RCTRaCk Project: RCTs in Rehabilitation Checklist
Study project

Research financing

Study development

Study reporting

Study conducting (judgement)

Review

Education to research

Epidemiologists

Cochrane

Cochrane Rehabilitation
RCTRaCk Project
RCT in Rehabilitation Checklist

Study project

Ethical committees

Research financing

Study development

RCTRaCk Project
RCT in Rehabilitation Checklist

Study conducting (judgement)

Review

Cochrane

Study reporting

Top journals

Education to research

Epidemiologists
RCT Rehabilitation Checklist - RCTRaCk

To produce a checklist of items to be followed

• in the reporting of RCTs in rehabilitation
  – as an add-on (not substitution) to the CONSORT Non-Pharmacological Treatment Studies checklist

• in the conduct and risk of bias evaluation of RCTs in rehabilitation
  – as an add-on (not substitution) to the Cochrane Risk of Bias tool.

To identify areas of methodological research to fill gaps in the actual relevant knowledge – toward a constant development of the RCTRaCk
Preparation

Cochrane Rehabilitation Methodology Meeting @ ISPRM 2018
  – EJPRM Special Issue

Systematic review on the existing methodological Checklists relevant to rehabilitation
  – Armijo-Olivo S et al. Phys Ther 2014; 94(9), 1272-84

Scoping Review on methodological problems in rehabilitation research
  – Arienti C et al. submitted

Clinical replicability of rehabilitation interventions in Randomized Controlled Trials reported in main journals is inadequate
  – Negrini S et al. J Clin Epidemiol (2nd revision submitted)

Database in Cochrane Rehabilitation website of all relevant methodological literature
1st Consensus Conference @ Kobe ISPRM 2019

Stefano Negrini (Ita)
Thorsten Meyer (Ger)
Antti Malmivaara (Fin)
Julia Patrick Engkasen (Mal)
Walter Roura Frontera (Usa)
Allen Heinemann (Usa)
Frane Grubisic (Cro)
Carlotte Kiekens (Bel)

William Levack (Nzl)
Wendy Machalichek (Usa)
Aydan Oral (Tur)
Melissa Selb (Swi)
Gerold Stucki (Swi)
Will Taylor (Nzl)
Susan Armijo-Olivo (Can)
Chiara Arienti (Ita)
RCTRaCk Executive Committee

Stefano Negrini (Ita)
Allen Heinemann (Usa)
Gert Kwakkel (Ned)
Wendy Machalicheck (Usa)
Antti Malmivaara (Fin)
Thorsten Meyer (Ger)
Gerold Stucki (Swi)
Susan Armijo-Olivo (Can)
Chiara Arienti (Ita)

Invited
• Walter Roura Frontera (Usa)
• Carlotte Kiekens (Bel)
• William Levack (Nzl)
• Will Taylor (Nzl)

Management
• Michele Patrini
• Stefano Giuseppe Lazzarini
• Roberta Bettinsoli
Topics to be focused

1. Patient selection (population)  
   Thorsten Mayer, Cecile Roe
2. Blinding  
   Allen Heineman
3. Treatment group  
   John Whyte
4. Control group & co-interventions  
   William Levack
5. Attrition, follow up and protocol deviation  
   Wendy Machalicek, Susan Armijo-Olivo
6. Outcomes
7. [Statistical analysis]
8. [Generalities on research (design, question, effectiveness)]  
   Chiara Arienti
9. [Appropriate randomization]
Technical Working Groups

**Aim:** identification of the item(s) to be added to the CONSORT Non-Pharmacological Treatments Guideline in the RCTRaCk checklist

**Composition:** Responsible and the team he/she will chose

- **Methods**
  - *Systematic/scoping review* on the identified topic OUTSIDE the world of rehabilitation
  - Proposal of the preliminary item(s) for the *draft version of the RCTRaCk*

- **Results**
  - Presentation at the *Orlando 2020 Consensus Meeting* for general discussion
  - *Publication* of the systematic/scoping review
Consensus Conference 2020 @ ISPRM Orlando

Participants

• RCTRaCk Executive Committee
• Chief-Editor of the Special issue (Tbd)

Technical Working Groups reporting:

• Presentation of systematic/scoping reviews
• Proposal of preliminary item(s) and relevant description

Definition of the preliminary items to be kept in the draft RCTRaCk
Consensus participants

Cochrane Advisory Board

Rehabilitation Journals Chief-Editors

Representatives of

• Scientific Societies
• Groups dealing with evidence and methodology in rehabilitation
  – PEDrO, TIDieR, CERT
• Cochrane methods groups
• Patients groups

Authors of

• Papers on methodology in rehabilitation
• Cochrane Reviews relevant to rehabilitation
• RCTs published in rehabilitation journals
Delphi Rounds

Thresholds

- >80% agreement: accept
- 40-80%: equipoise – further round
- <40% disagreement: reject

First round: refinement of items and descriptions
- Suggestions and possible approval

Second round: further refinement of items and descriptions
- New version and approval

Third round: final approval
- Final approval
Final products

Publication
• Major medical/epidemiological journal
• Co-publication in all adhering rehabilitation journals

Manual
• Special issue of a rehabilitation journal

Presentations
• Main meetings worldwide by member of the Executive Committee