTS THAT ARE NOT ALLOWED:**

Brace, deep friction, laser, shockwave therapy.

**TREATMENTS THAT ARE DISCOURAGED:**

Craniosacral therapy, ultrasound.

Use this column if **STIFFNESS IS PREDOMINANT**

- Advice and education ★ ★
- Home exercises (instruction/review) ★ ★
- Supervised exercises (active/self-assisted) ★
- Supervised exercises (function-based) ★
- Supervised exercises (sustained stretching)
- Supervised exercises (strengthening)
- Manual shoulder mobilization
- Soft-tissue techniques
- PNF
- Spinal/scapulothoracic manual therapy
- Posture correction

**TREATMENTS THAT ARE NOT ALLOWED:**

Brace, craniosacral therapy, deep friction, interferential, laser, shockwave therapy

**TREATMENTS THAT ARE DISCOURAGED:**

Bowen therapy, electroacupuncture, graded motor imagery, mirror therapy, SWD, ultrasound.

Please record any other treatments given  
(e.g. gym class, neural dynamics, referral to another specialty such as Occupational Therapy).

Do you feel the patient has done his /her home exercises adequately?  Yes  No  
(Please place a cross in one box only)

Comments:

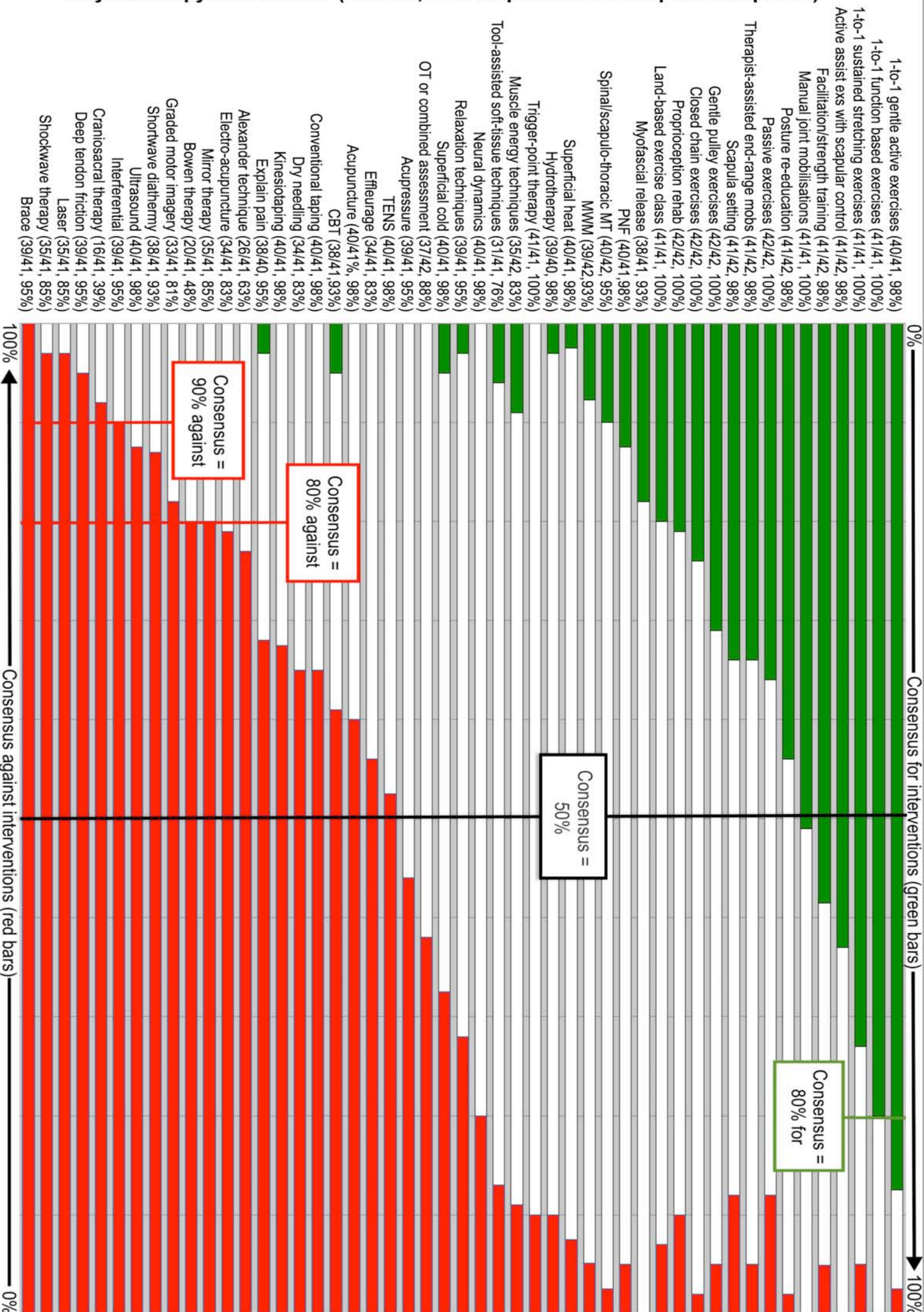
Please record any serious adverse effects of treatment, including surgery (e.g. joint infection, nerve injury), and notify the Research Nurse:

