

## **The structure of research questions in randomized controlled trials in the rehabilitation field**

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1 **Title:** The structure of research questions in randomized-controlled trials in rehabilitation field: a  
2 methodological study

3

4 **Running title:** Rehabilitation trials research question structure

5

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23

24 **Abstract**

25 **Objective:** The aim of this study is to assess whether and how PICO format is described to frame  
26 research questions in randomized controlled trials (RCTs) looking at effectiveness of rehabilitation  
27 interventions.

28 **Design:** A methodological study was conducted. RCTs in the rehabilitation field, published  
29 between July 1st, 2019 and December 31st, 2019 were included. The framing of the primary  
30 research question (RQ) from each trial was evaluated.

31 **Results:** Ninety-seven RCTs were included in the analysis. The most frequent framing of the  
32 primary RQ was as an “objective” statement (55%) and in 33% of the articles this was stated as an  
33 “objective” together with a “hypothesis” description. All PICO elements were present in 55% of  
34 RQ, but only 49% have used the statement suggested by Cochrane. The results showed that the  
35 most frequent framing of primary RQ was “objective” using all PICO elements, but few articles  
36 followed the statement suggested by Cochrane to describe them.

37 **Conclusion:** our findings suggest that a specific item about the “*research question*” and the  
38 rationale that drove to the proposed design following the form suggested by Cochrane is included in  
39 the RCTRACK checklist.

40 **Keywords:** rehabilitation, framing research question, PICO format

41

42 **What is known**

- 43 • A structured research question could be associated with better methodological quality;
- 44 • A structured RQ could guide the development of a research study to evaluates the
- 45 effectiveness/efficacy of an intervention

46 **What is new**

- 47 • Currently the primary research question of published RCTs is most often framed as an
- 48 “objective”;
- 49 • Currently few published RCTs describe the PICO elements as recommended by Cochrane;
- 50 • The findings suggest that a specific item about the “*research question*” and the rationale
- 51 that drove to the proposed design following the form suggested by Cochrane is included in
- 52 the RCTTRACK checklist

53

54

## 55 **Introduction**

56 Randomized controlled clinical trials (RCTs) are considered the gold standard study design to  
57 evaluate the effectiveness/efficacy of interventions in biomedical research<sup>1</sup>. The choice of an  
58 appropriate study design is informed by a clear research question (RQ)<sup>2-5</sup>. The RQ represents the  
59 starting point for research studies to evaluate the effectiveness/efficacy of interventions because it  
60 guides the definition of the population, interventions and outcomes; consequently, this influences  
61 the development of the right study design to answer the question of interest.

62 Clinical epidemiologists have proposed the use of a structured RQ to guide the development of a  
63 research study that evaluates the effectiveness/efficacy of interventions<sup>6</sup>. The RQ should contain the  
64 following four elements: Population, Intervention, Comparator and Outcomes. These elements are  
65 commonly referred to by the acronym PICOs. A well-structured RQ increases the likelihood of  
66 finding a solution to the problem, informs selection of the study design, guides analysis decisions  
67 and the interpretation of results<sup>2</sup>. The explicit statement of the four PICOs elements prompts the  
68 researcher to think about the design to use and to consider the balance between RQ and the  
69 feasibility to answer it. Some studies show that a structured research question could be associated  
70 with better methodological quality, but more research is needed to confirm this finding<sup>2-5</sup>.

71 In rehabilitation research, a scoping review by Arienti et al.,<sup>7</sup> reported a lack of clarity in the RQs  
72 and that RCTs in the rehabilitation field rarely use the PICOs format to define key terms. Several  
73 authors have argued that RCTs in rehabilitation frequently use inadequate designs for answering  
74 RQs related to rehabilitation and this could depend on how the RQ is formulated. The detailed  
75 specification of the RQ requires consideration of several key components which can be  
76 encapsulated by the 'PICO' element that practicing clinicians, healthcare professionals, researchers,  
77 policy makers, and patients deal with<sup>8</sup>. The accuracy of RQ framing is one of the main  
78 methodological issues described in rehabilitation research.

