

RCT Rehabilitation Checklist - RCTRACK: Project for a reporting guideline for RCTs in rehabilitation

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Abstract

Background. During the first Cochrane Rehabilitation Methodological Meeting, held in Paris in July 2018, a series of methodological problems in rehabilitation research have been discussed: the results have been published in a special issue of the Eur J Phys Rehabil Med. Afterwards, a scoping review has listed these methodological issues, and the REREP study has shown the very low clinical replicability of RCTs in rehabilitation. This preliminary work highlighted that Randomised controlled trials (RCTs) in rehabilitation face specific methodological challenges related to the practice itself that are not faced in the classical reporting checklists. Precise reporting in these domains is essential to allow interpretation and quality evaluation of published work.

Objectives. The aim is to develop a checklist of items to be followed in the reporting of RCTs in rehabilitation.

Methods. The RCT Rehabilitation Checklist (RCTRACK) project has been developed and deposited in the EQUATOR Network. Working areas (WAs) have been identified in the launching Meeting and studied with systematic or scoping reviews to identify methodological needs. WAs included: PICO elements, blinding, statistical analysis and appropriate randomization, attrition, follow up and protocol deviation, research question and study design. During a Consensus Conference held in Orlando in March 2020 the results of the WAs work have been discussed and the first draft version of RCTRACK has been proposed. This will be submitted to a series of Delphi Rounds involving all rehabilitation journals' Editorial Boards, authors of RCTs and methodologists/epidemiologists of the area to achieve the final checklist version by the end of 2020.

Results. The preliminary results of systematic reviews and scoping reviews performed by each WAs highlighted a series of items to be added to current CONSORT checklists. These rehabilitation needs relate to the items objective, participants, interventions, and outcomes, but also statistical analysis.

Conclusions. The RCTRACK checklist will include a set of items that directly address the methodological issues of rehabilitation research. Further, it will be a useful educational tool for authors, reviewers and clinicians to improve the quality of evidence in this specific field.

Patient or healthcare consumer involvement. Not applicable.