Please record and give reasons for any substantial deviation from the UK FROST PPP Instructions (in terms of treatments given/not given, or number of sessions) and notify the Research Nurse:

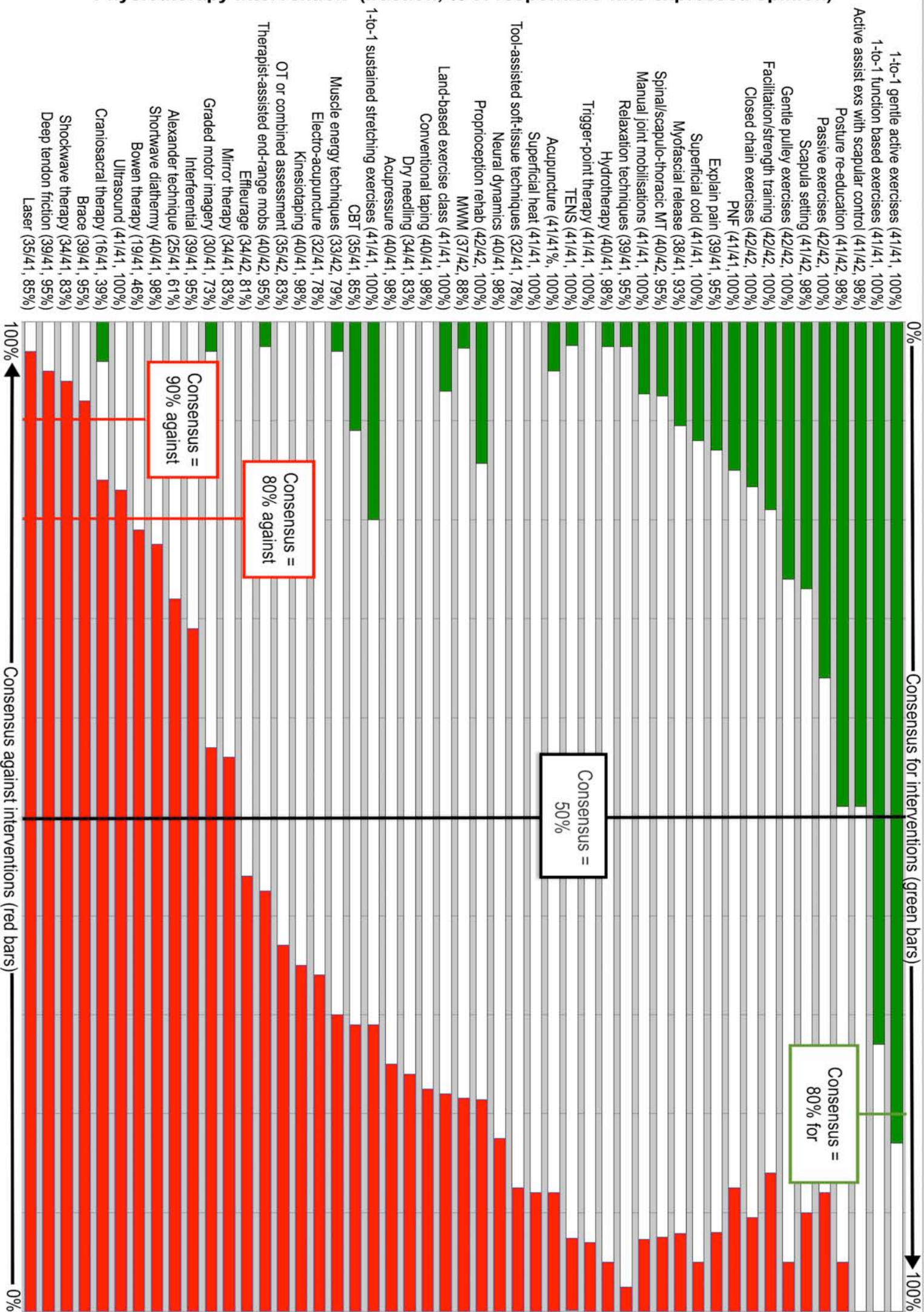
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Figure 7. Post-procedural (post-operative) physiotherapy log sheet.