79 In recognition of this problem, Cochrane Rehabilitation highlighted the need to develop a specific  
80 checklist to guide the design, conducting, and reporting of trials in the rehabilitation field<sup>9</sup>. During  
81 the second Cochrane Rehabilitation Methodological Meeting held in Kobe, Japan, in 2019, the RCT  
82 Rehabilitation Checklist (RCTRACK) project was launched to produce a reporting guideline for  
83 rehabilitation RCTs. During the kick-off meeting, 8 topics were identified for the RCTRACK  
84 Technical Working Groups (TWGs): one of these was the “research question”.

85 Therefore, the aim of this study is to assess whether and how PICO format is described to frame  
86 research questions in RCTs about efficacy/effectiveness of rehabilitation interventions and if it is an  
87 important element that should be put and described in RCTRACK checklist.

88

## 89 **Methods**

### 90 **Study design and search strategy**

91 A methodological study, described as a study for the assessing research methods and summarizing  
92 methodological issues in the conduct, analysis, and reporting of health research<sup>10,11</sup>, was conducted  
93 by “Research Question” TWG, on RCTs in the rehabilitation field published between July 1<sup>st</sup>, 2019  
94 and December 31<sup>st</sup>, 2019 in journals suggested by the European Society of Physical Rehabilitation  
95 and Medicine (PRM) were included. This study conforms to all PRISMA guidelines and reports the  
96 required information accordingly (see **Supplementary Checklist**). Specific criteria<sup>12-14</sup> for  
97 inclusion of these journals were: 1) belong to the first quartile (Q1) according to the Journal Impact  
98 Factor (JIF) from the Web of Science Journal Citation Reports and 2) they were journals dealing  
99 with “Rehabilitation” medicine and related disciplines specifically. The eligible journals were:  
100 *Annals of Physical and Rehabilitation Medicine (JIF=4.196)*, *Archives of Physical Medicine and*  
101 *Rehabilitation (JIF= 2.697)*, *Clinical Rehabilitation (JIF= 2.738)*, *Disability and Rehabilitation*  
102 *(JIF= 2.054)*, *European Journal of Cancer Care (JIF= 2.421)*, *IEEE Transactions on Neural*  
103 *Systems and Rehabilitation Engineering (JIF= 3.478)*, *Journal of Fluency Disorders (JIF= 2.349)*,

104 *Journal of Head Trauma Rehabilitation* (JIF= 2.667), *Journal of NeuroEngineering and*  
105 *Rehabilitation* (JIF= 3.582), *Journal of Neurologic Physical Therapy* (JIF= 2.614), *Journal of*  
106 *Orthopaedic & Sports Physical Therapy* (IF= 3.058), *Journal of Physiotherapy* (JIF= 5.551),  
107 *Manual Therapy* (JIF= 2.622), *Neurorehabilitation and Neural Repair* (JIF= 3.757), *Physical*  
108 *Therapy* (JIF= 3.043), *Physiotherapy* (JIF= 2.534), *PM&R - The journal of injury, function and*  
109 *rehabilitation* (JIF= 1.902), *Supportive Care in Cancer* (JIF= 2.754), *the American Journal of*  
110 *Physical Medicine & Rehabilitation* (JIF= 1.908), *the European Journal of Physical and*  
111 *Rehabilitation Medicine* (JIF= 2.101), *the International Journal of Rehabilitation Research* (JIF=  
112 1.378) and *the Journal of Rehabilitation Medicine* (JIF= 1.907). The search for eligible RCTs  
113 published in those journals was conducted on PubMed on May 12<sup>th</sup>, 2020 and performed by an  
114 author (SGL) as general search. See **Supplementary Table 1** for the full search strategy.

