

The structure of research questions in rehabilitation randomized-controlled clinical trials: a methodological study

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Abstract

Background. Randomized-controlled clinical trials (RCTs) are considered the gold standard study design to evaluate the effectiveness of interventions in biomedical research. The choice of appropriate study design is informed by a clear research question (RQ). The RQ represents the starting point for research studies to evaluate effectiveness of interventions because it guides the definition of population, interventions, comparators and outcomes (PICO), and this consequently informs the development of the optimal study design to answer the question of interest. It is reported that RQs of rehabilitation RCTs lack clarity and are rarely defined using the PICO format.

Objectives. The aim of this study is to assess whether and how PICO format is described to frame RQs in RCTs focussed on the effectiveness of rehabilitation interventions.

Methods. A methodological study, systematically exploring the RQs within RCTs of rehabilitation interventions has been carried out. All the best journals according to European Society of Physical Rehabilitation and Medicine criteria were searched. Eligibility criteria were: RCTs published between January 1st and December 31st, 2019, and addressing a RQ relating to the effectiveness of an intervention in any clinical rehabilitation setting. Two reviewers extracted information relating to the RQ, objective or hypothesis, and assessed whether each of the four PICO elements were presented. Risk of bias of the included studies was assessed using the Cochrane Risk of Bias assessment tool. We calculated the percentage of trials that clearly stated each PICO element and associated 95% confidence interval (95% CI). Variables were considered to be statistically significant at alpha = 0.05.

Results. After removal of duplicates, 247 records have been screened; of these, 97 RCTs met the inclusion criteria and were included in the analysis. Preliminary results show that 48% of the studies

use “objective” form for the aim and 33% do not use the PICO format. The analysis is still ongoing and the final results will be shown during the Cochrane Colloquium.

Conclusion. RCTs of rehabilitation interventions published in 2019 often fail to adequately report all four PICO elements. In order to support evidence-based rehabilitation, it is important that steps are taken to improve the definition and reporting of PICO elements. To address this, a new reporting checklist for rehabilitation RCTs (RCTRACK checklist) is under development to incorporate an item relating to adequate reporting of RQs.

Patient or healthcare consumer involvement. Not applicable.