# Physiotherapy intervention (fraction, % of responders who expressed opinion)



# Physiotherapy intervention (fraction, % of responders who expressed opinion)



Consensus for interventions (green bars)

Consensus = 80% for

Consensus = 50%

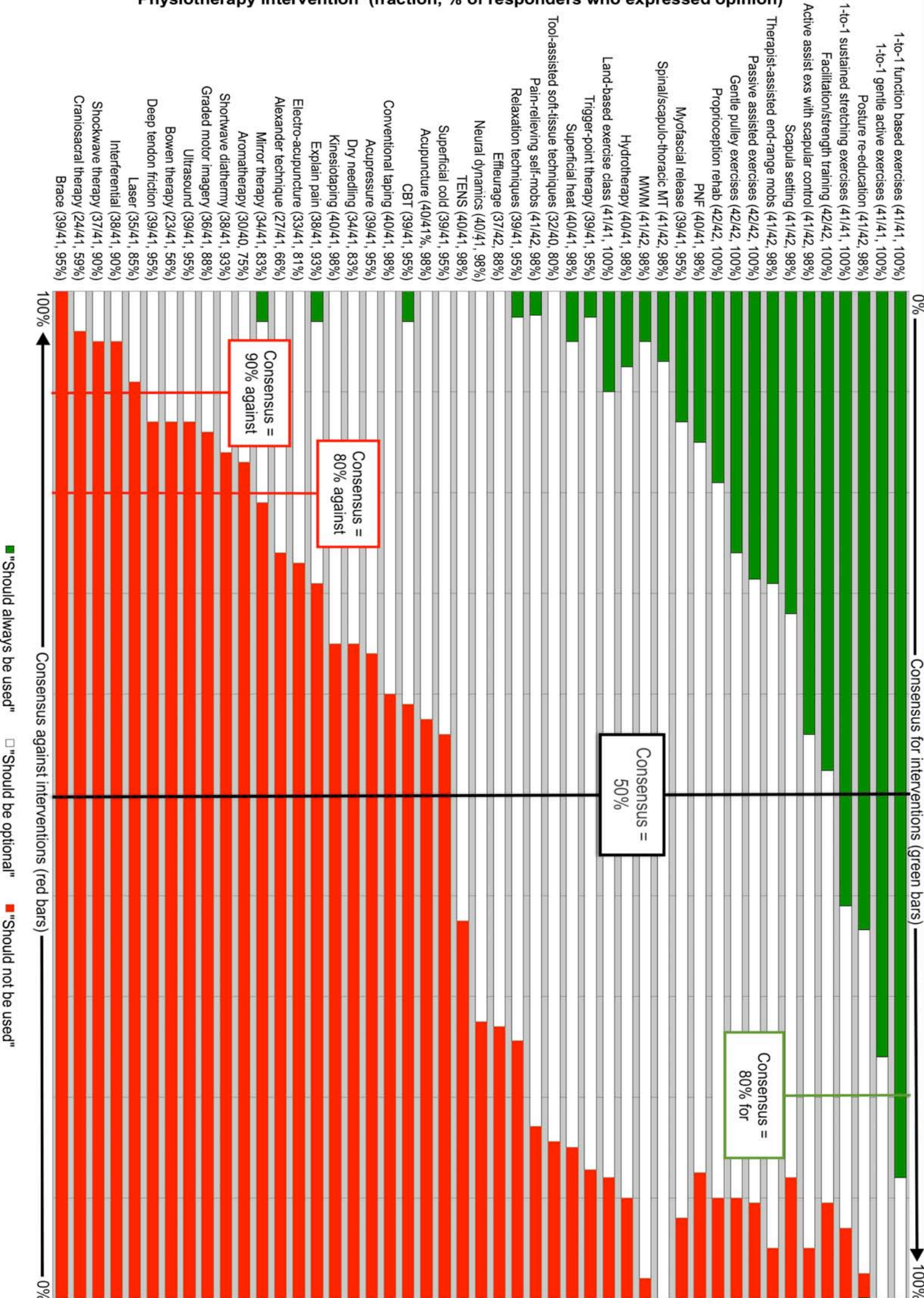
Consensus = 80% against

Consensus = 90% against

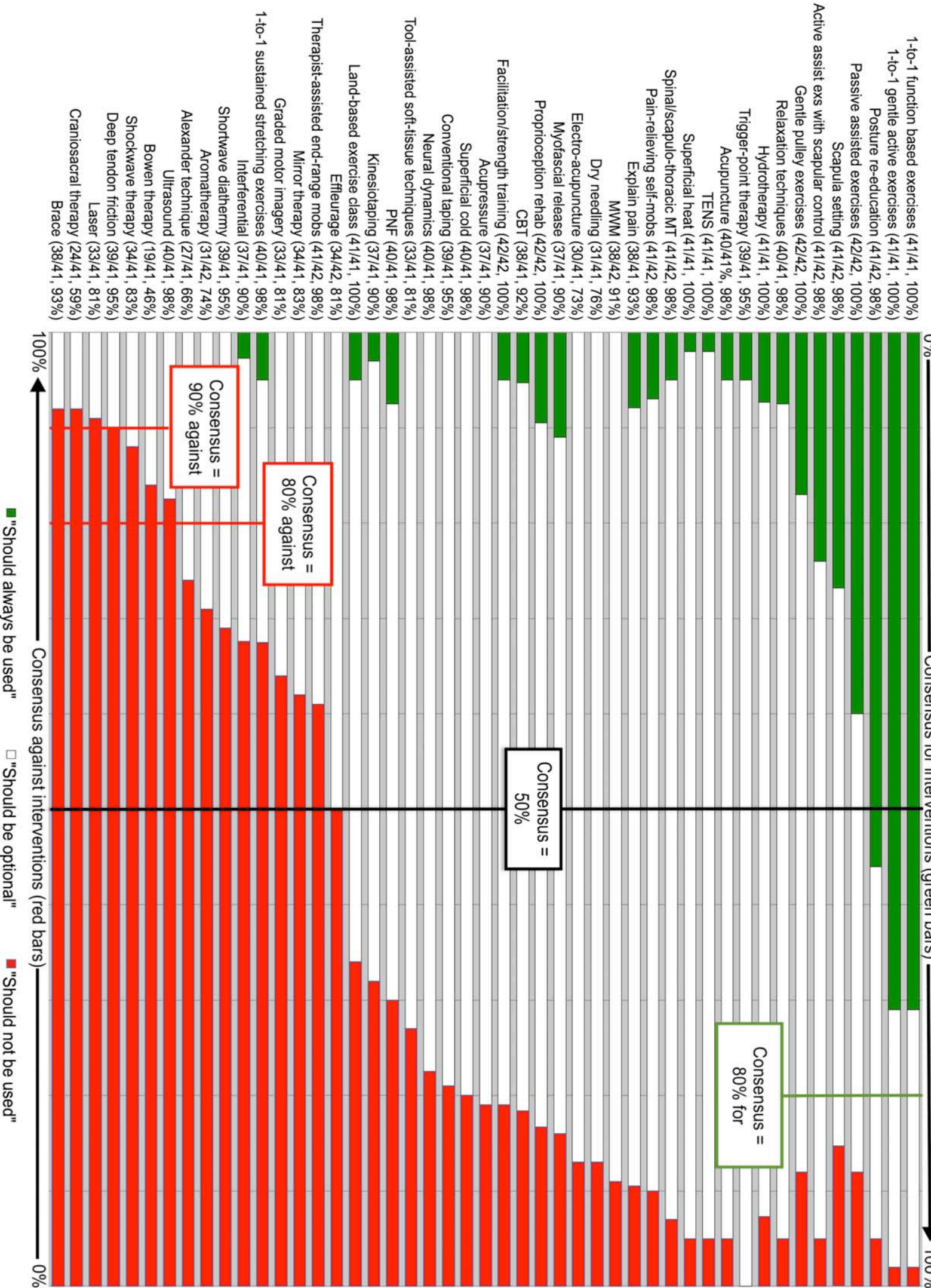
■ "Should always be used" □ "Should be optional" ■ "Should not be used"