115

## 116 **Eligibility and screening**

117 We included all RCTs addressing a RQ regarding effectiveness/efficacy of interventions in the field  
118 of rehabilitation published in print or ahead of print in the targeted period. Cross-over and non-  
119 randomized clinical trials (NRCTs), secondary analysis of RCTs data, preliminary results, pilot  
120 studies, protocols, RCTs in which the randomization process was stratified by any factor and  
121 articles addressing not-rehabilitation interventions were excluded.

122 The selection process was performed in duplicate by two independent authors (SGL and MP)  
123 during: a) title and abstract and b) full text screening phases. A third author (CA) resolved the  
124 discrepancies.

125

## 126 **Rating the framing of the research question**

127 We used the methodology proposed by Rios (2010) to analyze how the research question was  
128 described<sup>2</sup>. In brief, the framing of the primary RQ of each study was evaluated firstly based on the  
129 introduction and secondly from the title and methodology sections. This evaluation was performed  
130 regardless of whether the RQ was formulated as a question, objective or hypothesis. Each reviewer  
131 identified a paragraph/ or sections where the RQ was discussed and then identified whether the four  
132 elements of PICO were present in those sections. We used a “PICO score” with a possible score  
133 between 0 and 4, as a measure of the completeness of the description of the primary research  
134 question, study objective or research hypothesis. A score of 4 confirmed that all PICO elements  
135 were described (Complete PICO). Reports that did not describe these 4 elements (Incomplete PICO)  
136 did not qualify as providing a structured RQ. Next, the adequacy of question formulation was  
137 evaluated based on the structure recommended by Cochrane. Cochrane proposes that the statement  
138 of a RQ should begin with a precise statement of the primary objective, ideally in a single sentence.  
139 The recommended sentence style and order is as follows: *«to assess the effects of [intervention or  
140 comparison] for [health problem] in [types of people, disease or problem and setting if  
141 specified]»<sup>15</sup>. This specific order helps to clarify the aim of an RCTs, enhancing a reader’s  
142 understanding of the goal of a study of the effectiveness/efficacy of an interventions,. For the  
143 purpose of this study, this specific statement was defined as the "PICO structure" and scored score  
144 of 1 was assigned if it was used, and a score of 0 if it was not used.*

145

#### 146 **Assessment of the quality of reporting in included studies**

147 The included studies were assessed for reporting using the CONSORT Statement for Randomized  
148 Trials of Nonpharmacologic Treatments checklist (CONSORT-NPTs checklist) to assess the quality  
149 of reporting in nonpharmacologic trials. This is an extension of the CONSORT checklist, developed  
150 to improve the reporting of RCTs investigating nonpharmacological treatments<sup>16,17</sup>.



151 The CONSORT-NPT checklist includes 45 items and each of them was scored 1 if it was reported  
152 and 0 if it was not clearly stated or definitely not stated. Item 4a) “Eligibility criteria for  
153 participants; When applicable, eligibility criteria for centers and for care providers” has been split to  
154 address both topics independently. Therefore, an overall quality score (OQS) was defined with  
155 possible value between 0 (no adherence) and 45 (complete adherence) points to measure the  
156 completeness of the reporting, i.e. adherence with the CONSORT-NPT checklist. A pre-training  
157 quality of reporting assessment was performed by the reviewers (SGL and MP) to define the  
158 evaluation criteria for the reporting quality. After the reporting evaluation, any disagreements were  
159 resolved involving a third reviewer (CA).

160

#### 161 **Data extraction**

162 We used a standardized data abstraction form to extract data from each article. We collected the  
163 following article characteristics: first author, year, title, the RQ description and type (question,  
164 objective or hypothesis format) firstly described in introduction section and secondly in title and  
165 methods section, outcome measures from each trial, rehabilitation interventions and PICO format.  
166 Two reviewers blinded to each other’s ratings extracted data independently and rated the framing of  
167 the RQ, they resolved any disagreement through consensus.

