

## **Complex interventions require description beyond methodological items to allow clinical replicability: the REREP study of RCTs in rehabilitation**

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### **Abstract**

**Objective.** To check if Randomised Controlled Trials (RCTs) on complex rehabilitation interventions published in the best Physical and Rehabilitation Medicine (PRM) journals include all the practical details needed to replicate the intervention in the everyday clinics.

**Design.** Survey on a pre-defined sample of PRM clinical expert teams representative of the different areas of the world and of different clinical competences.

**Participants.** 47 rehabilitation clinicians from 7 teams (Belgium, Italy, Malaysia, Pakistan, Poland, Puerto Rico, USA), including 20 PRM physicians, 12 physiotherapists, 6 occupational therapists, 6 rehabilitation psychologists and 3 others. The team leaders were clinicians and researchers.

**Methods.** All RCTs published between July and December 2016 in the main PRM journals (77 RCTs.) have been submitted to each participant that was asked to fill in a questionnaire per study.

**Main outcome measurements.** The survey, consisting of 14 questions, was developed from CONSORT and TIDieR checklists through consensus and piloting. The rate of agreement has been verified.

**Results.** The response rate was 99%. Overall, included RCTs were finally considered not replicable in clinics by 31% of participants. 53% of the studies have been considered replicable by all teams, while in 23% of cases all the team considered it not replicable; in no cases one single RCT was considered not replicable by all teams.

**Conclusions.** This study shows that there are problems in the clinical replicability of complex rehabilitation interventions RCTs and suggests the need to better focus the clinical items not described by classical methodological checklists like CONSORT.

**Patient or healthcare consumer involvement.** Not applicable

**Relevance to diversity.** The research addressed to rehabilitation clinicians and how to improve the replicability of complex rehabilitation interventions in daily clinical practice.