Consensus against interventions (red bars)

Physiotherapy intervention (fraction, % of responders who expressed opinion)



**Physiotherapy intervention (fraction, % of responders who expressed opinion)**



Consensus for interventions (green bars)

Consensus = 80% for

Consensus = 50%

Consensus = 80% against

Consensus = 90% against

"Should always be used"

"Should be optional"

"Should not be used"

Consensus against interventions (red bars)

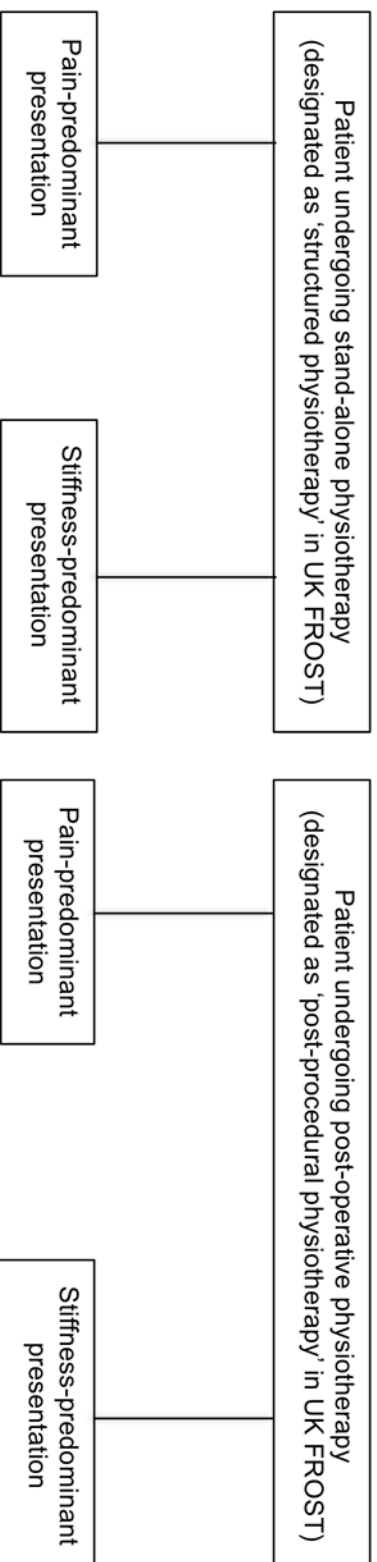


Figure 1. The four clinical contexts in UK FROST