168

#### 169 **Statistical analysis**

170 We calculated the percentage of trials that clearly stated each PICO element and associated 95%  
171 confidence interval (95% CI). We reported descriptive statistics on categorical data as frequencies  
172 and percentages. We reported scores (i.e., PICO score and OQS) as median and interquartile range  
173 (IQR). Considering, the not normally distribution of the data (Shapiro e Wilk’s test), we evaluated if  
174 high PICO score was associated with high reporting quality by conducting linear regression analysis

175 with PICO score and OQS as variables using Spearman's correlation coefficient (Spearman's rho  
176  $r_s$ ). Variables were considered to be statistically significant at alpha = 0.05. We conducted all  
177 analyses using STATA V.14.0 (StataCorp LP, College Station, TX, USA).

## 178 **Results**

179 After removal of duplicates, 227 records were screened; of these, 97 RCTs met the inclusion criteria  
180 and were included in the analysis. The characteristics of the included studies are reported in  
181 **Supplementary Table 2**. The reasons for exclusion and the number of articles excluded, at title-  
182 abstract and at full text screening stage, are listed in the PRISMA flow diagram (**Figure 1**). Twenty  
183 seven percent (n=26) of articles were published in the journal Clinical Rehabilitation, 14% (n=14)  
184 in Archives of Physical Medicine & Rehabilitation, 13% (n=13) in the American Journal of  
185 Physical Medicine & Rehabilitation and 10% (n=10) in European Journal of Physical and  
186 Rehabilitation Medicine (see **Table 1 for details of the search strategy**). The most frequent  
187 framing of the primary RQ was as an "objective" statement (55%) and in 33% of the articles this  
188 was as "objective" together with a "hypothesis" description. The frequency of each PICO element  
189 reported in all included articles is provided in **Table 2**. Patients, interventions and outcomes were  
190 often adequately described, whilst in 36% of the articles, the comparison interventions were not  
191 described. All PICO elements were present in 55% of RQ, but only 49% have used the statement  
192 suggested by Cochrane. Of these, 85% had the completeness of PICO (PICO score median of 4 (2-  
193 4)).

194 The CONSORT-NPT Checklist assessment revealed that the articles described 80% (36) of all  
195 checklist items, with median OQS of 36 (26-41). Items for which the lowest adherence to the  
196 checklist was found were: the adherence of care providers (2%) and participants (35%) to  
197 interventions, blinding description (16%) and the description of any attempts to limit the blinding as  
198 bias (5%), the period of recruitment and follow-up description (23%), the presentation of both  
199 absolute and relative effect size in binary outcomes (15%) and the description of generalizability of

200 the trial findings according to the intervention, comparators, patients, care providers and centers  
201 involved in the trial (44%). The highest adherence to the checklist was observed in the description  
202 of title and abstract (91%), background and aim (100%), trial design (93%), participants (100%),  
203 interventions (86%), outcomes (100%), sample size (80%), statistical methods (99%) and  
204 interpretation of results. Eighty six percent of the RCTs were registered in a trial registration  
205 database (see **Supplementary Table 3**). The Spearman's correlation coefficient between the  
206 completeness of PICO and the overall reporting quality was  $r_s=-0.051$ .

207

## 208 **Discussion**

209 This study evaluated whether and how PICO format is described to frame research questions in  
210 RCTs addressing effectiveness/efficacy of rehabilitation interventions published in the highest-  
211 ranking rehabilitation journals during the second half of the year 2019.

212 The results showed that the most frequent framing of primary RQ was in a form of a statement  
213 about study objective using all PICO elements, but few articles followed the statement suggested by  
214 the Cochrane (PICO structure) to describe them. The comparison intervention was the least  
215 frequently described element when compared to the other elements (i.e. population, intervention  
216 and outcome). The lack of comparison intervention description is quite frequent in rehabilitation  
217 context in which establishing the control treatment is difficult because: 1. this type of intervention is  
218 rarely a single specific item with a high level of heterogeneity in terms of name used for defined it  
219 and of protocol ingredients, leading to a non-linear causal-effect relationships<sup>18</sup>. 2. The  
220 rehabilitation setting, where the control intervention is delivered, usually represents a complex  
221 clinical situation that could affect the clinical replicability of interventions<sup>14</sup>. Therefore, our study  
222 showed that the overall reporting quality, evaluated with CONSORT-NPT checklist, was  
223 satisfactory, with 80% of reporting completeness and the best items described were those more  
224 related to PICO elements, but it was not directly related to the completeness of PICO. This could be

225 explained by the characteristics of CONSORT-NPT checklist that is an extension of CONSORT  
226 and includes 20 more items regarding more details on the description of the experimental treatment,  
227 comparator, care providers expertise, centers, blinding status, adherence to the protocol and the  
228 treatment, statistical methods and the generalizability of the trial findings according to the  
229 intervention, comparators, patients, care providers and centers involved in the trial<sup>16,17</sup>. These  
230 specific items represent the main methodological issues found in rehabilitation research<sup>7</sup>. Most of  
231 them are related to the methodological quality rather than reporting quality, in particular to the  
232 conduct of the study that include elements such as allocation concealment (selection bias), method  
233 of blinding (performance and detection bias), incomplete outcome data (attrition bias), protocol  
234 availability (reporting bias) and compliance related biases<sup>19</sup>. All these biases could affect the  
235 treatment estimates of RCTs and consequently the effectiveness/efficacy of rehabilitation  
236 interventions<sup>20</sup>. Therefore, a structured RQ could be associated with better methodological quality  
237 and could facilitate and make the research question more understandable to guide clinicians and  
238 researchers in the literature search, in the protocol development and in the conduct of a study<sup>2</sup> in  
239 rehabilitation research. The incompleteness and unclearness of RQ have been also found in other  
240 fields in biomedical research, such as endocrinology<sup>21</sup>, urology<sup>22</sup>, venous ulcer disease<sup>3</sup>, surgery<sup>23</sup>  
241 and anesthesia<sup>5</sup> literature. These studies highlighted a significant association between the  
242 completeness of the RQ description and quality of reporting and this could involve the overall  
243 quality of methodology of the studies<sup>6</sup>. Since the risk of bias assessment, one of methodology  
244 quality element, is closely linked to quality of reporting, further research should include the  
245 evaluation of both reporting and methodological quality<sup>24</sup>. A structured RQ might be considered as  
246 a systematic way to construct the RQ and to conduct a study with the aim to give information for  
247 the clinical decision-making<sup>6</sup> in rehabilitation research. These considerations highlight the need to  
248 develop a specific checklist for the rehabilitation field, like RCTRACK, which includes a specific  
249 item on the framing of RQ to guide the development of future RCT studies.

250 The limitations were: firstly, the PICO score and OQS are not validated and have not been  
251 rigorously tested for validity and reliability. Secondly, the inter-rater agreements were not  
252 calculated; however, the reviewers performed a pre-training reporting quality assessment to define  
253 the evaluation criteria and the disagreements were always resolved by consensus with the third  
254 reviewer.

255

## 256 **Conclusion**

257 The lack of well-designed and reported clinical trials reduces confidence in RCT results. Asking a  
258 clearly defined RQ is the first step in conducting a well-designed study. Consequently, the key  
259 implication of this study is that trialists in the rehabilitation field should pay attention to the proper  
260 framing of the research question using a structured approach, such as the PICO format. This should  
261 comprise a precise statement of the primary objective, ideally in a single sentence as suggested by  
262 Cochrane. This clearly defined RQ should inform how the study is designed, conducted and  
263 reported. Consequently, our “Research Question” TWG have now recommended that the  
264 RCTTRACK checklist includes the following specific item about the “*research question*”:  
265 “definition of the research question and rationale of the chosen design to answer to the research  
266 question described according to the PICO format”.

267 .

268

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271

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345

346 **Figure Legends**

347 **Fig 1.** PRISMA flow diagram